California (Mr. MCCLINTOCK) and the gentleman from Maryland (Mr. RASKIN) each will control 20 minutes.

The Chair recognizes the gentleman from California.

GENERAL LEAVE

Mr. MCCLINTOCK. Madam 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 on S. 616.

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

There was no objection.

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

Madam Speaker, I rise in support of S. 616, the Foundation of the Federal Bar Association Charter Amendments Act of 2025.

The Federal Bar Association was founded in 1920 as a nonprofit organization. In 1954, Congress chartered the Federal Bar Association as a congressionally chartered organization under title 36.

The FBA seeks to strengthen the Federal legal system and administration of justice by providing services to Federal practitioners, the Federal judiciary, and the public.

The FBA serves the Federal legal community by promoting standards of professional competence and ethical conduct, providing educational programs to the public and the profession, and facilitating the administration of justice. The FBA is also committed to bringing civics education programs to classrooms across the country.

Over the years, it has become necessary for the FBA to update its bylaws. Because the FBA is a congressionally chartered organization, it takes an act of Congress to make changes in its charter to permit the FBA to update those bylaws.

S. 616 amends the FBA's current charter in several ways: It removes the requirement for the FBA to be incorporated and domiciled in Washington, D.C.;

It allows the board of directors to choose the location of the principal office;

It specifies that the FBA's bylaws establish membership requirements, responsibilities of the board of directors, and the election of officers;

It prohibits a director or officer from contributing or participating in political activities;

It prohibits loans to members and employees; and

It specifies that in the event of dissolution, any remaining assets are to be distributed by as provided by the board of directors.

Mr. Speaker, I urge my colleagues to join me in supporting this bill, and I reserve the balance of my time.

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

Mr. Speaker, I rise today in support of S. 616, the Foundation of the Federal Bar Association Charter Amendments Act of 2025.

I was proud to lead this bill, along with our former colleague, Congressman STEVE CHABOT, in the 117th Congress when the bill passed the House by unanimous consent. Sadly, the bill stalled in the Senate at that time.

However, I am delighted to see that our colleagues across the Capitol were finally able to come to an agreement this Congress and move this important legislation.

S. 616 makes technical changes to the Foundation of the Federal Bar Association's charter that will give the foundation the flexibility it needs to advance its significant mission in this century.

The changes made would enable the foundation to swiftly meet the needs and priorities of the organization and improve the administration of Federal justice for all of our citizens.

□ 1600

It is critical for attorneys who practice in the Federal judiciary to have the professional support that they need to illuminate the legal issues that they are litigating on and to advance the interests of their clients.

The Foundation of the Federal Bar Association provides just that support, and it is crucial that the foundation be allowed to grow and to serve our people with flexibility.

I thank our colleagues Senator KENNEDY and Senator WHITEHOUSE for working together to get this bill finally across the finish line. I urge all of our colleagues to support it, and I yield back the balance of my time.

Mr. MCCLINTOCK. Mr. Speaker, I urge adoption of S. 616, and I yield back the balance of my time.

The SPEAKER pro tempore (Mr. NEWHOUSE). The question is on the motion offered by the gentleman from California (Mr. MCCLINTOCK) that the House suspend the rules and pass the bill, S. 616.

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

A motion to reconsider was laid on the table.

MIKAELA NAYLON GIVE KIDS A CHANCE ACT

Mr. CARTER of Georgia. Mr. Speaker, I move to suspend the rules and pass the bill (H.R. 1262) to amend the Federal Food, Drug, and Cosmetic Act with respect to molecularly targeted pediatric cancer investigations, and for other purposes, as amended.

The Clerk read the title of the bill.

The text of the bill is as follows:

H.R. 1262

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

SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

(a) SHORT TITLE.—This Act may be cited as the ''Mikaela Naylon Give Kids a Chance Act''.

(b) TABLE OF CONTENTS.—The table of contents for this Act is as follows:

SEC. 2. RESEARCH INTO PEDIATRIC USES OF DRUGS; ADDITIONAL AUTHORITIES OF FOOD AND DRUG ADMINISTRATION REGARDING MOLECULARLY TARGETED CANCER DRUGS.

(a) IN GENERAL.—

(1) ADDITIONAL ACTIVE INGREDIENT FOR APPLICATION DRUG; LIMITATION REGARDING NOVEL-COMBINATION APPLICATION DRUG.—Section 505B(a)(3) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355c(a)(3)) is amended—

(A) by redesignating subparagraphs (B) and (C) as subparagraphs (C) and (D), respectively; and

(B) by striking subparagraph (A) and inserting the following:

''(A) IN GENERAL.—For purposes of paragraph (1)(B), the investigation described in this paragraph is a molecularly targeted pediatric cancer investigation of—

''(i) the drug or biological product for which the application referred to in such paragraph is submitted; or

''(ii) such drug or biological product used in combination with—

''(I) an active ingredient of a drug or biological product—

''(aa) for which an approved application under section 505(j) under this Act or under section 351(k) of the Public Health Service Act is in effect; and

''(bb) that is determined by the Secretary, after consultation with the applicant, to be part of the standard of care for treating a pediatric cancer; or

''(II) an active ingredient of a drug or biological product—

''(aa) for which an approved application under section 505(b) of this Act or section 351(a) of the Public Health Service Act to treat an adult cancer is in effect and is held by the same person submitting the application under paragraph (1)(B); and

''(bb) that is directed at a molecular target that the Secretary determines to be substantially relevant to the growth or progression of a pediatric cancer.

''(B) ADDITIONAL REQUIREMENTS.—

''(i) DESIGN OF INVESTIGATION.—A molecularly targeted pediatric cancer investigation referred to in subparagraph (A) shall be designed to yield clinically meaningful pediatric study data that is gathered using appropriate formulations for each age group for which the study is required, regarding dosing, safety, and preliminary efficacy to inform potential pediatric labeling.

''(ii) LIMITATION.—An investigation described in subparagraph (A)(ii) may be required only if the drug or biological product

for which the application referred to in paragraph (1)(B) contains either—

''(I) a single new active ingredient; or

''(II) more than one active ingredient, if an application for the combination of active ingredients has not previously been approved but each active ingredient is in a drug product that has been previously approved to treat an adult cancer.

''(iii) RESULTS OF ALREADY-COMPLETED PRECLINICAL STUDIES OF APPLICATION DRUG.—With respect to an investigation required pursuant to paragraph (1)(B), the Secretary may require the results of any completed preclinical studies relevant to the initial pediatric study plan be submitted to the Secretary at the same time that the initial pediatric study plan required under subsection (e)(1) is submitted.

''(iv) RULE OF CONSTRUCTION REGARDING INACTIVE INGREDIENTS.—With respect to a combination of active ingredients referred to in subparagraph (A)(ii), such subparagraph shall not be construed as addressing the use of inactive ingredients with such combination.''.

(2) DETERMINATION OF APPLICABLE REQUIREMENTS.—Section 505B(e)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355c(e)(1)) is amended by adding at the end the following: ''The Secretary shall determine whether subparagraph (A) or (B) of subsection (a)(1) applies with respect to an application before the date on which the applicant is required to submit the initial pediatric study plan under paragraph (2)(A).''.

(3) CLARIFYING APPLICABILITY.—Section 505B(a)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355c(a)(1)) is amended by adding at the end the following:

''(C) RULE OF CONSTRUCTION.—No application that is subject to the requirements of subparagraph (B) shall be subject to the requirements of subparagraph (A), and no application (or supplement to an application) that is subject to the requirements of subparagraph (A) shall be subject to the requirements of subparagraph (B).''.

(4) CONFORMING AMENDMENTS.—Section 505B(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355c(a)) is amended—

(A) in paragraph (3)(C), as redesignated by paragraph (1)(A) of this subsection, by striking ''investigations described in this paragraph'' and inserting ''investigations referred to in subparagraph (A)''; and

(B) in paragraph (3)(D), as redesignated by paragraph (1)(A) of this subsection, by striking ''the assessments under paragraph (2)(B)'' and inserting ''the assessments required under paragraph (1)(A)''.

(b) GUIDANCE.—The Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, shall—

(1) not later than 12 months after the date of enactment of this Act, issue draft guidance on the implementation of the amendments made by subsection (a); and

(2) not later than 12 months after closing the comment period on such draft guidance, finalize such guidance.

(c) APPLICABILITY.—The amendments made by this section apply with respect to any application under section 505(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(b)) and any application under section 351(a) of the Public Health Service Act (42 U.S.C. 262(a)), that is submitted on or after the date that is 3 years after the date of enactment of this Act.

(d) REPORTS TO CONGRESS.—

(1) SECRETARY OF HEALTH AND HUMAN SERVICES.—Not later than 6 years after the date of enactment of this Act, the Secretary of Health and Human Services shall submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate a report on the Secretary's efforts, in coordination with industry, to ensure implementation of the amendments made by subsection (a).

(2) GAO STUDY AND REPORT.—

(A) STUDY.—Not later than 8 years after the date of enactment of this Act, the Comptroller General of the United States shall conduct a study of the effectiveness of requiring assessments and investigations described in section 505B of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355c), as amended by subsection (a), in the development of drugs and biological products for pediatric cancer indications, including consideration of any benefits to, or burdens on, pediatric cancer drug development.

(B) FINDINGS.—Not later than 10 years after the date of enactment of this Act, the Comptroller General shall submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate a report containing the findings of the study conducted under subparagraph (A).

SEC. 3. ENSURING COMPLETION OF PEDIATRIC STUDY REQUIREMENTS.

(a) EQUAL ACCOUNTABILITY FOR PEDIATRIC STUDY REQUIREMENTS.—Section 505B(d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355c(d)) is amended—

(1) in paragraph (1), by striking ''Beginning 270'' and inserting ''NONCOMPLIANCE LETTER.—Beginning 270'';

(2) in paragraph (2)—

(A) by striking ''The drug or'' and inserting ''EFFECT OF NONCOMPLIANCE.—The drug or''; and

(B) by striking ''(except that the drug or biological product shall not be subject to action under section 303)'' and inserting ''(except that the drug or biological product shall be subject to action under section 303 only if such person demonstrated a lack of due diligence in satisfying the applicable requirement)''; and

(3) by adding at the end the following:

''(3) LIMITATION.—The Secretary shall not issue enforcement actions under section 303 for failures under this subsection in the case of a drug or biological product that is no longer marketed.''.

(b) DUE DILIGENCE.—Section 505B(d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355c(d)), as amended by subsection (a), is further amended by adding at the end the following:

''(4) DUE DILIGENCE.—Before the Secretary may conclude that a person failed to submit or otherwise meet a requirement as described in the matter preceding paragraph (1), the Secretary shall—

''(A) issue a noncompliance letter pursuant to paragraph (1);

''(B) provide such person with a 45-day period beginning on the date of receipt of such noncompliance letter to respond in writing as set forth in such paragraph; and

''(C) after reviewing such written response, determine whether the person demonstrated a lack of due diligence in satisfying such requirement.''.

(c) CONFORMING AMENDMENTS.—Section 303(f)(4)(A) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 333(f)(4)(A)) is amended by striking ''or 505–1'' and inserting ''505–1, or 505B''.

(d) TRANSITION RULE.—The Secretary of Health and Human Services may take enforcement action under section 303 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 333) only for failures described in section 505B(d) of such Act (21 U.S.C. 355c(d)) that occur on or after the date that is 180 days after the date of enactment of this Act.

SEC. 4. FDA REPORT ON PREA ENFORCEMENT.

Section 508(b) of the Food and Drug Administration Safety and Innovation Act (21 U.S.C. 355c–1(b)) is amended—

(1) in paragraph (11), by striking the semicolon at the end and inserting '', including an evaluation of compliance with deadlines provided for in deferrals and deferral extensions;'';

(2) in paragraph (15), by striking ''and'' at the end;

(3) in paragraph (16), by striking the period at the end and inserting ''; and''; and

(4) by adding at the end the following:

''(17) a listing of penalties, settlements, or payments under section 303 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353) for failure to comply with requirements under such section 505B, including, for each penalty, settlement, or payment, the name of the drug, the sponsor thereof, and the amount of the penalty, settlement, or payment imposed.''.

SEC. 5. EXTENSION OF AUTHORITY TO ISSUE PRIORITY REVIEW VOUCHERS TO ENCOURAGE TREATMENTS FOR RARE PEDIATRIC DISEASES.

(a) EXTENSION.—Paragraph (5) of section 529(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360ff(b)) is amended by striking ''December 20, 2024, unless'' and all that follows through the period at the end and inserting ''September 30, 2029.''.

(b) USER FEE PAYMENT.—Section 529(c)(4) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360ff(c)(4)) is amended by striking subparagraph (A) and inserting the following:

''(A) IN GENERAL.—The priority review user fee required by this subsection shall be due upon the submission of a human drug application under section 505(b)(1) or section 351(a) of the Public Health Service Act for which the priority review voucher is used. All other user fees associated with the human drug application shall be due as required by the Secretary or under applicable law.''.

(c) GAO REPORT ON EFFECTIVENESS OF RARE PEDIATRIC DISEASE PRIORITY VOUCHER AWARDS IN INCENTIVIZING RARE PEDIATRIC DISEASE DRUG DEVELOPMENT.—

(1) GAO STUDY.—

(A) STUDY.—The Comptroller General of the United States shall conduct a study of the effectiveness of awarding rare pediatric disease priority vouchers under section 529 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360ff), as amended by subsection (a), in the development of human drug products that treat or prevent rare pediatric diseases (as defined in such section 529).

(B) CONTENTS OF STUDY.—In conducting the study under subparagraph (A), the Comptroller General shall examine the following:

(i) The indications for each drug or biological product that—

(I) is the subject of a rare pediatric disease product application (as defined in section 529 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360ff)) for which a priority review voucher was awarded; and

(II) was approved under section 505 of the Federal Food, Drug, and Cosmetic Act (42 U.S.C. 355) or licensed under section 351 of the Public Health Service Act (42 U.S.C. 262).

(ii) Whether, and to what extent, an unmet need related to the treatment or prevention of a rare pediatric disease was met through the approval or licensure of such a drug or biological product.

(iii) The size of the company to which a priority review voucher was awarded under section 529 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360ff) for such a drug or biological product.

(iv) The value of such priority review voucher if transferred.

(v) Identification of each drug for which a priority review voucher awarded under such section 529 was used.

(vi) The size of the company using each priority review voucher awarded under such section 529.

(vii) The length of the period of time between the date on which a priority review voucher was awarded under such section 529 and the date on which it was used.

(viii) Whether, and to what extent, an unmet need related to the treatment or prevention of a rare pediatric disease was met through the approval under section 505 of the Federal Food, Drug, and Cosmetic Act (42 U.S.C. 355) or licensure under section 351 of the Public Health Service Act (42 U.S.C. 262) of a drug for which a priority review voucher was used.

(ix) Whether, and to what extent, companies were motivated by the availability of priority review vouchers under section 529 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360ff) to attempt to develop a drug for a rare pediatric disease.

(x) Whether, and to what extent, pediatric review vouchers awarded under such section were successful in stimulating development and expedited patient access to drug products for treatment or prevention of a rare pediatric disease that wouldn't otherwise take place without the incentive provided by such vouchers.

(xi) The impact of such priority review vouchers on the workload, review process, and public health prioritization efforts of the Food and Drug Administration.

(xii) Any other incentives in Federal law that exist for companies developing drugs or biological products described in clause (i).

(2) REPORT ON FINDINGS.—Not later than 5 years after the date of the enactment of this Act, the Comptroller General of the United States shall submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate a report containing the findings of the study conducted under paragraph (1).

SEC. 6. LIMITATIONS ON EXCLUSIVE APPROVAL OR LICENSURE OF ORPHAN DRUGS.

(a) IN GENERAL.—Section 527 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360cc) is amended—

(1) in subsection (a), in the matter following paragraph (2), by striking ''same disease or condition'' and inserting ''same approved use or indication within such rare disease or condition'';

(2) in subsection (b)—

(A) in the matter preceding paragraph (1), by striking ''same rare disease or condition'' and inserting ''same approved use or indication for which such 7-year period applies to such already approved or licensed drug''; and

(B) in paragraph (1), by inserting '', relating to the approved use or indication,'' after ''the needs'';

(3) in subsection (c)(1), by striking ''same rare disease or condition as the already approved drug'' and inserting ''same use or indication for which the already approved or licensed drug was approved or licensed''; and

(4) by adding at the end the following:

''(f) APPROVED USE OR INDICATION DEFINED.—In this section, the term 'approved use or indication' means the use or indication approved under section 505 of this Act or licensed under section 351 of the Public Health Service Act for a drug designated under section 526 for a rare disease or condition.''.

(b) APPLICATION OF AMENDMENTS.—The amendments made by subsection (a) shall apply with respect to any drug designated under section 526 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bb), regardless of the date on which the drug was so designated, and regardless of the date on which the drug was approved under section 505 of such Act (21 U.S.C. 355) or licensed under section 351 of the Public Health Service Act (42 U.S.C. 262).

SEC. 7. PROGRAM FOR PEDIATRIC STUDIES OF DRUGS.

Section 409I(d)(1) of the Public Health Service Act (42 U.S.C. 284m(d)(1)) is amended by striking ''section,'' and all that follows through the period at the end and inserting ''section, $25,000,000 for each of fiscal years 2026 through 2028.''.

SEC. 8. ORGAN PROCUREMENT AND TRANSPLANTATION NETWORK.

Section 372 of the Public Health Service Act (42 U.S.C. 274) is amended—

(1) in subsection (b)(2)—

(A) by moving the margins of subparagraphs (M) through (O) 2 ems to the left;

(B) in subparagraph (A)—

(i) in clause (i), by striking '', and'' and inserting ''; and''; and

(ii) in clause (ii), by striking the comma at the end and inserting a semicolon;

(C) in subparagraph (C), by striking ''twenty-four-hour telephone service'' and inserting ''24-hour telephone or information technology service'';

(D) in each of subparagraphs (B) through (M), by striking the comma at the end and inserting a semicolon;

(E) in subparagraph (N), by striking ''transportation, and'' and inserting ''transportation;'';

(F) in subparagraph (O), by striking the period and inserting a semicolon; and

(G) by adding at the end the following:

''(P) encourage the integration of electronic health records systems through application programming interfaces (or successor technologies) among hospitals, organ procurement organizations, and transplant centers, including the use of automated electronic hospital referrals and the grant of remote, electronic access to hospital electronic health records of potential donors by organ procurement organizations, in a manner that complies with the privacy regulations promulgated under the Health Insurance Portability and Accountability Act of 1996, at part 160 of title 45, Code of Federal Regulations, and subparts A, C, and E of part 164 of such title (or any successor regulations); and

''(Q) consider establishing a dashboard to display the number of transplants performed, the types of transplants performed, the number and types of organs that entered the Organ Procurement and Transplantation Network system and failed to be transplanted, and other appropriate statistics, which should be updated more frequently than annually.''; and

(2) by adding at the end the following:

''(d) REGISTRATION FEES.—

''(1) IN GENERAL.—The Secretary may collect registration fees from any member of the Organ Procurement and Transplantation Network for each transplant candidate such member places on the list described in subsection (b)(2)(A)(i). Such registration fees shall be collected and distributed only to support the operation of the Organ Procurement and Transplantation Network. Such registration fees are authorized to remain available until expended.

''(2) COLLECTION.—The Secretary may collect the registration fees under paragraph (1) directly or through awards made under subsection (b)(1)(A).

''(3) DISTRIBUTION.—Any amounts collected under this subsection shall—

''(A) be credited to the currently applicable appropriation, account, or fund of the Department of Health and Human Services as discretionary offsetting collections; and

''(B) be available, only to the extent and in the amounts provided in advance in appropriations Acts, to distribute such fees among awardees described in subsection (b)(1)(A).

''(4) TRANSPARENCY.—The Secretary shall—

''(A) promptly post on the website of the Organ Procurement and Transplantation Network—

''(i) the amount of registration fees collected under this subsection from each member of the Organ Procurement and Transplantation Network; and

''(ii) a list of activities such fees are used to support; and

''(B) update the information posted pursuant to subparagraph (A), as applicable for each calendar quarter for which fees are collected under paragraph (1).

''(5) GAO REVIEW.—Not later than 2 years after the date of enactment of this subsection, the Comptroller General of the United States shall, to the extent data are available—

''(A) conduct a review concerning the activities under this subsection; and

''(B) submit to the Committee on Health, Education, Labor, and Pensions and the Committee on Finance of the Senate and the Committee on Energy and Commerce of the House of Representatives, a report on such review, including related recommendations, as applicable.

''(6) SUNSET.—The authority to collect registration fees under paragraph (1) shall expire on the date that is 3 years after the date of enactment of the Mikaela Naylon Give Kids a Chance Act.''.

SEC. 9. ESTABLISHMENT OF ABRAHAM ACCORDS OFFICE WITHIN FOOD AND DRUG ADMINISTRATION.

(a) IN GENERAL.—Chapter X of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 391 et seq.) is amended by adding at the end the following:

''SEC. 1015. ABRAHAM ACCORDS OFFICE.

''(a) IN GENERAL.—The Secretary, acting through the Commissioner of Food and Drugs, shall establish within the Food and Drug Administration an office, to be known as the Abraham Accords Office, to be headed by a director.

''(b) OFFICE.—Not later than two years after the date of enactment of this section, the Secretary shall—

''(1) in consultation with the governments of Abraham Accords countries, as well as appropriate United States Government diplomatic and security personnel—

''(A) select the location of the Abraham Accords Office in an Abraham Accords country; and

''(B) establish such office; and

''(2) assign to such office such personnel of the Food and Drug Administration as the Secretary determines necessary to carry out the functions of such office.

''(c) DUTIES.—The Secretary, acting through the Director of the Abraham Accords Office, shall—

''(1) after the Abraham Accords Office is established—

''(A) as part of the Food and Drug Administration's work to strengthen the international oversight of regulated commodities, provide technical assistance to regulatory partners in Abraham Accords countries on strengthening regulatory oversight and converging regulatory requirements for the oversight of regulated products, including good manufacturing practices and other issues relevant to manufacturing medical products that are regulated by the Food and Drug Administration; and

''(B) facilitate interactions between the Food and Drug Administration and interested parties in Abraham Accords countries, including by sharing relevant information

regarding United States regulatory pathways with such parties, and facilitate feedback on the research, development, and manufacturing of products regulated in accordance with this Act; and

''(2) carry out other functions and activities as the Secretary determines to be necessary to carry out this section.

''(d) ABRAHAM ACCORDS COUNTRY DEFINED.—In this section, the term 'Abraham Accords country' means a country identified by the Department of State as having signed the Abraham Accords Declaration.

''(e) NATIONAL SECURITY.—Nothing in this section shall be construed to require any action inconsistent with a national security recommendation provided by the Federal Government.''.

(b) REPORT TO CONGRESS.—

(1) IN GENERAL.—Not later than 3 years after the date of enactment of this Act, the Secretary of Health and Human Services shall submit to the Congress a report on the Abraham Accords Office, including—

(A) an evaluation of how the Office has advanced progress toward conformance with Food and Drug Administration regulatory requirements by manufacturers in the Abraham Accords countries;

(B) a numerical count of parties that the Office has helped facilitate interactions or feedback pursuant to section 1015(c)(1)(B) of the Federal Food, Drug, and Cosmetic Act (as added by subsection (a));

(C) a summary of technical assistance provided to regulatory partners in Abraham Accords countries pursuant to subparagraph (A) of such section 1015(c)(1); and

(D) recommendations for increasing and improving coordination between the Food and Drug Administration and entities in Abraham Accords countries.

(2) ABRAHAM ACCORDS COUNTRY DEFINED.—In this subsection, the term ''Abraham Accords country'' has the meaning given such term in section 1015(d) of the Federal Food, Drug, and Cosmetic Act (as added by subsection (a)).

SEC. 10. INCREASING TRANSPARENCY IN GENERIC DRUG APPLICATIONS.

(a) IN GENERAL.—Section 505(j)(3) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(3)) is amended by adding at the end the following:

''(H)(i) Upon request (in controlled correspondence or an analogous process) by a person that has submitted or intends to submit an abbreviated application under this subsection for a drug that is required by regulation to contain one or more of the same inactive ingredients in the same concentrations as the listed drug referred to, or for which the Secretary determines there is a scientific justification for an approach that is in vitro, in whole or in part, to be used to demonstrate bioequivalence for a drug if such a drug contains one or more of the same inactive ingredients in the same concentrations as the listed drug referred to, the Secretary shall inform the person whether such drug is qualitatively and quantitatively the same as the listed drug. The Secretary may also provide such information to such a person on the Secretary's own initiative during the review of an abbreviated application under this subsection for such drug.

''(ii) Notwithstanding section 301(j), if the Secretary determines that such drug is not qualitatively or quantitatively the same as the listed drug, the Secretary shall identify and disclose to the person—

''(I) the ingredient or ingredients that cause such drug not to be qualitatively or quantitatively the same as the listed drug; and

''(II) for any ingredient for which there is an identified quantitative deviation, the amount of such deviation.

''(iii) If the Secretary determines that such drug is qualitatively and quantitatively the same as the listed drug, the Secretary shall not change or rescind such determination after the submission of an abbreviated application for such drug under this subsection unless—

''(I) the formulation of the listed drug has been changed and the Secretary has determined that the prior listed drug formulation was withdrawn for reasons of safety or effectiveness; or

''(II) the Secretary makes a written determination that the prior determination must be changed because an error has been identified.

''(iv) If the Secretary makes a written determination described in clause (iii)(II), the Secretary shall provide notice and a copy of the written determination to the person making the request under clause (i).

''(v) The disclosures authorized under clauses (i) and (ii) are disclosures authorized by law, including for purposes of section 1905 of title 18, United States Code. This subparagraph shall not otherwise be construed to authorize the disclosure of nonpublic qualitative or quantitative information about the ingredients in a listed drug, or to affect the status, if any, of such information as trade secret or confidential commercial information for purposes of section 301(j) of this Act, section 552 of title 5, United States Code, or section 1905 of title 18, United States Code.''.

(b) GUIDANCE.—

(1) IN GENERAL.—Not later than one year after the date of enactment of this Act, the Secretary of Health and Human Services shall issue draft guidance, or update guidance, describing how the Secretary will determine whether a drug is qualitatively and quantitatively the same as the listed drug (as such terms are used in section 505(j)(3)(H) of the Federal Food, Drug, and Cosmetic Act, as added by subsection (a)), including with respect to assessing pH adjusters.

(2) PROCESS.—In issuing guidance under this subsection, the Secretary of Health and Human Services shall—

(A) publish draft guidance;

(B) provide a period of at least 60 days for comment on the draft guidance; and

(C) after considering any comments received and not later than one year after the close of the comment period on the draft guidance, publish final guidance.

(c) APPLICABILITY.—Section 505(j)(3)(H) of the Federal Food, Drug, and Cosmetic Act, as added by subsection (a), applies beginning on the date of enactment of this Act, irrespective of the date on which the guidance required by subsection (b) is finalized.

SEC. 11. MEDICARE IMPROVEMENT FUND.

Section 1898(b)(1) of the Social Security Act (42 U.S.C. 1395iii(b)(1)) is amended by striking ''$1,403,000,000'' and inserting ''$2,622,000,000''.

The SPEAKER pro tempore. Pursuant to the rule, the gentleman from Georgia (Mr. CARTER) and the gentlewoman from Michigan (Mrs. DINGELL) each will control 20 minutes.

The Chair recognizes the gentleman from Georgia.

GENERAL LEAVE

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

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

There was no objection.

Mr. CARTER of Georgia. Mr. Speaker, I yield 3 minutes to the gentleman from Florida (Mr. BILIRAKIS), a very valuable member of the Committee on Energy and Commerce.

Mr. BILIRAKIS. Mr. Speaker, I am rising in strong support of H.R. 1262, the Mikaela Naylon Give Kids a Chance Act, led by my friend, the gentleman from Texas, Congressman MCCAUL.

This piece of legislation is comprised of bipartisan solutions to increase access to innovative treatments for those living with rare diseases, particularly children and adolescents.

Ten years ago, Mr. Speaker, the idea that we would be able to not just treat but cure sickle cell disease sounded like a dream that was too far out of reach. Today, we are curing sickle cell disease. We are curing spinal muscular atrophy. We are curing hemophilia and blood cancers. These cures are just a few of the success stories attributable to the FDA's Rare Pediatric Disease Priority Review Voucher Program.

The PRV program is a powerful incentive that spurs the development of treatments for rare pediatric diseases, providing a lifeline for patients who require specialized treatments.

I also want to highlight the other provisions in this bill that seek to bolster important components of our healthcare system.

This legislation supports the improvement of the Organ Procurement and Transplantation Network by allowing the Secretary of HHS to collect member registration fees to support the operation of the OPTN.

This bill also helps secure our medical product supply chain by requiring the FDA to establish an office in a country that has signed the Abraham Accords.

I am grateful to Representatives Harshbarger and Vargas for their work to facilitate operations between the FDA and regulatory authorities and innovators in Abraham Accords countries.

Last but not least, this bill also includes a provision championed by Representatives DUNN and MULLIN that will ensure more affordable drug options are available to patients faster rather than being delayed by unnecessary red tape.

Mr. Speaker, this bill has one of the largest totals of bipartisan cosponsors of any legislation we will see this Congress.

One of the reasons for that is the tireless work of the patient advocates. They come to our office on a regular basis and tell us their personal stories. It makes such a difference, Mr. Speaker.

This bill now bears the name of one of those heroic kids, Mikaela Naylon, who passed away earlier this year after battling cancer for nearly 6 years. May her memory be eternal. She was 16 years old, and I will never forget the videos.

Throughout her battle, Mikaela was a fierce advocate of this bill to create

hope for a cure, not just for herself but for the thousands of kids around the country who are fighting the same fight.

This is a very important bill, and I want to get it to the Senate as soon as possible so it can become law.

Mr. Speaker, I encourage my colleagues to support this bill.

Mrs. DINGELL. Mr. Speaker, I yield such time as he may consume to the gentleman from New Jersey (Mr. PALLONE), the distinguished ranking member of the Energy and Commerce Committee.

Mr. PALLONE. Mr. Speaker, I thank the sponsor of this legislation on the Democratic side, the gentlewoman from Michigan (Mrs. DINGELL), for yielding.

I rise today in support of this legislation, the Mikaela Naylon Give Kids a Chance Act, sponsored by Representatives DINGELL and MCCAUL.

This bill includes several strong, bipartisan pieces of legislation to help expand access to care for patients with rare diseases and complex medical needs. It increases research and development into rare pediatric diseases, improves regulatory certainty, strengthens the medical product supply chain, and enhances patient access to lower-cost medicines.

This bill will help in our efforts to bring new treatments to pediatric patients with more advanced forms of cancer. It also includes important enforcement authority for the Food and Drug Administration to take action against companies that do not conduct required studies for pediatric patients.

The bill also includes critical language to clarify the FDA's long-held treatment of orphan drug exclusivity and bring new treatments to more patients suffering from rare diseases. It will also allow for disclosure of certain information related to drug formulations to generic drug manufacturers to bring lower-cost medications to patients more quickly.

These provisions all advance our goal of accelerating the development of novel, safe, effective, and affordable treatments while improving outcomes for patients.

I am also pleased that the legislation provides the Health Resources and Services Administration, or HRSA, with the authority to modernize the organ transplant system. This language will allow HRSA to collect registration fees and distribute them among the multiple contractors that will be supporting the OPTN. The system is lifesaving for Americans, and I am glad that we can continue to support these much-needed reform efforts.

Mr. Speaker, this bill also includes important provisions to ensure that our medical product supply chain can be strengthened by working with international partners that believe in both tolerance and respect for every person, as well as advancement of science and medicine.

As a whole, this bill is going to make a difference, but I continue to believe that additional guardrails are needed for the PRV program to function the way Congress intended it to.

Previous reports from the Government Accountability Office on the program and continued research from academics show that there is little evidence that it incentivizes the products that Congress intended to help come to market.

This is especially concerning as the FDA has introduced a new priority review program with potentially massive financial benefits for pharmaceutical companies without any transparency or congressional authorization. That is why I am pleased that this bill includes a requirement for the GAO to conduct a new study and report on the effectiveness of the PRV program in achieving our original intent.

Let us not overstate the impact of this bill, however. While we are working together to advance the bill forward on incremental but important bipartisan legislation to advance both drug discovery and drug affordability, the Trump administration continues its devastating attacks on public health, including in cancer research.

□ 1610

The Trump administration's substantial cuts to research funding for the biomedical community is chilling the innovation that we are trying to promote through this bill.

The Trump administration is decimating research and endangering the pipeline of new cancer therapies that could come to FDA for approval. Their actions are putting patients at risk and leaving pediatric patients without the treatments that we are trying to ensure can be tested and brought to them.

Meanwhile, the Trump administration is using the FDA as a tool to provide lucrative gifts to drugmakers and allies of President Trump, undermining the Agency's science-based review process, and endangering the health of the American public with potentially unsafe and rushed drug reviews.

The Trump administration is also decimating our vaccine infrastructure, from the programs that cover our vaccines and ensure that patients can afford them to destroying the pipeline to future vaccines through their ideological, pseudoscience agenda.

Mr. Speaker, one day, I hope that my Republican colleagues will join us in calling on the Trump administration to reverse these terrible policies that are only harming the public health.

Mr. CARTER of Georgia. Mr. Speaker, I yield myself such time as I may consume.

Mr. Speaker, I rise today in strong support of the bipartisan Give Kids a Chance Act, which supports research and development of drugs for children with cancer and other rare diseases.

Nearly 70 percent of rare diseases start in childhood, and most still have no approved treatments. The Rare Pediatric Disease Priority Review Voucher Program has been a catalyst for developing therapies for these vulnerable populations.

Thanks to this program, treatments have reached children who are suffering from nearly 40 rare diseases, many of which previously had no FDA-approved options and often led to severe disability or death before adulthood. Since 2012, the Rare Pediatric Disease PRV Program has helped bring more than 60 new treatments to market and has driven investment in hundreds of additional therapies for rare pediatric diseases that would otherwise be financially unviable.

The Give Kids a Chance Act restores this critical program, ensuring that we continue to spur innovation, improve outcomes for young patients, and close gaps in pediatric drug research.

Mr. Speaker, I encourage my colleagues to support this bill.

Mr. Speaker, I reserve the balance of my time.

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

Mr. Speaker, I rise today to share my strong support for H.R. 1262, the Mikaela Naylon Give Kids a Chance Act. I am proud to co-lead this important, bipartisan legislation alongside Representatives MICHAEL MCCAUL, Dr. KIM SCHRIER, and GUS BILIRAKIS.

This bill will accelerate pediatric cancer treatments and expand access to lifesaving therapies for children battling rare diseases.

It is impossible to fully express the pain and the devastation that a family experiences when their child is diagnosed with cancer.

One of the bill's advocates was one that we are all going to talk about, Mikaela Naylon, a 16-year-old girl in Colorado who battled bone cancer. She was a fierce fighter for this bill. She talked to all of us, and we all sent videos to her. Unfortunately, she died on October 30.

Her mother told all of us, the sponsors and the cosponsors of this bill, that we gave her reason to live, and she hopes that other children will not die at her age and that this bill will help save lives.

She supported and spoke on the importance of funding cancer research to be able to help other kids like herself. She was a fighter her entire life, and this lifesaving bill has been renamed in her honor.

There are too many others facing the fight, as Mikaela has, each year. Nearly 16,000 children in just the United States are diagnosed with cancer each year.

Mr. Speaker, 1 in every 285 children in the U.S. will be diagnosed with cancer before they reach 20 years of age. In fact, children comprise as many as half of those living with rare diseases. Yet, here is the reality for those children: Treatment options for children remain extremely limited compared to those for adults.

We know that children respond to cancer treatments differently, but

there is limited research on how these therapies impact them. We owe our kids better than that, and their families deserve more.

We need this bill to offer more children a fighting chance. The Give Kids a Chance Act would reauthorize the Food and Drug Administration Priority Review Voucher Program to allow pharmaceutical companies to expedite FDA review of more profitable drugs in return for developing treatments for rare pediatric diseases.

Since 2011, 53 PRVs have been awarded for 35 different rare pediatric diseases. Additionally, thousands of successful drug combination therapies are now being studied and developed for adults but not for kids; not for our children.

The Give Kids a Chance Act also authorizes the FDA to direct companies to study a combination of cancer drugs and therapies in pediatric trials, as well. Together, we can show these young children and their families that they are not alone in this fight.

Mr. Speaker, I do thank the 313 cosponsors of this bill for their support, along with Chairman GUTHRIE and Ranking Member PALLONE for their assistance and support for this important bill. It has taken too long to get here today, but we are here. Let's show the kids in this country that we care.

Mr. Speaker, I urge my colleagues to vote ''yes,'' and I reserve the balance of my time.

Mr. CARTER of Georgia. Mr. Speaker, I yield such time as he may consume to the gentleman from Texas (Mr. MCCAUL), the esteemed Member who has announced that this will be his last session and who has had a stellar career in this august body and who has led in many, many ways, in many committees, and whose career we all want to emulate.

Mr. MCCAUL. Mr. Speaker, I thank my dear friend from Georgia (Mr. CARTER) for those kind words. I thank Chairman GUTHRIE, GUS BILIRAKIS, Mr. PALLONE, and, especially, Chairwoman DINGELL for their steadfast advocacy for these kids. I can't think of anything more important in my 22 years.

As chairman of the Childhood Cancer Caucus, I host a yearly childhood cancer summit. Mrs. DINGELL is a co-chair. It is a time for pediatric cancer patients, survivors, and advocates to rally together around these precious children, the most precious thing we have, and to spread hope to them.

Each year, I meet a child who impacts me in a very strong way. This year, I was blessed to get to know this beautiful, beautiful young woman by the name of Mikaela Naylon. I could see in her eyes that she was at the height of her struggle with cancer. It took so much strength for her to come to the summit, but she believed that she was meant to be there. She wanted her presence and her voice to help shape our policies and change our world for the better.

We got her into a joint clinical trial at MD Anderson and Texas Children's Hospital, but, unfortunately, it was too late. She had to be put on a ventilator 3 weeks after our summit, and she passed away.

As Congresswoman DINGELL mentioned, we sent videos to her to remind her of how important she is. In her final moments on this Earth, I reached out to her and told her that her story would not be forgotten and that her legacy would continue to help thousands of other children. I wanted her to know that her impact would outlive all of us.

Mr. Speaker, today, in her honor, the United States Congress will vote on the Mikaela Naylon Give Kids a Chance Act.

Mr. Speaker, 16 years ago, I founded the Childhood Cancer Caucus because I saw that children with cancer did not have a voice here in Washington. We cared about adult treatments, but no one was paying attention to the precious children who are battling this heartbreaking disease. In fact, they called it rare orphan diseases.

□ 1620

Since then, we have made a change for the better, and today is proof of that. Put simply, this bill gives kids the same chance to beat cancer that adults already have.

Right now, thousands of successful drug combination therapies are being studied and developed for adults, but not for children. The Give Kids a Chance Act will change that. It authorizes the FDA to direct companies to study those same drugs and therapies in children, as well.

It will also reauthorize my Creating Hope Reauthorization Act, which created a pediatric review voucher program within the FDA. It was the first-ever market incentive for pharmaceutical companies to develop childhood cancer treatments. Prior to that, there were none.

Since its inception in 2012, 63 vouchers have been awarded for treatments of at least 39 different rare pediatric diseases, 36 of which previously had no FDA-approved treatments. These diseases typically lead to death before a child can reach adulthood, but not anymore.

A dear friend of mine, Dr. Allison from MD Anderson in my home State of Texas, was able to use this voucher program to obtain FDA approval for a treatment called CAR-T immunotherapy. He received the Nobel Prize in medicine for it, and this voucher program had everything to do with the FDA approval of it. This breakthrough treatment could change everything, and it has changed everything, not just for kids with cancer, but also for many adults.

This bill will keep this successful voucher program going for another 5 years, fueling more innovation and more hope for children and families who desperately need it.

Mr. Speaker, I thank all of my friends on the Committee on Energy and Commerce—I am not on the committee—who helped me get this bill done. I also want to recognize the childhood cancer survivors who are in the gallery today.

With 313 cosponsors, this bill has the most bipartisan support in Congress, and that is because there is nothing political about a child with cancer. There is nothing more important than saving the lives of the next generation.

My prayers remain with Mikaela's family, and we are honored to have them here with us today: her mother, Kassandra; her father, Doug; and her brother, Ayden. I thank them for sharing Mikaela's beautiful story with us.

Mikaela represents all the children who have suffered with this heartbreaking disease. After meeting with many of them over all of these years, I can tell you these kids are tougher and more resilient than any adult I have ever seen, and they are truly my biggest inspiration. Many survive, but many don't, and that needs to change. Losing these kids has been the hardest part of my career over 22 years.

Today, I am encouraged because Mikaela's legacy and all of their legacies, all those who have died and survived this horrible disease, will live on in this bill forever.

Mr. Speaker, it is rare in this place that you can pass a bill that will end up saving children's lives. I can think of nothing more important.

I urge my colleagues to do right by our children and pass the Mikaela Naylon Give Kids a Chance Act without delay.

Mrs. DINGELL. Mr. Speaker, I am ready to close, but before doing so, I thank my colleague, with whom I have been proud to co-chair the caucus. We both know too many children who have died, but we know a lot who we were able to get help for. We make a commitment to all the families in the gallery, and those who we have not gotten to know, that no matter where the gentleman is going, he and I are in this fight for the rest of our lives. I thank him for all of his work. I am going to miss my colleague.

Mr. Speaker, I yield back the balance of my time and beg everybody to support this bill.

The SPEAKER pro tempore. The Chair reminds Members not to refer to persons in the gallery.

Mr. CARTER of Georgia. Mr. Speaker, I apologize. I do have one other speaker.

Mr. Speaker, I yield such time as he may consume to the gentleman from California (Mr. OBERNOLTE).

Mr. OBERNOLTE. Mr. Speaker, I thank my friend, the gentleman from Georgia, for recognizing me.

Mr. Speaker, I rise in strong support as both a member of the Health Subcommittee and a proud cosponsor of this bill, H.R. 1262, the Give Kids a Chance Act.

Mr. Speaker, we live in the most technologically advanced society in the history of human civilization, and modern medicine has recently come up

with amazing solutions and cures for many of the physical ailments that have afflicted humanity.

Unfortunately, Mr. Speaker, we have many rare pediatric diseases for which there is no cure. While we are researching the cures for those diseases, thousands and thousands of children continue to suffer.

Mr. Speaker, we need to give every priority and do everything we possibly can to speed up the delivery of these treatments for rare pediatric diseases, and that is what this bill is all about. The Give Kids a Chance Act will reauthorize the FDA's Priority Review Voucher system to speed the research and development of these technologies and innovative treatments and bring them to market. It also clarifies the FDA's authority over expediting these therapies and reauthorizes needed funding for the NIH to fund research and development into these cures.

Mr. Speaker, this bill will help us finally bring solutions to these thousands of suffering children.

Mr. Speaker, I thank my bipartisan cosponsors for their hard work on this bill. I urge this body to pass it this evening and urge its speedy consideration in the Senate.

Mr. CARTER of Georgia. 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. The question is on the motion offered by the gentleman from Georgia (Mr. CARTER) that the House suspend the rules and pass the bill, H.R. 1262, 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.

HOSPITAL INPATIENT SERVICES MODERNIZATION ACT

Mr. SMITH of Missouri. Mr. Speaker, I move to suspend the rules and pass the bill (H.R. 4313) to amend title XVIII of the Social Security Act to extend acute hospital care at home waiver flexibilities, and to require an additional study and report on such flexibilities, as amended.

The Clerk read the title of the bill.

The text of the bill is as follows:

H.R. 4313

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 ''Hospital Inpatient Services Modernization Act''.

SEC. 2. EXTENDING ACUTE HOSPITAL CARE AT HOME WAIVER FLEXIBILITIES.

Section 1866G(a)(1) of the Social Security Act (42 U.S.C. 1395cc–7(a)(1)) is amended by striking ''January 30, 2026'' and inserting ''September 30, 2030''.

SEC. 3. REQUIRING ADDITIONAL STUDY AND REPORT ON ACUTE HOSPITAL CARE AT HOME WAIVER FLEXIBILITIES.

Section 1866G of the Social Security Act (42 U.S.C. 1395cc–7), as amended by section 2, is further amended—

(1) in subsection (a)(3)(E)—

(A) in clause (ii), by striking ''the study described in subsection (b)'' and inserting ''the studies described in subsections (b) and (c)''; and

(B) by adding at the end the following new flush sentence:

''The Secretary may require that such data and information be submitted through a hospital's cost report, through such survey instruments as the Secretary may develop, through medical record information, or through such other means as the Secretary determines appropriate.'';

(2) in subsection (b)—

(A) in the subsection heading, by striking ''STUDY'' and inserting ''INITIAL STUDY''; and

(B) in paragraph (3), by inserting ''or subsection (c)'' before the period at the end;

(3) by redesignating subsections (c) and (d) as subsections (d) and (e), respectively; and

(4) by inserting after subsection (b) the following new subsection:

''(c) SUBSEQUENT STUDY AND REPORT.—

''(1) IN GENERAL.—Not later than September 30, 2028, the Secretary shall conduct a study to—

''(A) analyze, to the extent practicable, the criteria established by hospitals under the Acute Hospital Care at Home initiative to determine which individuals may be furnished services under such initiative; and

''(B) analyze and compare (both within and between hospitals participating in the initiative, and relative to comparable hospitals that do not participate in the initiative, for relevant parameters such as diagnosis-related groups)—

''(i) quality of care furnished to individuals with similar conditions and characteristics in the inpatient setting and through the Acute Hospital Care at Home initiative, including health outcomes, hospital readmission rates (including readmissions both within and beyond 30 days post-discharge), hospital mortality rates, length of stay, infection rates, composition of care team (including the types of labor used, such as contracted labor), the ratio of nursing staff, transfers from the hospital to the home, transfers from the home to the hospital (including the timing, frequency, and causes of such transfers), transfers and discharges to post-acute care settings (including the timing, frequency, and causes of such transfers and discharges), and patient and caregiver experience of care;

''(ii) clinical conditions treated and diagnosis-related groups of discharges from inpatient settings relative to discharges from the Acute Hospital Care at Home initiative;

''(iii) costs incurred by the hospital for furnishing care in inpatient settings relative to costs incurred by the hospital for furnishing care through the Acute Hospital Care at Home initiative, including costs relating to staffing, equipment, food, prescriptions, and other services, as determined by the Secretary;

''(iv) the quantity, mix, and intensity of services (such as in-person visits and virtual contacts with patients and the intensity of such services) furnished in inpatient settings relative to the Acute Hospital Care at Home initiative, and, to the extent practicable, the nature and extent of family or caregiver involvement;

''(v) socioeconomic information on individuals treated in comparable inpatient settings relative to the initiative, including racial and ethnic data, income, housing, geographic proximity to the brick-and-mortar facility and whether such individuals are dually eligible for benefits under this title and title XIX; and

''(vi) the quality of care, outcomes, costs, quantity and intensity of services, and other relevant metrics between individuals who entered into the Acute Hospital Care at Home initiative directly from an emergency department compared with individuals who entered into the Acute Hospital Care at Home initiative directly from an existing inpatient stay in a hospital.

''(2) SELECTION BIAS.—In conducting the study under paragraph (1), the Secretary shall, to the extent practicable, analyze and compare individuals who participate and do not participate in the initiative controlling for selection bias or other factors that may impact the reliability of data.

''(3) REPORT.—Not later than September 30, 2028, the Secretary of Health and Human Services shall submit to the Committee on Ways and Means of the House of Representatives and the Committee on Finance of the Senate a report on the study conducted under paragraph (1).

''(4) FUNDING.—In addition to amounts otherwise available, there is appropriated to the Centers for Medicare & Medicaid Services Program Management Account for fiscal year 2026, out of any amounts in the Treasury not otherwise appropriated, $2,500,000, to remain available until expended, for purposes of carrying out this subsection.''.

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 ''$1,403,000,000'' and inserting ''$1,400,500,000''.

The SPEAKER pro tempore. Pursuant to the rule, the gentleman from Missouri (Mr. SMITH) and the gentlewoman from Wisconsin (Ms. MOORE) each will control 20 minutes.

The Chair recognizes the gentleman from Missouri.

GENERAL LEAVE

Mr. SMITH of Missouri. Mr. Speaker, I ask unanimous consent that all Members may have 5 legislative days in which to revise and extend their remarks and submit extraneous material on this bill under consideration.

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

There was no objection.

Mr. SMITH of Missouri. Mr. Speaker, I yield myself such time as I may consume.

Mr. Speaker, I rise in support of the Hospital Inpatient Services Modernization Act introduced by the Committee on Ways and Means Health Subcommittee chairman, Mr. BUCHANAN, and Congressman DWIGHT EVANS.

I think one of the healthcare-related conversations that frustrates a lot of us around here is the typical year-end healthcare policy extender mess.

□ 1630

The legislation in front of us takes the successful hospital at home program and removes it from that chaos by providing it with a renewed 5-year authorization so more Americans can receive care in the comfort and convenience of their own home.

Hospital at home has become embedded in the fabric of our healthcare system. More than 400 hospitals in nearly 40 States have participated in the program, which has built a track record of improved patient outcomes.

In Health Subcommittee Chairman BUCHANAN's home State of Florida