AMENDMENT TO H.R. 6

OFFERED BY MR. UPTON OF MICHIGAN

(Page and line numbers refer to UPTON_005)

Page 17, after line 5, insert the following:

''(C) WORKFORCE.—In developing and maintaining a strategic plan under this subsection, the Director of NIH shall ensure that maintaining the biomedical workforce of the future, including the participation by scientists from groups traditionally underrepresented in the scientific workforce, remains a priority.''.

Page 21, line 19, insert ''PLAN PREPARATION AND'' before ''IMPLEMENTATION OF''.

Page 21, line 21, insert ''prepare a plan, including time frames, and'' after ''shall''.

Page 22, line 8, strike ''The Director'' and insert ''Not later than two years after the date of enactment of this Act, the Director''.

Page 24, after line 21, insert the following:

SEC. 1029. SENSE OF CONGRESS ON INCREASED INCLUSION OF UNDERREPRESENTED COMMUNITIES IN CLINICAL TRIALS.

It is the sense of Congress that the National Institute on Minority Health and Health Disparities (NIMHD) should include within its strategic plan ways to increase representation of underrepresented communities in clinical trials.

Page 41, line 19, strike ''Secretary'' and insert ''Comptroller General of the United States''.

Page 41, line 20, insert ''and the Secretary'' after ''Congress,''.

Page 42, line 24, strike ''emphasis'' and insert ''analysis''.

Page 51, line 13, strike ''to sponsor'' and insert ''that sponsor''.

Page 117, lines 6 through 7, strike ''with the development and approval of such a drug''.

Page 145, line 22, through page 151, line 6, amend section 2123 to read as follows:

SEC. 2123. ENCOURAGING THE DEVELOPMENT AND USE OF NEW ANTIMICROBIAL DRUGS.

(a) ADDITIONAL PAYMENT FOR NEW ANTIMICROBIAL DRUGS UNDER MEDICARE.—

(1) IN GENERAL.—Section 1886(d)(5) of the Social Security Act (42 U.S.C. 1395ww(d)(5)) is amended by adding at the end the following new subparagraph:

''(M)(i) As part of the annual rulemaking under this subsection for payment for subsection (d) hospitals for each fiscal year beginning with fiscal year 2018, the Secretary shall—

''(I) include publication of a list of the new antimicrobial drugs for such fiscal year; and

''(II) with respect to discharges by eligible hospitals that involve a drug so published, provide for an additional payment to be made under this subsection in accordance with the provisions of this subparagraph.

''(ii) Additional payments may not be made for a drug under this subparagraph—

''(I) other than during the 5-fiscal-year period beginning with the fiscal year in which the drug is first included in the publication described in clause (i)(I); and

''(II) with respect to which payment has ever been made pursuant to subparagraph (K).

''(iii) For purposes of this subparagraph, the term 'new antimicrobial drug' means a product that is approved for use, or a product for which an indication is first approved for use, by the Food and Drug Administration on or after December 1, 2014, and that the Food and Drug Administration determines—

''(I) either—

''(aa) is intended to treat an infection caused by, or likely to be caused by, a qualifying pathogen (as defined under section 505E(f) of the Federal Food, Drug, and Cosmetic Act); or

''(bb) meets the definition of a qualified infectious disease product under section 505E(g) of the Federal Food, Drug, and Cosmetic Act; and

''(II) is intended to treat an infection—

''(aa) for which there is an unmet medical need; and

''(bb) which is associated with high rates of mortality or significant patient morbidity, as determined in consultation with the Director of the Centers for Disease Control and Prevention

and the infectious disease professional community.

Such determination may be revoked only upon a finding that the request for such determination contained an untrue statement of material fact.

''(iv) For purposes of this subparagraph, the term 'eligible hospital' means a subsection (d) hospital that participates in the National Healthcare Safety Network of the Centers for Disease Control and Prevention (or, to the extent a similar surveillance system reporting program that includes reporting about antimicrobial drugs is determined by the Secretary to be available to such hospitals, such similar surveillance system as the Secretary may specify).

''(v)(I) Subject to the succeeding provisions of this clause, the additional payment under this subparagraph, with respect to a drug, shall be in the amount provided for such drug under section 1847A.

''(II) The Secretary shall, as part of the rulemaking referred to in clause (i) for each fiscal year, estimate—

''(aa) the total amount of the additional payments that will be made under this subsection pursuant to this subparagraph for discharges in such fiscal year without regard to the application of subclause (III); and

''(bb) the total program payments to be made under this subsection for all discharges in such fiscal year.

''(III) If the estimated total amount described in subclause (II)(aa) for a fiscal year exceeds the applicable percentage of the estimated total program payments described in subclause (II)(bb) for such fiscal year, the Secretary shall reduce in a pro rata manner the amount of each additional payment under this subsection pursuant to this subparagraph for such fiscal year in order to ensure that the total amount of the additional payments under this subsection pursuant to this subparagraph for such fiscal year do not exceed the applicable percentage of the estimated total program payments described in subclause (II)(bb) for such fiscal year.

''(IV) For purposes of subclause (III), the term 'applicable percentage' means 0.03 percent.''.

(2) CONFORMING AMENDMENTS.—

(A) NO DUPLICATIVE NTAP PAYMENTS.—Section 1886(d)(5)(K)(vi) of the Social Security Act (42 U.S.C. 1395ww(d)(5)(K)(vi)) is amended by inserting ''if additional payment has never been made under this subsection pursuant to subparagraph (M) with respect to the

service or technology'' after ''if the service or technology''.

(B) ACCESS TO PRICE INFORMATION.—Section 1927(b)(3)(A)(iii) of the Social Security Act (42 U.S.C. 1396r–8(b)(3)(A)(iii)) is amended—

(i) in subclause (II), by inserting '', or under section 1886(d) pursuant to paragraph (5)(M) of such section,'' after ''1847A,''; and

(ii) in the matter following subclause (III), by inserting ''or section 1886(d)(5)(M)'' after ''1881(b)(13)(A)(ii)''.

(b) STUDY AND REPORT ON REMOVING BARRIERS TO DEVELOPMENT OF NEW ANTIMICROBIAL DRUGS.—

(1) STUDY.—The Comptroller General of the United States shall, in consultation with the Director of the National Institutes of Health, the Commissioner of Food and Drugs, and the Director of the Centers for Disease Control and Prevention, conduct a study to—

(A) identify and examine the barriers that prevent the development of new antimicrobial drugs, as defined in section 1886(d)(5)(M)(iii)

of the Social Security Act (42 U.S.C. 1395ww(d)(5)(M)(iii)); and

(B) develop recommendations for actions to be taken in order to overcome any barriers identified under subparagraph (A).

(2) REPORT.—Not later than 1 year after the date of the enactment of this Act, the Comptroller General shall submit to Congress a report on the study conducted under paragraph (1).

Page 181, line 6, through page 193, line 20, amend section 2221 to read as follows:

SEC. 2221. THIRD-PARTY QUALITY SYSTEM ASSESSMENT.

(a) ESTABLISHMENT OF THIRD-PARTY QUALITY SYSTEM ASSESSMENT PROGRAM.—Chapter V of the Federal Food, Drug, and Cosmetic Act is amended by inserting after section 524A (21 U.S.C. 360n–1) the following new section:

"SEC. 524B. THIRD-PARTY QUALITY SYSTEM ASSESSMENT.

''(a) ACCREDITATION AND ASSESSMENT.—

''(1) IN GENERAL; CERTIFICATION OF DEVICE QUALITY SYSTEM.—The Secretary shall in accordance with this section establish a third-party quality system assessment program—

''(A) to accredit persons to assess whether a requestor's quality system, including its de-

sign controls, can reasonably assure the safety and effectiveness of in-scope devices subject to device-related changes (as defined in paragraph (2));

''(B) under which accredited persons shall as applicable certify that a requestor's quality system meets the criteria issued under paragraph (5) with respect to the in-scope devices at issue; and

''(C) under which the Secretary shall rely on such certifications for purposes of determining the safety and effectiveness (or as applicable, substantial equivalence) of in-scope devices subject to the device-related changes involved, in lieu of compliance with the following submission requirements:

''(i) A premarket notification (as defined in paragraph (2)).

''(ii) A thirty-day notice (as defined in paragraph (2)).

''(iii) A Special PMA supplement (as defined in paragraph (2)).

''(2) DEFINITIONS.—For purposes of this section—

"(A) the term 'device-related changes' means changes made by a requestor with respect to in-scope devices, which are—

"(i) changes to a device found to be substantially equivalent under sections 513(i) and 510(k) to a predicate device, that—

"(I) would otherwise be subject to a premarket notification; and

"(II) do not alter—

"(aa) the intended use of the changed device; or

"(bb) the fundamental scientific technology of such device;

"(ii) manufacturing changes subject to a 30-day notice;

"(iii) changes that qualify for a Special PMA Supplement; and

"(iv) such other changes relating to the devices or the device manufacturing process as the Secretary determines appropriate;

"(B) the term 'in-scope device' means a device within the scope of devices agreed to by the requestor and the accredited person for pur-

poses of a request for certification under this section;

"(C) the term 'premarket notification' means a premarket notification under section 510(k);

"(D) the term 'quality system' means the methods used in, and the facilities and controls used for, the design, manufacture, packaging, labeling, storage, installation, and servicing of devices, as described in section 520(f);

"(E) the term 'requestor' means a device manufacturer that is seeking certification under this section of a quality system used by such manufacturer;

"(F) the term 'Special PMA' means a Special PMA supplement under section 814.39(d) of title 21, Code of Federal Regulations (or any successor regulations); and

"(G) the term 'thirty-day notice' means a notice described in section 515(d)(6).

"(3) ACCREDITATION PROCESS; ACCREDITATION RENEWAL.—Except as inconsistent with this section, the process and qualifications for accreditation of persons and renewal of such accreditation under section 704(g) shall apply with respect to accreditation

of persons and renewal of such accreditation under this section.

''(4) USE OF ACCREDITED PARTIES TO CONDUCT ASSESSMENTS.—

''(A) INITIATION OF ASSESSMENT SERVICES.—

''(i) DATE ASSESSMENTS AUTHORIZED.—Beginning after issuance of the final guidance under paragraph (5), an accredited person may conduct an assessment under this section.

''(ii) INITIATION OF ASSESSMENTS.—Use of one or more accredited persons to assess a requestor's quality system under this section with respect to in-scope devices shall be at the initiation of the person who registers and lists the devices at issue under section 510.

''(B) COMPENSATION.—Compensation for such accredited persons shall—

''(i) be determined by agreement between the accredited person and the person who engages the services of the accredited person; and

"(ii) be paid by the person who engages such services.

"(C) ACCREDITED PERSON SELECTION.—Each person who chooses to use an accredited person to assess a requestor's quality system, as described in this section, shall select the accredited person from a list of such persons published by the Secretary in accordance with section 704(g)(4).

"(5) GUIDANCE; CRITERIA FOR CERTIFICATION.—

"(A) IN GENERAL.—The criteria for certification of a quality system under this section shall be as specified by the Secretary in guidance issued under this paragraph.

"(B) CONTENTS; CERTIFICATION CRITERIA.—The guidance under this paragraph shall include specification of—

"(i) evaluative criteria to be used by an accredited person to assess and as applicable certify a requestor's quality system under this section with respect to in-scope devices; and

''(ii) criteria for accredited persons to apply a waiver of and exemptions from the certification criteria under clause (i).

''(C) TIMEFRAME FOR ISSUING GUIDANCE.—The Secretary shall issue under this paragraph—

''(i) draft guidance not later than 12 months after the enactment of the 21st Century Cures Act; and

''(ii) final guidance not later than 12 months after issuance of the draft guidance under clause (i).

''(b) USE OF THIRD-PARTY ASSESSMENT.—

''(1) ASSESSMENT SUMMARY; CERTIFICATION.—

''(A) SUBMISSION OF ASSESSMENT TO SECRETARY.—An accredited person who assesses a requestor's quality system under subsection (a) shall submit to the Secretary a summary of the assessment—

''(i) within 30 days of the assessment; and

''(ii) which as applicable shall include—

"(I) the accredited person's certification that the requestor has satisfied the criteria issued under subsection (a)(5) for quality system certification with respect to the in-scope devices at issue ; and

"(II) any waivers or exemptions from such criteria applied by the accredited person.

"(B) TREATMENT OF ASSESSMENTS.—Subject to action by the Secretary under subparagraph (C), with respect to assessments which include a certification under this section—

"(i) the Secretary's review of the assessment summary shall be deemed complete on the day that is 30 days after the date on which the Secretary receives the summary under subparagraph (A); and

"(ii) the assessment summary and certification of the requestor shall be deemed accepted by the Secretary on such 30th day.

"(C) ACTIONS BY SECRETARY.—

''(i) IN GENERAL.—Within 30 days of receiving an assessment summary and certification under subparagraph (A), the Secretary may, by written notice to the accredited person submitting such assessment certification, deem any such certification to be provisional beyond such 30-day period, suspended pending further review by the Secretary, or otherwise qualified or cancelled, based on the Secretary's determination that (as applicable)—

''(I) additional information is needed to support such certification;

''(II) such assessment or certification is unwarranted; or

''(III) such action with regard to the certification is otherwise justified according to such factors and criteria as the Secretary finds appropriate.

''(ii) ACCEPTANCE OF CERTIFICATION.—If following action by the Secretary under clause (i) with respect to a certification, the Secretary determines that such certification is acceptable, the Secretary shall issue written notice to the ap-

plicable accredited person indicating such acceptance.

''(2) NOTIFICATIONS TO SECRETARY BY CERTIFIED REQUESTORS OR ACCREDITED PERSONS FOR PROGRAM EVALUATION PURPOSES.—

''(A) ANNUAL SUMMARY REPORT FOR DEVICE-RELATED CHANGES OTHERWISE SUBJECT TO PREMARKET NOTIFICATION.—A requestor certified under this section that effectuates device-related changes with respect to in-scope devices, without prior submission of a premarket notification, shall ensure that an annual summary report is submitted to the Secretary by the accredited person which—

''(i) describe the changes made to the in-scope device; and

''(ii) indicate the effective dates of such changes.

''(B) PERIODIC NOTIFICATION FOR MANUFACTURING CHANGES OTHERWISE SUBJECT TO THIRTY-DAY NOTICE.—A requestor certified under this section that effectuates device-related changes with respect to in-scope devices, without prior submission of a thirty-day notice, shall provide notification to the Secretary of

such changes in the requestor's next periodic report under section 814.84(b) of title 21, Code of Federal Regulations (or any successor regulation). Such notification shall—

''(i) describe the changes made; and

''(ii) indicate the effective dates of such changes.

''(C) PERIODIC NOTIFICATION FOR DEVICE-RELATED CHANGES OTHERWISE SUBJECT TO SPECIAL PMA SUPPLEMENT.—A requestor certified under this section that effectuates device-related changes with respect to in-scope devices, without prior submission of a Special PMA Supplement, shall provide notification to the Secretary of such changes in the requestor's next periodic report under section 814.84(b) of title 21, Code of Federal Regulations (or any successor regulation). Such notification shall—

''(i) describe the changes made, including a full explanation of the basis for the changes; and

''(ii) indicate the effective dates of such changes.

''(D) USE OF NOTIFICATIONS FOR PROGRAM EVALUATION PURPOSES.—Information

submitted to the Secretary under subparagraphs (A) through (C) shall be used by the Secretary for purposes of the program evaluation under subsection (d).

''(c) DURATION AND EFFECT OF CERTIFICATION.—A certification under this section—

''(1) shall remain in effect for a period of two years from the date such certification is accepted by the Secretary, subject to paragraph (6);

''(2) may be renewed through the process described in subsection (a)(3);

''(3) shall continue to apply with respect to device-related changes made during such two-year period, provided the certification remains in effect, irrespective of whether such certification is renewed after such two-year period;

''(4) shall have no effect on the need to comply with applicable submission requirements specified in subsection (a)(1)(C) with respect to any change pertaining to in-scope devices which is not a device-related change under subsection (a)(2);

''(5) shall have no effect on the authority of the Secretary to conduct an inspection or otherwise determine the requestor's conformance with the applicable requirements of this Act; and

''(6) may be revoked by the Secretary upon a determination that the requestor's quality system no longer meets the certification criteria issued under subsection (a)(5) with respect to the in-scope devices at issue.

The Secretary shall provide written notification to the requestor of a revocation pursuant to paragraph (6) within 10 working days of the determination described in such paragraph. Upon receipt of the written notification, the requestor shall satisfy the applicable submission requirements specified in subsection (a)(1)(C) for any device-related changes effectuated after the date of such determination. After such revocation, such requestor is eligible to seek re-certification under this section of its quality system.

''(d) PROGRAM EVALUATION; SUNSET.—

''(1) PROGRAM EVALUATION AND REPORT.—

''(A) EVALUATION.—The Secretary shall complete an evaluation of the third-party quality system assessment program under this section no later than January 31, 2021, based on—

''(i) analysis of information from a representative group of device manufacturers obtained from notifications provided by

certified requestors or accredited persons under subsection (b)(2); and

''(ii) such other available information and data as the Secretary determines appropriate.

''(B) REPORT.—No later than one year after completing the evaluation under subparagraph (A), the Secretary shall issue a report of the evaluation's findings on the website of the Food and Drug Administration, which shall include the Secretary's recommendations with respect to continuation and as applicable expansion of the program under this section to encompass—

''(i) device submissions beyond those identified in subsection (a)(1)(C); and

''(ii) device changes beyond those described in subsection (a)(2)(A). .

''(2) SUNSET.—This section shall cease to be effective October 1, 2022.

''(e) RULE OF CONSTRUCTION.—Nothing in this section shall be construed to limit the authority of the Secretary to request and review the complete assessment of a certified requestor under this section on a for-cause basis.''.

(b) CONFORMING AMENDMENTS.—

(1) REQUIREMENTS FOR PREMARKET APPROVAL SUPPLEMENTS.—Section 515(d)(6)(A)(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360e(d)(6)(A)(i)) is amended by inserting ", subject to section 524B," after "that affects safety or effectiveness".

(2) REQUIREMENTS FOR THIRTY-DAY NOTICE.—Section 515(d)(6)(A)(ii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360e(d)(6)(A)(ii)) is amended by inserting ", subject to section 524B," after "the date on which the Secretary receives the notice".

(3) REQUIREMENTS FOR PREMARKET NOTIFICATION; TECHNICAL CORRECTION TO REFERENCE TO SECTION 510(K).—Section 510(l) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(l)) is amended by striking "of this subsection under subsection (m)" and inserting "of subsection (k) under subsection (m) or section 524B".

(4) MISBRANDED DEVICES.—Section 502(t) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352(t)) is amended by inserting "or 524B" after "section 519".

Page 215, line 17, insert ", the FDA Human Subject Regulations," after "the HHS Human Subject Regulations".

Page 216, line 18, strike "12 months" and insert "36 months".

Page 218, line 25, strike "subject to clause (ii),".

Page 218, after line 14, insert the following new subsection (and make such conforming changes as may be necessary):

(e) DRAFT NIH POLICY.—Not later than 12 months after the date of enactment of this Act, the Secretary, acting through the Director of the National Institutes of Health, shall finalize the draft policy entitled "Draft NIH Policy on Use of a Single Institutional Review Board for Multi-Site Research".

Page 219, lines 10 through 12, strike "as applicable to the human subjects involved in research described in subparagraph (B)" and insert "as applicable to research that is subject to the FDA Human Subject Regulations".

Page 219, line 17, through page 220, line 7, strike paragraph (2).

Page 220, line 8, strike "(3)" and insert "(2)".

Page 229, after line 14, insert the following:

SEC. 2285. HIRING AUTHORITY FOR SCIENTIFIC, TECHNICAL, AND PROFESSIONAL PERSONNEL.

(a) IN GENERAL.—The Federal Food, Drug, and Cosmetic Act is amended by inserting after section 714 (21 U.S.C. 379d–3) the following:

"SEC. 714A. ADDITIONAL HIRING AUTHORITY.

''(a) IN GENERAL.—The Secretary may, without regard to the provisions of title 5, United States Code, governing appointments in the competitive service, appoint qualified candidates to scientific, technical, or professional positions within the following centers of the Food and Drug Administration:

''(1) The Center for Drug Evaluation and Research.

''(2) The Center for Biologics Evaluation and Research.

''(3) The Center for Devices and Radiological Health.

Such positions shall be within the competitive service.

''(b) COMPENSATION.—

''(1) IN GENERAL.—Notwithstanding any other provision of law, including any requirement with respect to General Schedule pay rates under subchapter III of chapter 53 of title 5, United States

Code, and consistent with the requirements of paragraph (2), the Secretary may determine and fix—

''(A) the annual rate of pay of any individual appointed under subsection (a); and

''(B) for purposes of retaining qualified employees, the annual rate of pay for any highly qualified scientific, technical, or professional personnel appointed to a position at any of the centers listed under subsection (a) before the date of enactment of this section.

''(2) LIMITATION.—The annual rate of pay established pursuant to paragraph (1) may not exceed the annual rate of pay of the President.

''(c) SUNSET.—The authority to appoint employees under this section shall terminate on September 30, 2022.

''(d) REPORT.—

''(1) IN GENERAL.—Not later than September 30, 2021, the Secretary shall submit a report to Congress that examines the extent to which the authority to appoint and retain personnel under this section enhanced the Food and Drug Administration's ability to meet the agency's critical need for highly qualified individuals for scientific, technical, or professional positions.

''(2) RECOMMENDATIONS.—The report under paragraph (1) shall include the recommendations of the Secretary on—

''(A) whether the authority to appoint personnel under this section should be reauthorized; and

''(B) other personnel authorities that would help the Food and Drug Administration to better recruit and retain highly qualified individuals for scientific, technical, or professional positions in the agency's medical product centers.''.

(b) RULE OF CONSTRUCTION.—The authority provided by section 714A of the Federal Food, Drug, and Cosmetic Act (as added by subsection (a)) shall not be construed to affect the authority provided under section 714 of such Act.

On page 229, after line 14, at the end of title II, add the following:

Subtitle Q—Exempting From Sequestration Certain Use Fees

SEC. 2301. EXEMPTING FROM SEQUESTRATION CERTAIN USER FEES OF FOOD AND DRUG ADMINISTRATION.

The Balanced Budget and Emergency Deficit Control Act of 1985 is amended—

(1) in section 255(g)(1)(A) (2 U.S.C. 905(g)(1)(A)), by inserting after ''Financial Agent Services'' the following new item:

''Food and Drug Administration, Salaries and Expenses, but only the portion of appropriations under such account corresponding to fees collected under sections 736, 738, 740, 741, 744B, and 744H of the Federal Food, Drug, and Cosmetic Act (75–9911–0–1–554)''; and

(2) in section 256(h) (2 U.S.C. 906(h)), by adding at the end the following new paragraph:

''(5) Notwithstanding any other provision of the law, this subsection shall not apply with respect to the portion of administrative expenses incurred by the Food and Drug Administration that are funded through fees collected under sections 736, 738, 740,

741, 744B, and 744H of the Federal Food, Drug, and Cosmetic Act.''.

Page 234, after line 23, insert the following:

''(5) ALLOWANCE FOR VARIATIONS.—Standards developed pursuant to a contract under this subsection, and the methods to test such standards, shall allow for variations on such standards as long as such variations are consistent with the standards so developed under this section.''.

Page 235, line 8, insert '', and methods to test such standards,'' after ''standards''.

Page 235, lines 12 and 13 strike '', in consultation with the National Coordinator,''.

Page 235, line 20, insert ''and methods to test such standards'' after ''criteria''.

Page 235, after line 25, insert the following:

''(3) MULTIPLE METHODS TO TEST INTEROPERABILITY STANDARDS.—For the purposes of developing methods to test interoperability standards for adoption under section 3004, the Secretary shall ensure that contracts under this section allow for multiple methods to test such standards to account for

variations in the adoption of such standards that do not conflict with section 3010(a).

Page 239, lines 9 and 10, strike ''the National Coordinator and''.

Page 255, line 21, strike ''Inspector General and''.

Page 277, strike line 17 and all that follows through page 280, line 10 and make such conforming amendments as are necessary.

Page 309, after line 14, insert the following:

TITLE IV—MEDICAID, MEDICARE, AND OTHER REFORMS

Subtitle A—Medicaid and Medicare Reforms

SEC. 4001. LIMITING FEDERAL MEDICAID REIMBURSEMENT TO STATES FOR DURABLE MEDICAL EQUIPMENT (DME) TO MEDICARE PAYMENT RATES.

(a) MEDICAID REIMBURSEMENT.—

(1) IN GENERAL.—Section 1903(i) of the Social Security Act (42 U.S.C. 1396b(i)) is amended—

(A) in paragraph (25), by striking ''or'' at the end;

(B) in paragraph (26), by striking the period at the end and inserting ''; or''; and

(C) by inserting after paragraph (26) the following new paragraph:

''(27) with respect to any amounts expended by the State on the basis of a fee schedule for items described in section 1861(n), as determined in the aggregate with respect to each class of such items as defined by the Secretary, in excess of the aggregate amount, if any, that would be paid for such items within such class on a fee-for-service basis under the program under part B of title XVIII, including, as applicable, under a competitive acquisition program under section 1847 in an area of the State.''.

(2) EFFECTIVE DATE.—The amendments made by this subsection shall be effective with respect to payments for items furnished on or after January 1, 2020.

(b) MEDICARE OMBUDSMAN.—Section 1808(c) of the Social Security Act (42 U.S.C. 1395b(c)), as amended by section 3101, is further amended by adding at the end the following new paragraph:

''(5) MONITORING DME REIMBURSEMENT UNDER MEDICAID.—The ombudsmen under each of paragraphs (1) and (4) shall evaluate the impact of the competitive acquisition program under section 1847, including as applied under section

1903(i)(27), on beneficiary health status and health outcomes.''.

SEC. 4002. MEDICARE PAYMENT INCENTIVE FOR THE TRANSITION FROM TRADITIONAL X-RAY IMAGING TO DIGITAL RADIOGRAPHY AND OTHER MEDICARE IMAGING PAYMENT PROVISION.

(a) PHYSICIAN FEE SCHEDULE.—

(1) PAYMENT INCENTIVE FOR TRANSITION.—

(A) IN GENERAL.—Section 1848(b) of the Social Security Act (42 U.S.C. 1395w–4(b)) is amended by adding at the end the following new paragraph:

''(9) SPECIAL RULE TO INCENTIVIZE TRANSITION FROM TRADITIONAL X-RAY IMAGING TO DIGITAL RADIOGRAPHY.—

''(A) LIMITATION ON PAYMENT FOR FILM X-RAY IMAGING SERVICES.—In the case of imaging services that are X-rays taken using film and that are furnished during 2017 or a subsequent year, the payment amount for the technical component (including the technical component portion of a global fee) of such services that would otherwise be determined under this section (without application of this paragraph and before application of any other adjustment

under this section) for such year shall be reduced by 20 percent.

''(B) PHASED-IN LIMITATION ON PAYMENT FOR COMPUTED RADIOGRAPHY IMAGING SERVICES.—In the case of imaging services that are X-rays taken using computed radiography technology—

''(i) in the case of such services furnished during 2018, 2019, 2020, 2021, or 2022 the payment amount for the technical component (including the technical component portion of a global fee) of such services that would otherwise be determined under this section (without application of this paragraph and before application of any other adjustment under this section) for such year shall be reduced by 7 percent; and

''(ii) in the case of such services furnished during 2023 or a subsequent year, the payment amount for the technical component (including the technical component portion of a global fee) of such services that would otherwise be determined under this section (without application of this

paragraph and before application of any other adjustment under this section) for such year shall be reduced by 10 percent.

''(C) COMPUTED RADIOGRAPHY TECHNOLOGY DEFINED.—For purposes of this paragraph, the term 'computed radiography technology' means cassette-based imaging which utilizes an imaging plate to create the image involved.

''(D) IMPLEMENTATION.—In order to implement this paragraph, the Secretary shall adopt appropriate mechanisms which may include use of modifiers.''.

(B) EXEMPTION FROM BUDGET NEUTRALITY.—Section 1848(c)(2)(B)(v) of the Social Security Act (42 U.S.C. 1395w–4(c)(2)(B)(v)) is amended, by adding at the end the following new subclause:

''(X) REDUCED EXPENDITURES ATTRIBUTABLE TO INCENTIVES TO TRANSITION TO DIGITAL RADIOGRAPHY.—Effective for fee schedules established beginning with 2017, reduced expenditures attributable to subparagraph (A) of subsection (b)(9)

and effective for fee schedules established beginning with 2018, reduced expenditures attributable to subparagraph (B) of such subsection.''.

(2) ELIMINATION OF APPLICATION OF MULTIPLE PROCEDURE PAYMENT REDUCTION.—Section 1848(b)(4) of the Social Security Act (42 U.S.C. 1395w–4(b)(4)) is amended by adding at the end the following new subparagraph:

''(E) ELIMINATION OF APPLICATION OF MULTIPLE PROCEDURE PAYMENT REDUCTION.—

''(i) IN GENERAL.—Not later than January 1, 2016, the Secretary shall not apply a multiple procedure payment reduction policy to the professional component of imaging services furnished in any subsequent year that is prior to a year in which the Secretary conducts and publishes, as part of the Medicare Physician Fee Schedule Proposed Rule for a year, the empirical analysis described in clause (ii).

''(ii) EMPIRICAL ANALYSIS DESCRIBED.—The empirical analysis described in this clause is an analysis of the

Resource-Based Relative Value Scale (commonly known as the 'RBRVS') Data Manager information that is used to determine what, if any, efficiencies exist within the professional component of imaging services when two or more studies are performed on the same patient on the same day. Such empirical analysis shall include—

''(I) work sheets and other information detailing which physician work activities performed given the typical vignettes were assigned reduction percentages of 0, 25, 50, 75 and 100 percent;

''(II) a discussion of the clinical aspects that informed the assignment of the reduction percentages described in subclause (I);

''(III) an explanation of how the percentage reductions for pre-, intra and post-service work were determined and calculated; and

''(IV) a demonstration that the Centers for Medicare & Medicaid Services has consulted with practicing

radiologists to gain knowledge of how radiologists interpret studies of multiple body parts on the same individual on the same day.''.

(b) PAYMENT INCENTIVE FOR TRANSITION UNDER HOSPITAL OUTPATIENT PROSPECTIVE PAYMENT SYSTEM.—Section 1833(t)(16) of the Social Security Act (42 U.S.C. 1395(t)(16)) is amended by adding at the end the following new subparagraph:

''(F) PAYMENT INCENTIVE FOR THE TRANSITION FROM TRADITIONAL X-RAY IMAGING TO DIGITAL RADIOGRAPHY.—Notwithstanding the previous provisions of this subsection:

''(i) LIMITATION ON PAYMENT FOR FILM X-RAY IMAGING SERVICES.—In the case of imaging services that are X-rays taken using film and that are furnished during 2017 or a subsequent year, the payment amount for the technical component (including the technical component portion of a global fee) of such services that would otherwise be determined under this section (without application of this paragraph and before application of any other adjustment

under this subsection) for such year shall be reduced by 20 percent.

''(ii) PHASED-IN LIMITATION ON PAYMENT FOR COMPUTED RADIOGRAPHY IMAGING SERVICES.—In the case of imaging services that are X-rays taken using computed radiography technology (as defined in section 1848(b)(9)(C))—

''(I) in the case of such services furnished during 2018, 2019, 2020, 2021, or 2022 the payment amount for the technical component (including the technical component portion of a global fee) of such services that would otherwise be determined under this section (without application of this paragraph and before application of any other adjustment under this subsection) for such year shall be reduced by 7 percent; and

''(II) in the case of such services furnished during 2023 or a subsequent year, the payment amount for the technical component (including the technical component portion of a

global fee) of such services that would otherwise be determined under this section (without application of this paragraph and before application of any other adjustment under this subsection) for such year shall be reduced by 10 percent.

''(iii) APPLICATION WITHOUT REGARD TO BUDGET NEUTRALITY.—The reductions made under this paragraph—

''(I) shall not be considered an adjustment under paragraph (2)(E); and

''(II) shall not be implemented in a budget neutral manner.''.

SEC. 4003. IMPLEMENTATION OF OFFICE OF INSPECTOR GENERAL RECOMMENDATION TO DELAY CERTAIN MEDICARE PRESCRIPTION DRUG PLAN PREPAYMENTS.

Section 1860D–15(d) of the Social Security Act (42 U.S.C. 1395w–115(d)) is amended by adding at the end the following:

''(5) TIMING OF PAYMENTS.—With respect to monthly reinsurance payment amounts under this section to a PDP sponsor for months in a year (be-

ginning with 2020), such payment amounts for a month shall be made on the first business day occurring on or after the following date for that month:

''(A) For the month of January, January 2nd.

''(B) For the month of February, February 5th.

''(C) For the month of March, March 10th.

''(D) For the month of April, April 15th.

''(E) For the month of May, May 20th.

''(F) For the month of June, June 25th.

''(G) For the month of July and each succeeding month (other than December) in a year, the first day of the next month.

''(H) For the month of December, December 24th.''.

Subtitle B—Cures Innovation Fund

SEC. 4041. CURES INNOVATION FUND.

(a) ESTABLISHMENT.—There is hereby established in the Treasury of the United States a fund to be known as the Cures Innovation Fund (in this section referred to as the ''Fund'').

(b) APPROPRIATIONS.—There is hereby appropriated to the Fund, out of any funds in the Treasury not other-

wise appropriated, $110,000,000 for each of fiscal years 2016 through 2020.

(c) EXPENDITURES.—Amounts in the Fund shall be available, as provided by appropriation Acts, for making expenditures for carrying out the following:

(1) Section 229A of the Public Health Service Act, as added by section 1123 (relating to data on natural history of diseases).

(2) Part E of title II of the Public Health Service Act, as added by section 1141 (relating to Council for 21st Century Cures).

(3) Section 2001 and the amendments made by such section (relating to development and use of patient experience data to enhance structured risk benefit assessment framework).

(4) Section 2021 and the amendments made by such section (relating to qualification of drug development tools).

(5) Section 2062 and the amendments made by such section (relating to utilizing evidence from clinical experience).

(6) Section 2161 (relating to grants for studying the process of continuous drug manufacturing).

(c) SUPPLEMENT, NOT SUPPLANT; PROHIBITION AGAINST TRANSFER.—Funds appropriated by subsection (b)—

(1) shall be used to supplement, not supplant, amounts otherwise made available to the National Institutes of Health and the Food and Drug Administration; and

(2) notwithstanding any transfer authority in any appropriation Act, shall not be used for any purpose other than the expenditures listed in subsection (c).

Subtitle C—Other Reforms

SEC. 4061. SPR DRAWDOWN.

(a) DRAWDOWN AND SALE.—Notwithstanding section 161 of the Energy Policy and Conservation Act (42 U.S.C. 6241), the Secretary of Energy shall draw down and sell 8,000,000 barrels of crude oil from the Strategic Petroleum Reserve during each of the fiscal years 2018 through 2025, except as provided in subsection (b). Amounts received for a sale under this subsection shall be deposited in the General Fund of the Treasury during the fiscal year in which the sale occurs.

(b) EMERGENCY PROTECTION.—The Secretary shall not draw down and sell crude oil under this section in amounts that would result in a Strategic Petroleum Re-

serve that contains an inventory of petroleum products representing less than 90 days of emergency reserves, based on the average daily level of net imports of crude oil and petroleum products in the previous calendar year.

(c) PROCEEDS.—Proceeds from a sale under this section shall be deposited into the general fund of the Treasury of the United States.

Subtitle D—Miscellaneous

SEC. 4081. LYME DISEASE AND OTHER TICK-BORNE DISEASES.

(a) IN GENERAL.—Title III of the Public Health Service Act (42 U.S.C. 241 et seq.) is amended by adding at the end the following new part:

"PART W—LYME DISEASE AND OTHER TICK-BORNE DISEASES

"SEC. 399OO. RESEARCH.

''(a) IN GENERAL.—The Secretary shall conduct or support epidemiological, basic, translational, and clinical research regarding Lyme disease and other tick-borne diseases.

''(b) BIENNIAL REPORTS.—The Secretary shall ensure that each biennial report under section 403 includes information on actions undertaken by the National Institutes of Health to carry out subsection (a) with respect to Lyme disease and other tick-borne diseases, including

an assessment of the progress made in improving the outcomes of Lyme disease and such other tick-borne diseases.

"SEC. 399OO–1. WORKING GROUP.

"(a) ESTABLISHMENT.—The Secretary shall establish a permanent working group, to be known as the Interagency Lyme and Tick-Borne Disease Working Group (in this section and section 399OO–2 referred to as the 'Working Group'), to review all efforts within the Department of Health and Human Services concerning Lyme disease and other tick-borne diseases to ensure interagency coordination, minimize overlap, and examine research priorities.

"(b) RESPONSIBILITIES.—The Working Group shall—

"(1) not later than 24 months after the date of enactment of this part, and every 24 months thereafter, develop or update a summary of—

"(A) ongoing Lyme disease and other tick-borne disease research related to causes, prevention, treatment, surveillance, diagnosis, diagnostics, duration of illness, intervention, and access to services and supports for individuals with Lyme disease or other tick-borne diseases;

''(B) advances made pursuant to such research;

''(C) the engagement of the Department of Health and Human Services with persons that participate at the public meetings required by paragraph (5); and

''(D) the comments received by the Working Group at such public meetings and the Secretary's response to such comments;

''(2) ensure that a broad spectrum of scientific viewpoints is represented in each such summary;

''(3) monitor Federal activities with respect to Lyme disease and other tick-borne diseases;

''(4) make recommendations to the Secretary regarding any appropriate changes to such activities; and

''(5) ensure public input by holding annual public meetings that address scientific advances, research questions, surveillance activities, and emerging strains in species of pathogenic organisms.

''(c) MEMBERSHIP.—

''(1) IN GENERAL.—The Working Group shall be composed of a total of 14 members as follows:

''(A) FEDERAL MEMBERS.—Seven Federal members, consisting of one or more representatives of each of—

''(i) the Office of the Assistant Secretary for Health;

''(ii) the Food and Drug Administration;

''(iii) the Centers for Disease Control and Prevention;

''(iv) the National Institutes of Health; and

''(v) such other agencies and offices of the Department of Health and Human Services as the Secretary determines appropriate.

''(B) NON-FEDERAL PUBLIC MEMBERS.—Seven non-Federal public members, consisting of representatives of the following categories:

''(i) Physicians and other medical providers with experience in diagnosing and treating Lyme disease and other tick-borne diseases.

''(ii) Scientists or researchers with expertise.

''(iii) Patients and their family members.

''(iv) Nonprofit organizations that advocate for patients with respect to Lyme disease and other tick-borne diseases.

''(v) Other individuals whose expertise is determined by the Secretary to be beneficial to the functioning of the Working Group.

''(2) APPOINTMENT.—The members of the Working Group shall be appointed by the Secretary, except that of the non-Federal public members under paragraph (1)(B)—

''(A) one shall be appointed by the Speaker of the House of Representatives; and

''(B) one shall be appointed by the Majority Leader of the Senate.

''(3) DIVERSITY OF SCIENTIFIC PERSPECTIVES.—In making appointments under paragraph (2), the Secretary, the Speaker of the House of Representatives, and the Majority Leader of the Senate shall ensure that the non-Federal public members of the Working Group represent a diversity of scientific perspectives.

''(4) TERMS.—The non-Federal public members of the Working Group shall each be appointed to serve a 4-year term and may be reappointed at the end of such term.

''(d) MEETINGS.—The Working Group shall meet as often as necessary, as determined by the Secretary, but not less than twice each year.

''(e) APPLICABILITY OF FACA.—The Working Group shall be treated as an advisory committee subject to the Federal Advisory Committee Act.

''(f) REPORTING.—Not later than 24 months after the date of enactment of this part, and every 24 months thereafter, the Working Group—

''(1) shall submit a report on its activities, including an up-to-date summary under subsection (b)(1) and any recommendations under subsection (b)(4), to the Secretary, the Committee on Energy and Commerce of the House of Representatives, and the Committee on Health, Education, Labor and Pensions of the Senate;

''(2) shall make each such report publicly available on the website of the Department of Health and Human Services; and

''(3) shall allow any member of the Working Group to include in any such report minority views.

''SEC. 399OO–2. STRATEGIC PLAN.

''Not later than 3 years after the date of enactment of this section, and every 5 years thereafter, the Secretary shall submit to the Congress a strategic plan, informed by the most recent summary under section 399OO–1(b)(1), for the conduct and support of Lyme disease and tick-borne disease research, including—

''(1) proposed budgetary requirements;

''(2) a plan for improving outcomes of Lyme disease and other tick-borne diseases, including progress related to chronic or persistent symptoms and chronic or persistent infection and co-infections;

''(3) a plan for improving diagnosis, treatment, and prevention;

''(4) appropriate benchmarks to measure progress on achieving the improvements described in paragraphs (2) and (3); and

''(5) a plan to disseminate each summary under section 399OO–1(b)(1) and other relevant information developed by the Working Group to the public, including health care providers, public health departments, and other relevant medical groups.''.

(b) NO ADDITIONAL AUTHORIZATION OF APPROPRIATIONS.—No additional funds are authorized to be appropriated for the purpose of carrying out this section and the amendment made by this section, and this section and

such amendment shall be carried out using amounts otherwise available for such purpose.

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