I

112TH CONGRESS
2D SESSION

H. R. 6626

To foster further innovation and entrepreneurship in the health information technology sector.

IN THE HOUSE OF REPRESENTATIVES

DECEMBER 3, 2012

Mr. HONDA introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committees on Ways and Means and Small Business, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

---

A BILL

To foster further innovation and entrepreneurship in the health information technology sector.

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 ''Health Care Innovation and Marketplace Technologies Act of 2012''.

SEC. 2. HEALTH INFORMATION TECHNOLOGY PLACED IN SERVICE BY MEDICAL CARE PROVIDER.

(a) IN GENERAL.—Part VI of subchapter B of chapter 1 of the Internal Revenue Code of 1986 is amended by adding at the end the following:

"SEC. 200. HEALTH IT PLACED IN SERVICE BY MEDICAL CARE PROVIDER.

''(a) IN GENERAL.—In the case of a medical care provider, there shall be allowed as a deduction an amount equal to the amount paid or incurred by the medical care provider for qualified health information technology placed in service by the provider during the taxable year.

''(b) LIMITATION.—The amount allowed as a deduction to a medical care provider by subsection (a) for a taxable year shall not exceed $250,000.

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

''(1) MEDICAL CARE PROVIDER.—The term 'medical care provider' means—

''(A) a provider of services (as defined in section 1861(u) of the Social Security Act (42 U.S.C. 1395x(u)),

''(B) a provider of medical or health services (as defined in section 1861(s) of the Social Security Act (42 U.S.C. 1395x(s)), and

''(C) any other person who furnishes, bills, or is paid for health care in the normal course of business.

''(2) QUALIFIED HEALTH INFORMATION TECHNOLOGY.—The term 'qualified health information technology' means the application of information processing involving both computer hardware and software that deals with the storage, retrieval, sharing, and use of health care information, data, and knowledge for communication and decisionmaking. Such term does not include certified EHR technology.

''(d) SPECIAL RULES.—

''(1) PASS-THRU ENTITIES.—In the case of a partnership or S corporation, this section shall be applied at the entity level and at the partner or similar level.

''(2) COORDINATION WITH OTHER DEDUCTIONS.—Any amount taken into account under subsection (a) shall not be allowed as a deduction under any other section of this chapter.

''(e) TERMINATION.—This section shall not apply to amounts paid or incurred after December 31, 2017.''.

(b) CLERICAL AMENDMENT.—The table of sections for part VI of subchapter B of chapter 1 of such Code is amended by adding at the end the following new item:

"Sec. 200. Health IT placed in service by medical care provider.".

(c) EFFECTIVE DATE.—The amendments made by this section shall apply to taxable years beginning after December 31, 2012.

SEC. 3. SMALL BUSINESS HEALTH INFORMATION TECHNOLOGY FINANCING PROGRAM.

The Small Business Act (15 U.S.C. 631 et seq.) is amended by redesignating section 45 as section 46 and by inserting the following new section after section 44:

"SEC. 45. LOAN GUARANTEES FOR HEALTH INFORMATION TECHNOLOGY.

''(a) DEFINITIONS.—As used in this section:

''(1) The term 'health information technology' means computer hardware, software, services, and related technology that is purchased by an eligible professional to aid in the provision of health care in a health care setting and that provides for—

''(A) enhancement of continuity of care for patients through electronic storage, transmission, and exchange of relevant personal health data and information, such that this information is accessible at the times and places

where clinical decisions will be or are likely to be made;

"(B) enhancement of communication between patients and health care providers;

"(C) improvement of quality measurement by eligible professionals enabling them to collect, store, measure, and report on the processes and outcomes of individual and population performance and quality of care;

"(D) improvement of evidence-based decision support;

"(E) enhancement of consumer and patient empowerment; or

"(F) services that assist with workflow redesign, training, system configuration, human change management and other similar services focused on getting the best value from existing technology that has already been purchased.

Such term shall not include information technology whose sole use is financial management, maintenance of inventory of basic supplies, or appointment scheduling.

"(2) The term 'eligible professional' means any of the following:

"(A) A physician (as defined in section 1861(r) of the Social Security Act (42 U.S.C. 1395x(r))).

"(B) A practitioner described in section 1842(b)(18)(C) of that Act.

"(C) A physical or occupational therapist or a qualified speech-language pathologist.

"(D) A qualified audiologist (as defined in section 1861(ll)(3)(B)) of that Act.

"(E) A State-licensed pharmacist.

"(F) A State-licensed, a State-certified, or a nationally accredited home health care provider.

"(3) The term 'qualified eligible professional' means an eligible professional whose office can be classified as a small business concern by the Administrator for purposes of this Act under size standards established under section 3 of this Act.

"(b) LOAN GUARANTEES FOR QUALIFIED ELIGIBLE PROFESSIONALS.—

"(1) IN GENERAL.—Subject to paragraph (2), the Administrator may guarantee up to 90 percent of the amount of a loan made to a qualified eligible professional to be used for the acquisition of health information technology for use in such eligible pro-

fessional's medical practice and for the costs associated with the installation of such technology. Except as otherwise provided in this section, the terms and conditions that apply to loans made under section 7(a) of this Act shall apply to loan guarantees made under this section.

''(2) LIMITATIONS ON GUARANTEE AMOUNTS.—The maximum amount of loan principal guaranteed under this subsection may not exceed—

''(A) $250,000 with respect to any single qualified eligible professional; and

''(B) $500,000 with respect to a single group of affiliated qualified eligible professionals.

''(c) FEES.—(1) The Administrator may impose a guarantee fee on the borrower for the purpose of reducing the cost (as defined in section 502(5) of the Federal Credit Reform Act of 1990) of the guarantee to zero in an amount not to exceed 2 percent of the total guaranteed portion of any loan guaranteed under this section. The Administrator may also impose annual servicing fees on lenders not to exceed 0.5 percent of the outstanding balance of the guarantees on lenders' books.

''(2) No service fees, processing fees, origination fees, application fees, points, brokerage fees,

bonus points, or other fees may be charged to a loan applicant or recipient by a lender in the case of a loan guaranteed under this section.

''(d) DEFERRAL PERIOD.—Loans guaranteed under this section shall carry a deferral period of not less than 1 year and not more than 3 years. The Administrator shall have the authority to subsidize interest during the deferral period.

''(e) EFFECTIVE DATE.—No loan may be guaranteed under this section after the date that is 6 months after the date of enactment of this section.

''(f) SUNSET.—No loan may be guaranteed under this section after the date that is 10 years after the date that is 6 months after the date of enactment of this section.

''(g) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated such sums as are necessary for the cost (as defined in section 502(5) of the Federal Credit Reform Act of 1990) of guaranteeing $25,000,000 in loans under this section. The Administrator shall determine such program cost separately and distinctly from other programs operated by the Administrator.''.

SEC. 4. CHALLENGE GRANT PROGRAM; DISRUPTIVE TECHNOLOGIES PRIZE PROGRAM.

(a) IN GENERAL.—Subtitle B of title XXX of the Public Health Service Act (42 U.S.C. 300jj–31 et. seq.) is amended—

(1) by redesignating sections 3017 and 3018 as sections 3019 and 3020, respectively; and

(2) by inserting after section 3016 the following new sections:

"SEC. 3017. CHALLENGE GRANT PROGRAM.

"(a) IN GENERAL.—Subject to the availability of appropriations, the Secretary, acting through the National Coordinator, shall award competitive grants to eligible entities to carry out the activities described in subsection (d).

"(b) ELIGIBLE ENTITY DEFINED.—In this section, the term 'eligible entity' means any individual or entity, except for an entity that—

"(1) has 500 or more employees; and

"(2) has an annual revenue of $7,000,000 or more.

"(c) APPLICATION.—An eligible entity seeking a grant under this section shall submit an application to the National Coordinator at such time, in such manner, and containing such information as the National Coordinator may require, including a description of the product, proc-

ess, or structure described in subsection (d) for which the entity intends to use the grant.

''(d) USES OF FUNDS.—An eligible entity that receives a grant under this section shall use such funds to develop an effective product, process, or structure that enhances the use, particularly by patients, of health information technology, by—

''(1) integrating more than one aspect of health information;

''(2) performing a medical consultation using technology;

''(3) providing health information to physicians or patients;

''(4) allowing better coordination during the delivery and follow-up after the delivery of health care; or

''(5) addressing any of the three areas that the Commission established under section 3018(e)(1) has identified pursuant to its duties under section 3018(e)(2)(A).

''(e) PROHIBITED USE OF FUNDS.—An eligible entity that receives a grant under this section may not use such grant to develop a product, process, or structure that meets only the requirements that are necessary to be a certified EHR technology.

''(f) GRANT AMOUNT.—A grant awarded under this section may not be greater than $75,000.

''(g) REPORT.—Not later than one year after the date of receipt of a grant under this section, an eligible entity shall submit to the National Coordinator and the Administrator of the Centers for Medicare & Medicaid Services a report that describes—

''(1) the progress that the entity has made on the product, process, or structure funded by the grant; and

''(2) how patients, health-care providers, and other individuals and entities involved in the delivery of health care, including the Centers for Medicare & Medicaid Services, could use the product, process, or structure funded by the grant to enhance the delivery of and reduce the cost of health care.

''(h) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out this section $5,000,000 for each of fiscal years 2014 through 2016.

''SEC. 3018. DISRUPTIVE TECHNOLOGIES PRIZE PROGRAM.

''(a) PRIZE PROGRAM AUTHORIZED.—For purposes of rewarding innovation in health information technology, the Secretary, acting through the National Coordinator, shall carry out a program to award one prize competitively in each of the three areas identified by the Commission

under subsection (e)(2)(A) using the benchmarks developed under subsection (e)(2)(B) to select the prize recipient in each category.

''(b) ADMINISTRATION OF PROGRAM.—In carrying out the program under subsection (a), the following shall apply:

''(1) ADVERTISING.—The National Coordinator shall widely advertise the prize competition to encourage broad participation.

''(2) REQUIREMENTS AND REGISTRATION.—The National Coordinator shall publish a notice in the Federal Register announcing—

''(A) the rules for being eligible to participate in the competition;

''(B) the process for participants to register for the competition;

''(C) the areas of health information technology that the Commission develops under subsection (e)(2)(A) for each prize; and

''(D) the benchmarks that the Commission develops under subsection (e)(2)(B) based on which a winner will be selected in each such area.

''(c) ELIGIBILITY.—To be eligible to win a prize under this section, an individual or entity—

''(1) shall register to participate in the competition in accordance with any rules promulgated by the National Coordinator under subsection (b)(2);

''(2) in the case of an entity, shall be incorporated in and maintain a primary place of business in the United States, and in the case of an individual, whether participating singly or in a group, shall be a citizen or permanent resident of the United States; and

''(3) may not be a Federal entity or Federal employee acting within the scope of their employment; and

''(4) shall submit an application that includes an explanation of the anticipated market viability of the technology that such individual or entity would develop with funds received under the prize program.

''(d) PRIZE AMOUNT.—

''(1) IN GENERAL.—Subject to paragraph (2), a prize awarded under this section shall be in the amount of $10,000,000.

''(2) ALTERNATIVE RULE.—In the case that the amount made available for prize awards under this section is less than $33,000,000, the National Coordinator may reserve not more than 10 percent for the administrative costs of carrying out this section,

and shall divide the remaining amount equally for the three prizes awarded under this section.

''(e) COMMISSION.—

''(1) IN GENERAL.—There is established a commission to carry out the activities described in paragraph (2) (referred to in this section as the 'Commission').

''(2) DUTIES.—

''(A) AREAS OF HEALTH INFORMATION TECHNOLOGY.—For the purposes of the prize program under subsection (a), the Commission shall identify three areas within the field of health information technology that are not adequately addressed by certified EHR technologies and the use of such technologies. Each area identified shall be an area that will promote the development of technologies that would be widely useful, would help decrease the cost of health care, and would improve the quality of health care, particularly for patients.

''(B) BENCHMARKS.—The Commission shall develop the benchmarks that the National Coordinator shall use to determine the prize recipient in each area identified under subpara-

graph (A). The Commission shall identify such benchmarks with the goals of—

''(i) attracting participants from outside the health information technology field that will take new approaches to addressing the areas identified by the Commission under subparagraph (A);

''(ii) solving such challenges; and

''(iii) promoting the development of technologies that will be widely adopted, particularly by patients.

''(C) RESTRICTION OF PRIZE AWARD.—The Commission shall determine how to restrict the prize recipients' use of the funds awarded as a prize under this section, with respect to the development of health information technology, in order to ensure that the prize recipients use such funds to further develop the technologies for which such prize was awarded.

''(3) MEMBERS.—

''(A) NUMBER AND APPOINTMENT.—The Commission shall be composed of 10 members appointed by the National Coordinator not later than 90 days after the date of the enactment of this Act.

"(B) COMPOSITION.—Each member of the Commission shall be appointed to represent one of the following four categories:

"(i) The varied disciplines within the health information technology field.

"(ii) The varied disciplines within the medical field that are not described in clause (i).

"(iii) Individuals who—

"(I) represent a patient-led, patient-centered organization with a patient constituency;

"(II) have experience with health information technology and privacy; and

"(III) are trained, knowledgeable, and prepared to participate in the decisionmaking process regarding health information technology.

"(iv) Officers or employees of the Federal Government.

"(C) REPRESENTATION OF MEMBERSHIP CATEGORIES.—At least two members of the Commission shall represent each of the categories described in subparagraph (B).

''(D) TRAVEL EXPENSES.—Each member shall receive travel expenses, including per diem in lieu of subsistence, in accordance with applicable provisions under subchapter I of chapter 57 of title 5, United States Code.

''(E) FIRST MEETING.—The Commission shall hold its first meeting not later than 180 days after the date of the enactment of this Act.

''(4) REPORT TO THE NATIONAL COORDINATOR.—Not later than one year after the date of enactment of this Act, the Commission shall submit to the National Coordinator a report containing the areas, benchmarks, and restrictions on the uses of prize awards that the Commission identifies for the prize program under paragraph (2).

''(5) TERMINATION.—The Commission shall terminate upon submitting its report to the National Coordinator under paragraph (4).

''(f) AUTHORIZATION OF APPROPRIATIONS.—In addition to sums authorized to be appropriated to carry out this subtitle under section 3020, there is authorized to be appropriated to carry out this section $33,000,000 for fiscal year 2014.''.

(b) CONFORMING AMENDMENTS.—

(1) Section 3011 of such Act (42 U.S.C. 300jj-31) is amended—

(A) in subsection (a), by striking ''section 3018'' and inserting ''section 3020''; and

(B) in subsection (b), by striking ''section 3018'' and inserting ''section 3020''.

(2) Section 3020 of such Act (as so redesignated) is amended by inserting ''except for section 3018,'' after ''For purposes of carrying out this subtitle,''.

SEC. 5. ESTABLISHMENT OF THE OFFICE OF WIRELESS HEALTH TECHNOLOGY.

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 new section:

''SEC. 1013. OFFICE OF WIRELESS HEALTH TECHNOLOGY.

''(a) ESTABLISHMENT.—There is established within the Office of the Commissioner an office to be known as the Office of Wireless Health Technology (referred to in this section as the 'Office'), which shall be headed by a director.

''(b) APPOINTMENT OF FIRST DIRECTOR.—The first Director of the Office shall be appointed by the Commissioner not later than 90 days after the date of enactment of this section.

''(c) DUTIES.—The Director of the Office shall—

''(1) through public meetings and other forms of communication with individuals and entities that design, produce, disseminate, or have a prevailing interest in wireless health technology, receive and analyze recommendations with respect to ways that existing regulations regarding wireless health technology might be made more reasonable and predictable, including ways that such regulations could be clarified and simplified;

''(2) coordinate with federal agencies, offices, institutes, and centers involved in the regulation of wireless health technology, including the Federal Communications Commission, the Office of the National Coordinator for Health Information Technology, the Centers for Medicare & Medicaid Services, the Agency for Healthcare Research and Quality, the National Institute of Standards and Technology, the Health Resources and Services Administration, and the National Institutes of Health, regarding activities of such agencies, offices, institutes, and centers that can be improved so as to make such regulation more robust, predictable, and easily understood and navigated by individuals and entities

that design, produce, disseminate, or have a prevailing interest in wireless health technology;

"(3) provide information to individuals and entities that design, produce, disseminate, or have a prevailing interest in wireless health technology on how to design, produce, or disseminate wireless health technology in accordance with existing law; and

"(4) publish and make available on the public Internet website of the Food and Drug Administration in a searchable format an annual report that—

"(A) explains how the Food and Drug Administration implemented regulations regarding wireless health technology during the prior year;

"(B) analyzes the effectiveness of—

"(i) such regulations; and

"(ii) other wireless health-related efforts by the Food and Drug Administration; and

"(C) provides specific recommendations on how the Food and Drug Administration should improve its practices with regard to wireless health technology (in a manner that ensures consistency within the Food and Drug Adminis-

tration regarding the application of its regulatory approach without compromising patient safety or privacy) in order to—

"(i) remove barriers to innovations in such technology; and

"(ii) align such practices with the practices of other Federal agencies.

"(d) CONSULTATION WITH WORKING GROUP AND COMMISSIONS.—In carrying out the duties specified in subsection (c), the Director of the Office shall consult with any working group convened under section 618(b)(1) of the Food and Drug Administration Safety and Innovation Act, and may consult with any Federal commission.

"(e) DEFINITION OF WIRELESS HEALTH TECHNOLOGY.—For purposes of this section, the term 'wireless health technology' has such meaning as specified by the Commissioner pursuant to regulation, but in no case shall include technology this is not regulated under the provisions of this Act (other than this section).

"(f) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out this section $1,000,000 for each of fiscal years 2014 through 2018.".

SEC. 6. MOBILE HEALTH SOFTWARE APPLICATION TECHNOLOGY RESPONSIBILITIES OF THE HEALTH INFORMATION TECHNOLOGY RESEARCH CENTER.

Section 3012 of the Public Health Service Act (42 U.S.C. 300jj-32) is amended—

(1) in subsection (b), by adding at the end the following new paragraph:

''(4) ENCOURAGEMENT OF DESIGN, PRODUCTION, AND DISSEMINATION OF MOBILE HEALTH SOFTWARE APPLICATION TECHNOLOGY.—

''(A) IN GENERAL.—In addition to the purposes under paragraph (3), the Center shall—

''(i) establish an educational website repository and a response mechanism (such as a national telephone number) to provide timely responses to questions in order to make information available and provide direct support to individuals and entities that design, produce, disseminate, or have a prevailing interest in mobile health software application technology regarding the actions such individuals and entities must take in order to ensure that such tech-

nology is designed, produced, and disseminated in accordance with Federal law; and

"(ii) publish and make available on the public Internet website of the Department in a searchable format an annual report that—

"(I) highlights and explains the laws and regulations that commonly impede efforts by individuals and entities to design, produce, or disseminate mobile health software application technology; and

"(II) discusses the work the Center has completed in the past year with regard to mobile health software application technology, including accomplishments by the Center and challenges that may require more work or outside support in order for the Center to accomplish the objectives outlined in this subparagraph.

"(B) DEFINITION OF MOBILE HEALTH SOFTWARE APPLICATION TECHNOLOGY.—For purposes of subparagraph (A), the term 'mobile

health software application technology' means a software program that—

''(i) offers health-related services and runs on a mobile device; or

''(ii) enables health-related services through other portals associated with the use of a mobile device.

''(C) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out this paragraph $500,000 for each of fiscal years 2014 through 2018.''; and

(2) in subsection (c)(8), by deleting ''paragraph (3)'' and inserting ''paragraphs (3) and (4)''.

SEC. 7. WORKFORCE RETRAINING GRANTS.

(a) IN GENERAL.—The National Coordinator for Health Information Technology may award to eligible entities grants to be used for training health care workers in health information technology (in this section referred to as ''HIT'').

(b) PERIOD OF GRANT.—The period of a grant under this section shall be 24 months.

(c) ELIGIBLE ENTITIES.—In this section, ''eligible entities'' means entities that provide clinical health care services to individuals within the United States.

(d) JOB TRANSITION.—As a condition on receipt of a grant under this section, a grantee shall ensure that each employee whose HIT training is funded by that grant assumes expanded duties with the grantee, either in the form of a new employment position or revised duties within such employee's existing employment position, that requires the use of HIT, not more than 1 year after the employee completes the training.

(e) REPORTING.—Each grantee shall submit a report not later than 24 months after receipt of a grant to the National Coordinator for Health Information Technology including the following:

(1) The number of employees who received training pursuant to the grant.

(2) The HIT skills covered during such training or trainings.

(3) Documentation that each trained employee commenced or will commence work in a new position that satisfies the condition set forth in subsection (d).

(f) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section $10,000,000 for each of fiscal years 2014 through 2018.

○