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110TH CONGRESS
1ST SESSION

H. R. 1368

To establish a program to provide financial incentives to encourage the adoption and use of interactive personal health records.

IN THE HOUSE OF REPRESENTATIVES

MARCH 7, 2007

Mr. KENNEDY (for himself, Mr. REICHERT, and Mr. SMITH of Washington) introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committee on Ways and Means, 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

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A BILL

To establish a program to provide financial incentives to encourage the adoption and use of interactive personal health records.

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 ''Personalized Health Information Act of 2007''.

SEC. 2. PERSONAL HEALTH RECORD (PHR) INCENTIVE PROGRAM.

(a) ESTABLISHMENT.—The Secretary of Health and Human Services (in this section referred to as the ''Secretary'') shall establish a program (in this section referred to as the ''program'') to provide financial incentives for the use of interactive qualifying personal health records by Medicare and other patients and their health care providers in order to—

(1) provide patients (or their authorized representatives) access to and control over their personal health data and information and educational information so as to become healthier and more informed and engaged health care consumers;

(2) make available to authorized health care providers a more accurate minimum data set of patient information at all points of care;

(3) protect patient security and privacy;

(4) improve patients' adherence to evidence-based care guidelines, preventive care, and screening protocols, thereby improving health outcomes and lowering health care costs;

(5) improve medication adherence by patients, thereby improving health outcomes and lowering health care costs;

(6) provide patients with more accurate, timely, and appropriate information related to their health care benefits and related administrative information;

(7) improve the quality and efficiency of communication between health care providers and patients;

(8) create a direct communications channel to patients in the event of health emergencies; and

(9) provide access with appropriate privacy safeguards to de-identified health care information to evaluate and advance public health and health research goals.

(b) INCENTIVE PAYMENTS.—

(1) IN GENERAL.—Under the program, each qualified physician (as defined in subsection (c)) that has a qualifying patient (as defined in subsection (d)) shall receive an incentive payment from the PHR Incentive Fund established under subsection (f). In the case of such a patient of more than one physician, each such physician (who does not share in the same group practice, as defined by the Secretary, with another qualifying physician of that patient) may receive such a payment.

(2) AMOUNT OF PAYMENT.—

(A) IN GENERAL.—Except as otherwise provided, the amount of the incentive payment to a qualifying physician under the program shall be at least $3 per year for each qualifying patient of the physician.

(B) ADJUSTMENT; LIMITATION.—The Secretary shall annually retrospectively set the incentive payment amount based on the amount of the contributions into the PHR Incentive Fund. The Secretary shall pay PHR incentives payments only from such Fund.

(C) ANNUAL LIMITATION.—The Secretary shall establish a maximum annual payment under this section to any qualifying physician.

(3) DURATION.—Payments shall be made under the program during a 3-year period beginning on the date of implementation of the program, except that the Secretary may continue the program for an additional two years if the Secretary determines that continuation of the program for such period would be a cost-effective way of achieving the goals of this Act.

(4) PROGRAM EDUCATION.—

(A) PUBLICATION OF NAMES QUALIFYING PHYSICIANS.—In order to assist patients in

identifying health care providers that use qualifying personal health records, Secretary shall publish on the official website for the Centers for Medicare & Medicaid Services (CMS), or other online locations of the Secretary's choosing, a list of qualifying physicians who participate in the Medicare program and who have received incentive payments under this section.

(B) EDUCATION.—

(i) PATIENT EDUCATION.—The Secretary shall, in consultation with appropriate organizations that represent health care consumers, take steps to educate Medicare beneficiaries and other patients about the health and convenience benefits of qualifying personal health records.

(ii) PROVIDER EDUCATION.—The Secretary shall take steps to educate Medicare providers about the patient, provider and overall health care benefits of using qualifying personal health records.

(c) QUALIFIED PHYSICIAN DEFINED.—For purposes of this section, the term ''qualified physician'' means a licensed physician (or other licensed health care provider, such as a clinic, designated by the Secretary) that meets

the following requirements, with respect to a qualifying patient of that physician and the qualifying personal health record of that patient:

(1) The physician (or provider), or authorized representative, uses the QPHR for patient registration for encounters, including taking demographic information, insurance information, medication list, problems list, family history, and other information included within the QPHR.

(2) The physician (or provider), or authorized representative or a QPHR service provider (as defined in subsection (e)(2)), updates the diagnosis and medication list (including all current medications and new medications prescribed or provided as samples) in the QPHR after each patient encounter, if appropriate and authorized by the patient, either by direct entry or through a data sharing arrangement using an appropriate electronic means, such as an electronic medical record or e-prescribing.

(3) The physician (or provider), or authorized representative, uses the QPHR as appropriate and authorized by the patient to communicate appropriate patient education and care management messages.

(4) There is submitted to the Secretary by the physician (or by the administrator of the QPHR on the physician's behalf) on a regular basis, but no less frequently than annually, a report documenting the number of such qualifying patients of the physician (or provider) and the use of QPHRs of such patients.

(5) The physician (or provider) meets other requirements as the Secretary may establish.

(d) QUALIFYING PATIENT DEFINED.—For purposes of this section, the term ''qualifying patient'' means an individual for whom a qualifying personal health record has been established and is in operation under the program and who is a Medicare beneficiary or is covered under a health benefits or other plan the sponsor of which is participating as a Fund partner under this section.

(e) QUALIFYING PERSONAL HEALTH RECORD (QPHR); QPHR SERVICE PROVIDER.—

(1) DEFINITION.—For purposes of this section, the terms ''qualifying personal health record'' and ''QPHR'' mean a record of health care related information that meets the following requirements:

(A) ACCESS TO THE RECORD.—

(i) ACCESS RIGHTS.—Access to the record is controlled solely by the patient

(or the patient's authorized representative), with the patient (or the patient's authorized representative) able to access online, print, copy to electronic media, or provide online access to authorized third parties, including health care providers, to all individually identifiable health information held in the record at any time.

(ii) TERMINATION RIGHTS.—The record allows a patient (or the patient's authorized representative) to terminate the further use of the record service at any time, including elimination of the patient's personal health information in the control of the QPHR service provider. Nothing in this clause shall require a health care provider to eliminate a patient's personal health information included in the QPHR that is in a medical record maintained by the provider.

(iii) TRANSPORTABILITY.—The patient's rights to control access to the record under this subparagraph are not affected by changes in relationships with particular providers or health plans.

(B) SECURITY.—The record meets minimum security standards, including the rules promulgated under section 264(c) of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) and other such minimum standards as identified by the Secretary under paragraph (3), and the QPHR service provider complies with any security and privacy standards, policies, and practices adopted under such paragraph.

(C) INTEROPERABILITY.—The record is capable of exchanging standards-based clinical and patient data with other sources and users of health data, including other QPHRs, electronic health records used by hospitals and physicians and other providers, pharmacies, pharmacy benefit managers, and health plans.

(D) WEB-BASED.—The record is web-based and capable of sharing information between patients and their providers, and enabling patient-provider communication.

(E) MESSAGING CAPABILITIES.—

(i) EDUCATION REMINDERS.—Subject to clause (v), the QPHR service provider is capable of sending patient-specific patient

education, reminders, and clinical messages to patients based upon data in the QPHR, but such messages shall not be sent unless such messages comply with standards adopted under paragraph (4). The Secretary shall work with the Secretary of Homeland Security and the Director of the Centers for Disease Control and Prevention to optimize the public health and emergency response capabilities of the networks created by QPHRs.

(ii) FEDERAL REMINDERS.—Subject to clause (v), the QPHR service provider provides for the sending on behalf of Federal agencies of objective, accurate, patient-specific messages to patients concerning their health care or benefits, but such messages shall not be sent unless the messages comply with standards adopted under paragraph (4).

(iii) FUND PARTNER MESSAGES.—Subject to clause (v), the QPHR service provider provides for the sending, on behalf of Fund partners who contribute to the Fund, appropriate patient-specific mes-

sages to consumers (with whom such partners have pre-existing relationships) concerning the patients' health care, medications, treatments, medical devices or benefits, but such messages shall not be sent unless such messages comply with standards adopted under paragraph (4). A fund partner may not send a message to a patient about a product or service unless that product or service has already been prescribed or recommended to the patient by a health care provider.

(iv) HEALTH PLAN NOTIFICATION.—The QPHR service provider notifies, no less frequently than quarterly, each Fund partner that operates a health benefit plan of the individuals who have received messages sent on behalf of the Fund partner under this section.

(v) LIMITATION ON COMMERCIAL SOLICITATION.—The QPHR service provider does not allow messages to be sent to patients unless—

(I) the patient is a patient or beneficiary of the sender or source of

the message, uses the sender's or source's product with a prescription or recommendation of a provider, or has some other pre-existing relationship (as defined by the Secretary) with the sender or source, or the sender or source is a public health agency;

(II) the message contains information directly related to the patient's health or health care and does not include marketing or commercial solicitations;

(III) the message complies with standards adopted under paragraph (3); and

(IV) the message clearly identifies the source of the content and the sender of the message.

(vi) PATIENT OPT-OUT.—The QPHR service provider allows a patient (or patient's authorized representative) to opt out of receiving messages entirely or from particular sources.

(F) PUBLIC HEALTH ANALYSIS AND RESEARCH.—The QPHR service provider is capable of providing de-identified data for public health analysis and for research purposes. The Secretary shall consult with the Commissioner of the Food and Drug Administration, the Director of the National Institutes of Health, the Director of the Centers for Disease Control and Prevention, and the Administrator of the Agency for Healthcare Research and Quality to optimize the public health and post-market surveillance capabilities of QPHRs.

(G) AUTHENTICATION.—The record includes functionality to authenticate the patient's identity prior to the record's use to receive electronic data feeds of personal health information (other than actual authentication information) from third party sources, such as pharmacies, pharmacy benefit managers, laboratories, and health plans, including the Medicare program.

(2) QPHR SERVICE PROVIDER DEFINED.—For purposes of this section, the term ''QPHR service provider'' means an entity that operates or administers a QPHR or part of a QPHR and has access

to patients' individually identifiable health information contained in the QPHR.

(3) PRIVACY AND CONSUMER PROTECTION STANDARDS.—

(A) IN GENERAL.—The Secretary shall set minimum security, privacy and data use standards for QPHRs, in addition to such standards as required under regulations promulgated under section 264(c) of the Health Insurance Portability and Accountability Act of 1996 (HIPAA), in order to optimally protect and safeguard patient health care information. Such standards shall include a required plain language notice of patients' privacy rights with respect to personal health records.

(B) TREATMENT OF QPHR SERVICE PROVIDER AS COVERED ENTITY.—A QPHR service provider shall be treated as a covered entity for purposes of applying the HIPAA regulations referred to in subparagraph (A).

(C) CONSUMER PROTECTION BOARD.—The Secretary shall establish a consumer protection board, a majority of whose members represent health care consumers, including individuals

with chronic diseases and with mental and addictive disorders. Such board shall—

(i) recommend to the Secretary minimum standards to protect patient-identifiable information stored in or transmitted from a QPHR;

(ii) recommend procedures to ensure the objectivity, relevance, and accuracy of messages sent to patients via their QPHRs; and

(iii) have the right to request and review the security and privacy capabilities, policies and practices of those entities administering QPHRs.

(D) NOTIFICATION OF BREACH.—A QPHR service provider must disclose any breach of the security of individually identifiable personal health information contained in a QPHR to any individual whose individually identifiable personal health information was, or is reasonably believed to have been, acquired by an unauthorized person and to the Secretary in a manner to be specified by the Secretary.

(E) AVAILABILITY OF INDIVIDUAL HEALTH INFORMATION IN ELECTRONIC FORM.—Effec-

tive beginning on January 1, 2010, an individual who requests a copy of the individual's individually identifiable health information pursuant to the HIPAA regulations referred to in subparagraph (A) shall be entitled to receive that information in electronic form capable of being imported into a QPHR, if such information was maintained in electronic form by the entity from which the information is requested.

(4) MESSAGE STANDARDS.—The Secretary shall establish minimum standards to ensure the objectivity, accuracy and relevance of messages sent to individual patients under paragraph (1)(E) from a QPHR and to protect against the use of such messages by Fund partners for commercial solicitations or marketing. Such standards shall incorporate existing standards governing communications to consumers established by the Food and Drug Administration or other Federal agencies.

(f) PHR INCENTIVE FUND.—

(1) IN GENERAL.—The Secretary shall establish a PHR Incentive Fund (in this section referred to as the ''PHR Incentive Fund'' or ''Fund''). The Fund may receive contributions from Fund partners for the sole purpose of paying PHR incentives under

subsection (a), conducting annual studies under subsection (g), and otherwise carrying out the program.

(2) FUNDING PARTNERS.—

(A) IN GENERAL.—The Secretary may enter into contracts with public or private payers, drug manufacturers, device manufacturers, or other public or private entities (in this section referred to as ''Fund partners'') to allow the Fund to receive contributions in accordance with this subsection and other terms determined by the Secretary.

(B) FEDERAL PARTNERS.—The Secretary shall seek the involvement and contributions of the Food and Drug Administration, the Centers for Disease Control and Prevention, the Agency for Healthcare Research and Quality, and the Department of Homeland Security to maximize the effectiveness of the QPHRs in meeting the health, national security, emergency response, biosurveillance, and research goals of the Federal government in a manner consistent with this Act.

(C) PARTNER ACCOUNTS.—The Fund shall include an account for each Fund partner, including Medicare, separately accounting for

each Fund partner's contributions to the Fund. Incentive payments shall be debited from each account in accordance with this subsection. Amounts in the account of a Fund partner that are not paid in fiscal year remain available for payment from such account in the subsequent fiscal year.

(D) CONTRIBUTION LEVELS.—Contribution levels to the Fund by Fund partners shall be set annually by the Secretary, except that the contribution level for the first year shall be as follows:

(i) MEDICARE CONTRIBUTION.—The Secretary shall contribute $3 for each Medicare beneficiary for whom any PHR incentive payment is made during such year by transferring the appropriate amount from the Medicare trust funds under parts A and B of the Medicare program, in such proportion as the Secretary may specify.

(ii) FDA-MESSAGING CONTRIBUTIONS.—Each manufacturer shall contribute $3 for each qualifying patient for each medication adherence program for

which one or more messages are sent under subsection (e)(1)(E)(iii) in the year.

(iii) OTHER CONTRIBUTIONS.—Any other fund partner shall contribute $3 for each qualifying patient for whom a PHR incentive payment is made, except that the Secretary may establish other contribution levels for device manufacturers or other Fund partners that employ messages sent under subsection (e)(1)(D)(iii).

(E) CHARGING FUND PARTNERS.—Each Fund partner's account shall be debited according to the same formula with which contributions were determined. In the event that a Fund partner's account does not have a sufficient balance to cover the Fund partner's liability, the Fund partner shall make a supplemental contribution to the Fund to cover the shortfall plus such penalty as the Secretary may assess.

(F) LIMITATION ON BENEFITS.—Contributions by a Fund partner to the Fund shall confer no preferential access to data or information or any other benefit to the partner other than public acknowledgment under paragraph (5)

and the ability to have messages sent to qualifying patients under subsection (e)(1)(D)(iii).

(3) PUBLICATION OF FUND CONTRIBUTORS.—The Secretary shall publish on the official website of the Centers for Medicare & Medicaid Services a list of Fund partners that have contributed to the Fund.

(g) ANNUAL STUDY.—

(1) IN GENERAL.—The Secretary shall provide for an annual study to assess the level of patient engagement in their QPHR, patients' management of their health (including adherence to prescribed medications and recommended preventive care), changes in health outcomes, and cost savings resulting from implementation of the program. The study shall include collection of aggregate data documenting the number of qualifying patient, number and kind of messages sent to patients, the percentage of messages opened by patients, and other measures of the program's effectiveness.

(2) FUNDING.—There are available from the PHR Incentive Fund not to exceed $2,000,000 each year to pay for the annual study under paragraph (1). Amounts so used shall be debited from each Fund partner's account on a pro-rata basis.

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