I

109TH CONGRESS
2D SESSION

H. R. 6289

To establish a program to provide financial incentives for the establishment of interactive personal health records.

IN THE HOUSE OF REPRESENTATIVES

SEPTEMBER 29, 2006

Mr. KENNEDY of Rhode Island 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

A BILL

To establish a program to provide financial incentives for the establishment 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 2006''.

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

(a) ESTABLISHMENT.—The Secretary of Health and Human Services (in this section referred to as the ''Sec-

retary'') shall establish a program (in this section referred to as the ''program'') to provide financial incentives for the establishment of interactive qualifying personal health records for 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 $2 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) uses the QPHR for electronic 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) implements policies to authenticate the patient's identities pursuant to standards established by the Secretary in order to enable the QPHR to receive electronic data feeds from appropriate third party sources, such as pharmacies, pharmacy benefit managers, laboratories, and health plans, including the Medicare program.

(3) The physician (or provider), or authorized representative, 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.

(4) The physician (or provider) uses the QPHR as appropriate and authorized by the patient to com-

municate appropriate patient education and care management messages.

(5) 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.

(6) 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).—

(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) CONTROL.—

(i) IN GENERAL.—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) ACCESS RIGHTS.—The record guarantees the control of the patient (or the patient's authorized representative) over who accesses the patient's individually identifiable information contained in the record.

(iii) TERMINATION RIGHTS.—The record allows a patient 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 administrator of the record. Nothing in this clause shall require a health care provider to eliminate a patient's personal

health information that is in a medical record maintained by the provider.

(iv) TRANSPORTABILITY.—The patient's rights to control of 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 (2), and the administrator of the record complies with any security and privacy standards, policies, and practices adopted under such paragraph.

(C) INTEROPERABILITY.—The record complies with interoperability data standards specified by the Secretary, to ensure the capability to integrate with other QPHRs and other sources of individual data, such as electronic health records, 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 record is capable of sending patient-specific patient education, reminders, and clinical messages to patients based upon data in the record, but such messages shall not be sent unless such messages comply with standards adopted under paragraph (3). 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 record 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 (3).

(iii) FUND PARTNER MESSAGES.—Subject to clause (v), the record provides for the sending, on behalf of Fund partners who contribute to the Fund, appropriate patient-specific messages 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 (3).

(iv) HEALTH PLAN NOTIFICATION.—The QPHR service notifies, no less frequently than quarterly, each Fund partner that administers a health benefit plan of the individuals who are enrolled in the plan and who have a QPHR established.

(v) LIMITATION ON COMMERCIAL SOLICITATION.—The record does not allow any commercial solicitations, marketing, or messages to patients unless the patient is

a patient or beneficiary of the sender, uses the sender's product with a prescription or recommendation of a provider, or has some other pre-existing relationship (as defined by the Secretary), or other messages that do not comply with standards adopted under paragraph (3), and the record ensures that every message clearly identifies the source of the content.

(vi) PATIENT OPT-OUT.—The record allow 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 record 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 the networks created by QPHRs.

(2) 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.

(B) 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.

(3) 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 records by Fund partners for commercial solicitations or marketing. Such standards shall incorporate existing standards 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 $2 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 $2 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 $2 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 changes patient engagement in their QPHR, behavior changes, 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.

○