I

112TH CONGRESS
1ST SESSION

H. R. 3239

To provide certain legal safe harbors to Medicare and Medicaid providers who participate in the EHR meaningful use program or otherwise demonstrate use of certified health information technology.

IN THE HOUSE OF REPRESENTATIVES

OCTOBER 21, 2011

Mr. MARINO introduced the following bill; which was referred to the Committee on Energy and Commerce

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A BILL

To provide certain legal safe harbors to Medicare and Medicaid providers who participate in the EHR meaningful use program or otherwise demonstrate use of certified health information technology.

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 ''Safeguarding Access For Every Medicare Patient Act''.

SEC. 2. COVERED ENTITIES.

(a) COVERED ENTITIES.—For purposes of this section, a covered entity means, with respect to certified

EHR technology (as defined in section 1848(o)(4) of the Social Security Act) and a year, any of the following:

(1) MEANINGFUL EHR USERS.—Any of the following, with respect to such year:

(A) An eligible professional (as defined in paragraph (5)(C) of section 1848(o) of the Social Security Act) determined to be a meaningful EHR user under paragraph (2) of such section for the EHR reporting period (as defined in paragraph (5)(B) of such section) during such year.

(B) In the case of a qualifying MA organization (as defined in paragraph (5) of section 1853(l) of such Act), an eligible professional described in paragraph (2) of such section of the organization who the organization attests under paragraph (6) of such section to be a meaningful EHR user for such year.

(C) In the case of a qualifying MA organization (as defined in paragraph (5) of section 1853(l) of such Act), an eligible hospital described in section 1853(m)(2) of such Act of the organization which attests under section 1853(l)(6) of such Act to be a meaningful EHR

user for the applicable period with respect to such year.

(D) An eligible hospital (as defined in paragraph (6)(B) of section 1886(n) of such Act) determined to be a meaningful EHR user under paragraph (3) of such section for the EHR reporting period (as defined in paragraph (6)(A) of such section) with respect to such year.

(E) A critical access hospital determined pursuant to section 1814(l)(3) of such Act to be a meaningful EHR user (as would be determined under paragraph (3) of section 1886(n) of such Act) for an EHR reporting period (as defined in paragraph (6)(A) of such section) for a cost reporting period beginning during such year.

(F) A Medicaid provider (as defined in paragraph (2) of section 1903(t) of such Act) eligible for payments described in paragraph (1) of such section for such year.

(2) HEALTH INFORMATION EXCHANGE ENTITIES.—Individuals and entities (other than States or State designated entities) which during such year are health information exchange contractors (con-

sisting of technology providers), health information exchange participants (consisting of organizations providing supportive technology to a health information exchange), and other users of health information exchanges (consisting of other entities that may be exchanging clinical or administrative data). Manufacturers of EHR Software and other health information technologies who participate in the reporting of adverse events or who otherwise contribute relevant patient safety work product under section 3(a) of this Act.

(3) CERTAIN OTHER EHR USERS.—A health care professional who, during such year—

(A) is a user of such certified EHR technology;

(B) is not eligible for incentive payments based on meaningful use of such technology under title XVIII or XIX of the Social Security Act solely because the professional is not—

(i) an eligible professional (as defined in paragraph (5)(C) of section 1848(o) of such Act);

(ii) an eligible professional described in paragraph (2) of section 1853(l) of such Act, with respect to a qualifying MA orga-

nization (as defined in paragraph (5) of such section);

(iii) an eligible hospital described in section 1853(m)(2) of such Act, with respect to such a qualifying MA organization;

(iv) an eligible hospital (as defined in paragraph (6)(B) of section 1886(n) of such Act);

(v) a critical access hospital; or

(vi) a Medicaid provider (as defined in paragraph (2) of section 1903(t) of such Act); and

(C) attests, to the satisfaction of the Secretary, that but for the reason described in subparagraph (B), the professional would otherwise satisfy criteria to be eligible for such incentive payments during such year.

SEC. 3. IMPROVING PATIENT SAFETY THROUGH ERROR REPORTING AND REMEDIATION, AND CLARIFICATION OF AUTHORITY.

(a) IN GENERAL.—A covered entity may submit to a Patient Safety Organization as defined in section 921. Title IX of the Public Health Service Act (42 U.S.C. 299 et seq.) information on EHR-related adverse events with

respect to certified EHR technology as defined in section 3001 of the Public Health Service Act (42 U.S.C. 300jj–11) used or provided by such entity, as applicable. The utilization of patient safety work product shall be for the purpose of providing direct feedback and assistance to covered entities to effectively minimize patient risk. Patient Safety Organizations may furnish the Office of the National Coordinator de-identified reports of their findings for the purposes of tracking the number and nature of such adverse events.

(b) APPLICATION OF SAFETY ORGANIZATION PRIVILEGE AND CONFIDENTIALITY PROTECTIONS.—In the case of a covered entity that submits to such a body information on such an adverse event and in the case of the collection and maintenance of such information by such a body, the provisions of section 922 of the Public Health Service Act shall apply to such information and to the body and the entity in the same manner such provisions apply to patient safety work product and a patient safety organization and provider under part C of title IX of such Act.

(c) CLARIFICATION OF AUTHORITY.—Certified EHR's shall not be considered a device for purposes of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.).

SEC. 4. RULES RELATING TO E-DISCOVERY.

In any health care lawsuit against a covered entity that is related to an EHR-related adverse event, with respect to certified EHR technology used or provided by the covered entity, electronic discovery shall be limited to—

(1) information that is related to such EHR-related adverse event; and

(2) information from the period in which such EHR-related adverse event occurred.

SEC. 5. LEGAL PROTECTIONS FOR COVERED ENTITIES.

(a) GENERAL.—For a covered entity described in section 2, the following protections apply:

(1) ENCOURAGING SPEEDY RESOLUTION OF CLAIMS.—

(A) GENERAL.—A claimant may not commence a health care lawsuit against a covered entity on any date that is 3 years after the date of manifestation of injury or 1 year after the claimant discovers, or through the use of reasonable diligence should have discovered, the injury, whichever occurs first. This limitation shall be tolled to the extent that the claimant is able to prove—

(i) fraud;

(ii) intentional concealment; or

(iii) the presence of a foreign body, which has no therapeutic or diagnostic purpose or effect, in the person of the injured person.

(B) TREATMENT OF A MINOR.—A health care lawsuit by or on behalf of a claimant under the age of 17 years at the time the injury was suffered may not be commenced after the date that is not later than 3 years after the date of the alleged manifestation of injury except that actions by a claimant under the full age of 6 years shall be commenced not later than 3 years after the date of manifestation of injury or prior to the claimant's 8th birthday, whichever provides a longer period. In addition to subsection (1)(A)(i)–(iii), this limitation shall be tolled for claimants under the age of 17 years for any period during which a parent or guardian and a health care provider or health care organization have committed fraud or collusion in the failure to bring an action on behalf of the claimant.

(2) EQUITABLE ASSIGNMENT OF RESPONSIBILITY.—In any health care lawsuit against a covered entity—

(A) each party to the lawsuit other than the claimant that is such a covered entity shall be liable for that party's several share of any damages only and not for the share of any other person and such several share shall be in direct proportion to that party's proportion of responsibility for the injury, as determined under clause (iii);

(B) whenever a judgment of liability is rendered as to any such party, a separate judgment shall be rendered against each such party for the amount allocated to such party; and

(C) for purposes of this paragraph, the trier of fact shall determine the proportion of responsibility of each such party for the claimant's harm.

(3) SUBSEQUENT REMEDIAL MEASURES.—Evidence of subsequent remedial measures to an EHR-related adverse event with respect to certified EHR technology used or provided by the covered entity (including changes to the certified EHR system, additional training requirements, or changes to standard operating procedures) by a covered entity shall not be admissible in health care lawsuits.

(4) INCREASED BURDEN OF PROOF PROTECTION FOR COVERED ENTITIES.—Punitive damages may, if otherwise permitted by applicable State or Federal law, be awarded against any covered entity in a health care lawsuit only if it is proven by clear and convincing evidence that such entity acted with reckless disregard for the health or safety of the claimant. In any such health care lawsuit where no judgment for compensatory damages is rendered against such entity, no punitive damages may be awarded with respect to the claim in such lawsuit.

(5) PROTECTION FROM LIBEL OR SLANDER.—Covered entities and employees, agents and representatives of covered entities are immune from civil action for libel or slander arising from information or entries made in certified EHR technology and for the transfer of such information to another eligible provider, hospital or health information exchange, if the information, transfer of information, or entries were made in good faith and without malice.

SEC. 6. DEFINITIONS.

(a) CLAIMANT.—The term ''claimant'' means any person who brings a health care lawsuit, including a person who asserts or claims a right to legal or equitable con-

tribution, indemnity, or subrogation, arising out of a health care liability claim or action, and any person on whose behalf such a claim is asserted or such an action is brought, whether deceased, incompetent, or a minor.

(b) COMPENSATORY DAMAGES.—The term ''compensatory damages'' means objectively verifiable monetary losses incurred as a result of the provisions of, use of, or payment for (or failure to provide, use, or pay for) health care services or medical products, such as past and future medical expenses, loss of past and future earnings, cost of obtaining domestic services, loss of employment, and loss of business or employment opportunities, damages for physical and emotional pain, suffering, inconvenience, physical impairment, mental anguish, disfigurement, loss of enjoyment in life, loss of society and companionship, loss of consortium (other than loss of domestic service), hedonic damages, injury to reputation, and all other non pecuniary losses of any kind or nature. Such term includes economic damages and noneconomic damages, as such terms as defined in this section.

(c) ECONOMIC DAMAGES.—The term ''economic damages'' means objectively verifiable monetary losses incurred as a result of the provisions of, use of, or payment for (or failure to provide, use, or pay for) health care services or medical products, such as past and future medical

expenses, loss of past and future earnings, cost of obtaining domestic services, loss of employment, and loss of business or employment opportunities.

(d) CERTIFIED EHR TECHNOLOGY.—The term ''certified EHR technology'' has the meaning given such term in section 1848(o)(4) of the Social Security Act.

(e) EHR-RELATED ADVERSE EVENT.—The term ''EHR-related adverse event'' means, with respect to a provider, a defect, malfunction, or error in the certified health information technology or electronic health record used by the provider, or in the input or output of data maintained through such technology or record, that results or could reasonably result in harm to a patient.

(f) HEALTH CARE LAWSUIT.—The term ''health care lawsuit'' means any health care liability claim concerning the provision of health care items or services or any medical product affecting interstate commerce, or any health care liability action concerning the provision of health care items or services or any medical product affecting interstate commerce, brought in a State or Federal court or pursuant to an alternative dispute resolution system, against a health care provider, a health care organization, or the manufacturer, distributor, supplier, marketer, promoter, or seller of a medical product, regardless of the theory of liability on which the claim is based, or the num-

ber of claimants, plaintiffs, defendants, or other parties, or the number of claims or causes of action, in which the claimant alleges a health care liability claim. Such term does not include a claim or action which is based on criminal liability; which seeks civil fines or penalties paid to Federal, State, or local government; or which is grounded in antitrust.

(g) HEALTH CARE LIABILITY ACTION.—The term ''health care liability action'' means a civil action brought in a State or Federal court or pursuant to an alternative dispute resolution system, against a health care provider, a health care organization, or the manufacturer, distributor, supplier, marketer, promoter, or seller of a medical product, regardless of the theory of liability on which the claim is based, or the number of plaintiffs, defendants, or other parties, or the number of causes of action, in which the claimant alleges a health care liability claim.

(h) HEALTH CARE LIABILITY CLAIM.—The term ''health care liability claim'' means a demand by any person, whether or not pursuant to alternative dispute resolution, against a health care provider, health care organization, or the manufacturer, distributor, supplier, marketer, promoter, or seller of a medical product, including third-party claims, cross-claims, counter-claims, or contribution claims, which are based upon the provision of, use of, or

payment for (or the failure to provide, use or pay for) health care services or medical products, regardless of the theory of liability on which the claim is based, or the number of plaintiffs, defendants, or other parties, or the number of causes of action.

(i) HEALTH CARE ORGANIZATION.—The term ''health care organization'' means any person or entity which is obligated to provide or pay for health benefits under any health plan, including any person or entity acting under a contract or arrangement with a health care organization to provide or administer any health benefit.

(j) HEALTH CARE PROVIDER.—The term ''health care provider'' means any person or entity required by State or Federal laws or regulations to be licensed, registered, or certified to provide health care services, and being either so licensed, registered, or certified, or exempted from such requirement by other statute or regulation.

(k) HEALTH CARE ITEMS OR SERVICES.—The term ''health care items or services'' means any items or services provided by a health care organization, provider, or by any individual working under the supervision of a health care provider, that relates to the diagnosis, prevention, or treatment of any human disease or impairment, or the assessment or care of the health of human beings.

(l) MALICIOUS INTENT TO INJURE.—The term ''malicious intent to injure'' means intentionally causing or attempting to cause physical injury other than providing health care items or services.

(m) MEDICAL PRODUCT.—The term ''medical product'' means a drug, device, or biological product intended for humans, and the terms ''drug'', ''device'', and ''biological product'' have the meanings given such terms in sections 201(g)(1) and 201(h) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(g)(1) and (h)) and section 351(a) of the Public Health Service Act (42 U.S.C. 262(a)), respectively, including any component or raw material used therein, but excluding health care services.

(n) NONECONOMIC DAMAGES.—The term ''noneconomic damages'' means damages for physical impairment, mental anguish, disfigurement, loss of enjoyment of life, loss of society and companionship, loss of consortium (other than loss of domestic service), hedonic damages, injury to reputation, and all other nonpecuniary losses of any kind of nature.

(o) PUNITIVE DAMAGES.—The term ''punitive damages'' means damages awarded, for the purpose of punishment or deterrence, and not solely for compensatory purposes, against a health care provider, health care organization, or a manufacturer, distributor, or supplier of a med-

ical product. Punitive damages are neither economic nor economic damages.

(p) STATE.—The term ''State'' means each of the several States, District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, American Samoa, the Northern Mariana Islands, the Trust Territory of the Pacific Islands, and any other territory or possession of the United States, or any political subdivision thereof.

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