

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

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.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Safeguarding Access
5 For Every Medicare Patient Act”.

6 **SEC. 2. COVERED ENTITIES.**

7 (a) COVERED ENTITIES.—For purposes of this sec-
8 tion, a covered entity means, with respect to certified

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

3 (1) MEANINGFUL EHR USERS.—Any of the fol-
4 lowing, with respect to such year:

5 (A) An eligible professional (as defined in
6 paragraph (5)(C) of section 1848(o) of the So-
7 cial Security Act) determined to be a meaning-
8 ful EHR user under paragraph (2) of such sec-
9 tion for the EHR reporting period (as defined
10 in paragraph (5)(B) of such section) during
11 such year.

12 (B) In the case of a qualifying MA organi-
13 zation (as defined in paragraph (5) of section
14 1853(l) of such Act), an eligible professional de-
15 scribed in paragraph (2) of such section of the
16 organization who the organization attests under
17 paragraph (6) of such section to be a meaning-
18 ful EHR user for such year.

19 (C) In the case of a qualifying MA organi-
20 zation (as defined in paragraph (5) of section
21 1853(l) of such Act), an eligible hospital de-
22 scribed in section 1853(m)(2) of such Act of
23 the organization which attests under section
24 1853(l)(6) of such Act to be a meaningful EHR

1 user for the applicable period with respect to
2 such year.

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

10 (E) A critical access hospital determined
11 pursuant to section 1814(l)(3) of such Act to be
12 a meaningful EHR user (as would be deter-
13 mined under paragraph (3) of section 1886(n)
14 of such Act) for an EHR reporting period (as
15 defined in paragraph (6)(A) of such section) for
16 a cost reporting period beginning during such
17 year.

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

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

1 sisting of technology providers), health information
2 exchange participants (consisting of organizations
3 providing supportive technology to a health informa-
4 tion exchange), and other users of health informa-
5 tion exchanges (consisting of other entities that may
6 be exchanging clinical or administrative data). Man-
7 ufacturers of EHR Software and other health infor-
8 mation technologies who participate in the reporting
9 of adverse events or who otherwise contribute rel-
10 evant patient safety work product under section 3(a)
11 of this Act.

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

14 (A) is a user of such certified EHR tech-
15 nology;

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

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

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

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

3 (iii) an eligible hospital described in
4 section 1853(m)(2) of such Act, with re-
5 spect to such a qualifying MA organiza-
6 tion;

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

10 (v) a critical access hospital; or

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

14 (C) attests, to the satisfaction of the Sec-
15 retary, that but for the reason described in sub-
16 paragraph (B), the professional would otherwise
17 satisfy criteria to be eligible for such incentive
18 payments during such year.

19 **SEC. 3. IMPROVING PATIENT SAFETY THROUGH ERROR RE-**
20 **PORTING AND REMEDIATION, AND CLARI-**
21 **FICATION OF AUTHORITY.**

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

1 respect to certified EHR technology as defined in section
2 3001 of the Public Health Service Act (42 U.S.C. 300jj–
3 11) used or provided by such entity, as applicable. The
4 utilization of patient safety work product shall be for the
5 purpose of providing direct feedback and assistance to cov-
6 ered entities to effectively minimize patient risk. Patient
7 Safety Organizations may furnish the Office of the Na-
8 tional Coordinator de-identified reports of their findings
9 for the purposes of tracking the number and nature of
10 such adverse events.

11 (b) APPLICATION OF SAFETY ORGANIZATION PRIVI-
12 LEGE AND CONFIDENTIALITY PROTECTIONS.—In the case
13 of a covered entity that submits to such a body informa-
14 tion on such an adverse event and in the case of the collec-
15 tion and maintenance of such information by such a body,
16 the provisions of section 922 of the Public Health Service
17 Act shall apply to such information and to the body and
18 the entity in the same manner such provisions apply to
19 patient safety work product and a patient safety organiza-
20 tion and provider under part C of title IX of such Act.

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

1 **SEC. 4. RULES RELATING TO E-DISCOVERY.**

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

6 (1) information that is related to such EHR-re-
7 lated adverse event; and

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

10 **SEC. 5. LEGAL PROTECTIONS FOR COVERED ENTITIES.**

11 (a) GENERAL.—For a covered entity described in sec-
12 tion 2, the following protections apply:

13 (1) ENCOURAGING SPEEDY RESOLUTION OF
14 CLAIMS.—

15 (A) GENERAL.—A claimant may not com-
16 mence a health care lawsuit against a covered
17 entity on any date that is 3 years after the date
18 of manifestation of injury or 1 year after the
19 claimant discovers, or through the use of rea-
20 sonable diligence should have discovered, the in-
21 jury, whichever occurs first. This limitation
22 shall be tolled to the extent that the claimant
23 is able to prove—

24 (i) fraud;

25 (ii) intentional concealment; or

1 (iii) the presence of a foreign body,
2 which has no therapeutic or diagnostic
3 purpose or effect, in the person of the in-
4 jured person.

5 (B) TREATMENT OF A MINOR.—A health
6 care lawsuit by or on behalf of a claimant under
7 the age of 17 years at the time the injury was
8 suffered may not be commenced after the date
9 that is not later than 3 years after the date of
10 the alleged manifestation of injury except that
11 actions by a claimant under the full age of 6
12 years shall be commenced not later than 3
13 years after the date of manifestation of injury
14 or prior to the claimant's 8th birthday, which-
15 ever provides a longer period. In addition to
16 subsection (1)(A)(i)–(iii), this limitation shall
17 be tolled for claimants under the age of 17
18 years for any period during which a parent or
19 guardian and a health care provider or health
20 care organization have committed fraud or col-
21 lusion in the failure to bring an action on be-
22 half of the claimant.

23 (2) EQUITABLE ASSIGNMENT OF RESPONSIBI-
24 LITY.—In any health care lawsuit against a cov-
25 ered entity—

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

9 (B) whenever a judgment of liability is ren-
10 dered as to any such party, a separate judg-
11 ment shall be rendered against each such party
12 for the amount allocated to such party; and

13 (C) for purposes of this paragraph, the
14 trier of fact shall determine the proportion of
15 responsibility of each such party for the claim-
16 ant's harm.

17 (3) SUBSEQUENT REMEDIAL MEASURES.—Evi-
18 dence of subsequent remedial measures to an EHR-
19 related adverse event with respect to certified EHR
20 technology used or provided by the covered entity
21 (including changes to the certified EHR system, ad-
22 ditional training requirements, or changes to stand-
23 ard operating procedures) by a covered entity shall
24 not be admissible in health care lawsuits.

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

12 (5) PROTECTION FROM LIBEL OR SLANDER.—
13 Covered entities and employees, agents and rep-
14 resentatives of covered entities are immune from
15 civil action for libel or slander arising from informa-
16 tion or entries made in certified EHR technology
17 and for the transfer of such information to another
18 eligible provider, hospital or health information ex-
19 change, if the information, transfer of information,
20 or entries were made in good faith and without mal-
21 ice.

22 **SEC. 6. DEFINITIONS.**

23 (a) CLAIMANT.—The term “claimant” means any
24 person who brings a health care lawsuit, including a per-
25 son who asserts or claims a right to legal or equitable con-

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

5 (b) COMPENSATORY DAMAGES.—The term “compen-
6 satory damages” means objectively verifiable monetary
7 losses incurred as a result of the provisions of, use of, or
8 payment for (or failure to provide, use, or pay for) health
9 care services or medical products, such as past and future
10 medical expenses, loss of past and future earnings, cost
11 of obtaining domestic services, loss of employment, and
12 loss of business or employment opportunities, damages for
13 physical and emotional pain, suffering, inconvenience,
14 physical impairment, mental anguish, disfigurement, loss
15 of enjoyment in life, loss of society and companionship,
16 loss of consortium (other than loss of domestic service),
17 hedonic damages, injury to reputation, and all other non
18 pecuniary losses of any kind or nature. Such term includes
19 economic damages and noneconomic damages, as such
20 terms as defined in this section.

21 (c) ECONOMIC DAMAGES.—The term “economic
22 damages” means objectively verifiable monetary losses in-
23 curred as a result of the provisions of, use of, or payment
24 for (or failure to provide, use, or pay for) health care serv-
25 ices or medical products, such as past and future medical

1 expenses, loss of past and future earnings, cost of obtain-
2 ing domestic services, loss of employment, and loss of busi-
3 ness or employment opportunities.

4 (d) CERTIFIED EHR TECHNOLOGY.—The term “cer-
5 tified EHR technology” has the meaning given such term
6 in section 1848(o)(4) of the Social Security Act.

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

14 (f) HEALTH CARE LAWSUIT.—The term “health care
15 lawsuit” means any health care liability claim concerning
16 the provision of health care items or services or any med-
17 ical product affecting interstate commerce, or any health
18 care liability action concerning the provision of health care
19 items or services or any medical product affecting inter-
20 state commerce, brought in a State or Federal court or
21 pursuant to an alternative dispute resolution system,
22 against a health care provider, a health care organization,
23 or the manufacturer, distributor, supplier, marketer, pro-
24 moter, or seller of a medical product, regardless of the
25 theory of liability on which the claim is based, or the num-

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

8 (g) HEALTH CARE LIABILITY ACTION.—The term
9 “health care liability action” means a civil action brought
10 in a State or Federal court or pursuant to an alternative
11 dispute resolution system, against a health care provider,
12 a health care organization, or the manufacturer, dis-
13 tributor, supplier, marketer, promoter, or seller of a med-
14 ical product, regardless of the theory of liability on which
15 the claim is based, or the number of plaintiffs, defendants,
16 or other parties, or the number of causes of action, in
17 which the claimant alleges a health care liability claim.

18 (h) HEALTH CARE LIABILITY CLAIM.—The term
19 “health care liability claim” means a demand by any per-
20 son, whether or not pursuant to alternative dispute resolu-
21 tion, against a health care provider, health care organiza-
22 tion, or the manufacturer, distributor, supplier, marketer,
23 promoter, or seller of a medical product, including third-
24 party claims, cross-claims, counter-claims, or contribution
25 claims, which are based upon the provision of, use of, or

1 payment for (or the failure to provide, use or pay for)
2 health care services or medical products, regardless of the
3 theory of liability on which the claim is based, or the num-
4 ber of plaintiffs, defendants, or other parties, or the num-
5 ber of causes of action.

6 (i) HEALTH CARE ORGANIZATION.—The term
7 “health care organization” means any person or entity
8 which is obligated to provide or pay for health benefits
9 under any health plan, including any person or entity act-
10 ing under a contract or arrangement with a health care
11 organization to provide or administer any health benefit.

12 (j) HEALTH CARE PROVIDER.—The term “health
13 care provider” means any person or entity required by
14 State or Federal laws or regulations to be licensed, reg-
15 istered, or certified to provide health care services, and
16 being either so licensed, registered, or certified, or exempt-
17 ed from such requirement by other statute or regulation.

18 (k) HEALTH CARE ITEMS OR SERVICES.—The term
19 “health care items or services” means any items or serv-
20 ices provided by a health care organization, provider, or
21 by any individual working under the supervision of a
22 health care provider, that relates to the diagnosis, preven-
23 tion, or treatment of any human disease or impairment,
24 or the assessment or care of the health of human beings.

1 (l) MALICIOUS INTENT TO INJURE.—The term “ma-
2 licious intent to injure” means intentionally causing or at-
3 tempting to cause physical injury other than providing
4 health care items or services.

5 (m) MEDICAL PRODUCT.—The term “medical prod-
6 uct” means a drug, device, or biological product intended
7 for humans, and the terms “drug”, “device”, and “biologi-
8 cal product” have the meanings given such terms in sec-
9 tions 201(g)(1) and 201(h) of the Federal Food, Drug,
10 and Cosmetic Act (21 U.S.C. 321(g)(1) and (h)) and sec-
11 tion 351(a) of the Public Health Service Act (42 U.S.C.
12 262(a)), respectively, including any component or raw ma-
13 terial used therein, but excluding health care services.

14 (n) NONECONOMIC DAMAGES.—The term “non-
15 economic damages” means damages for physical impair-
16 ment, mental anguish, disfigurement, loss of enjoyment of
17 life, loss of society and companionship, loss of consortium
18 (other than loss of domestic service), hedonic damages, in-
19 jury to reputation, and all other nonpecuniary losses of
20 any kind of nature.

21 (o) PUNITIVE DAMAGES.—The term “punitive dam-
22 ages” means damages awarded, for the purpose of punish-
23 ment or deterrence, and not solely for compensatory pur-
24 poses, against a health care provider, health care organiza-
25 tion, or a manufacturer, distributor, or supplier of a med-

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

3 (p) STATE.—The term “State” means each of the
4 several States, District of Columbia, the Commonwealth
5 of Puerto Rico, the Virgin Islands, Guam, American
6 Samoa, the Northern Mariana Islands, the Trust Terri-
7 tory of the Pacific Islands, and any other territory or pos-
8 session of the United States, or any political subdivision
9 thereof.

○