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24 yeas, 29 nays, +1 present

AMENDMENT TO H.R. 4954
OFFERED BY MR. MARKEY

(Amendment to Medicare Modernization and Prescription Drug Act of 2002)

(Page & line nos. refer to Committee Print #1 of title I of June 17, 2002)

Amend section 1807 of the Social Security Act, as proposed to be added by section 105 by adding at the end [page 58, after line 35] the following new subsection:

- 1 “(f) CONFIDENTIALITY OF PATIENT INFORMATION.—
- 2 “(1) IN GENERAL.—The Secretary shall require, as a
- 3 condition of endorsement of the prescription drug discount
- 4 card program offered by the entity, that the entity—
- 5 “(A) shall only use or disclose protected health in-
- 6 formation collected in connection with a prescription
- 7 drug discount card program as necessary to operate a
- 8 prescription drug discount card program as provided
- 9 under this subsection;
- 10 “(B) shall use the minimum amount of protected
- 11 health information collected in connection with a pre-
- 12 scription drug discount card program necessary to op-
- 13 erate the prescription drug discount card program;
- 14 “(C) shall not combine the protected health infor-
- 15 mation collected in connection with a prescription drug
- 16 discount card program with any other activity carried
- 17 out by the entity that is unrelated to the discount card
- 18 program; and
- 19 “(D) shall obtain a valid authorization for the use
- 20 and disclosure of protected health information collected
- 21 in connection with a prescription drug discount card
- 22 program for purposes other than the operation of the
- 23 program.
- 24 “(2) PRE-ENROLLMENT REQUIREMENTS.—



1 “(A) NOTICE AND CONSENT.—Enrollment in a
2 prescription drug discount card program endorsed
3 under this section is conditioned upon—

4 “(i) the receipt by the medicare beneficiary
5 prior to such enrollment of a notice (described in
6 subparagraph (B)) of the intended uses and disclo-
7 sures of protected health information by the entity
8 offering the program; and

9 “(ii) the express written consent by the medi-
10 care beneficiary to the intended uses and disclo-
11 sures included in the notice.

12 “(B) CONTENT OF NOTICE.—The notice required
13 under subparagraph (A) (i) shall—

14 “(i) identify all organizations or entities that
15 will have access to protected health information
16 under the program;

17 “(ii) be prepared on a separate piece of paper
18 as an addendum to the enrollment application; and

19 “(iii) be written in a clear and understandable
20 language and printed in a type and font size that
21 is appropriate for medicare beneficiaries, as deter-
22 mined by the Secretary.

23 “(3) LIMITATION ON USE OR DISCLOSURE BY BUSI-
24 NESS ASSOCIATES.—If an entity discloses protected health
25 information to a business associate acting on the entity’s
26 behalf, the business associate may only use the information
27 for the intended purpose of the disclosure and may not use
28 or disclose the information for any other purpose.

29 “(4) REQUIREMENTS FOR PRIOR AUTHORIZATION FOR
30 USE OR DISCLOSURE OF PROTECTED HEALTH INFORMA-
31 TION AND CERTAIN COMMUNICATIONS.—

32 “(A) AUTHORIZATION REQUIRED.—An entity of-
33 fering a prescription drug discount card program en-
34 dorsed under this section may not use or disclose pro-
35 tected health information for any purpose not directly
36 related to the provision of discounts under the pro-

1 gram, unless the entity has obtained a valid prior writ-
2 ten authorization for such use or disclosure.

3 “(B) SPECIFIC USES OR DISCLOSURES REQUIRING
4 PRIOR AUTHORIZATION.—Prior authorization is re-
5 quired with respect to the following uses or disclosures
6 by the entity of protected health information of a medi-
7 care beneficiary enrolled in the program offered by the
8 entity:

9 “(i) The use of protected health information to
10 communicate with the medicare beneficiary about
11 health products (including prescription drugs) other
12 than prescription drugs that are available at a dis-
13 count through the program.

14 “(ii) The use of protected health information
15 to communicate with the medicare beneficiary
16 about services related to prescription drugs, such
17 as disease management services, that are available
18 for a separate fee.

19 “(iii) The use of protected health information
20 to communicate with the medicare beneficiary
21 about services unrelated to prescription drugs.

22 “(iv) The use of protected health information
23 to communicate with the medicare beneficiary
24 about products or services that are unrelated to
25 health.

26 “(v) The disclosure of protected health infor-
27 mation to permit the recipient of the protected
28 health information to communicate with a medicare
29 beneficiary enrolled in a prescription drug discount
30 card program about health products (including pre-
31 scription drugs) other than prescription drugs that
32 are available at a discount through the program.

33 “(vi) The disclosure of protected health infor-
34 mation to permit the recipient of the protected
35 health information to communicate with a medicare
36 beneficiary enrolled in a prescription drug discount
37 card program about services related to prescription



1 drugs, such as disease management services, that
2 are available for a separate fee.

3 “(vii) The disclosure of protected health infor-
4 mation to permit the recipient of the protected
5 health information to communicate with a medicare
6 beneficiary enrolled in a prescription drug discount
7 card program about services unrelated to prescrip-
8 tion drugs.

9 “(viii) The disclosure of protected health infor-
10 mation to permit the recipient of the protected
11 health information to communicate with a medicare
12 beneficiary enrolled in a prescription drug discount
13 card program about products or services that are
14 unrelated to health.

15 “(ix) The disclosure, directly or through a
16 business associate, of protected health information
17 with respect to medicare beneficiaries enrolled
18 under the program to a manufacturer of prescrip-
19 tion drugs that is not the entity offering the pre-
20 scription drug discount card program.

21 “(C) USE OR DISCLOSURE CONSISTENT WITH AU-
22 THORIZATION.—If an entity obtains a valid authoriza-
23 tion for the use or disclosure of protected health infor-
24 mation by such entity for uses or disclosures referred
25 to in subparagraph (A) or (B), any use or disclosure
26 by such entity, or by the recipient of protected health
27 information pursuant to a valid authorization, shall be
28 consistent with such authorization.

29 “(5) VALID AUTHORIZATION.—For purposes of this
30 subsection, an authorization is valid if the authorization
31 meets the following requirements and is signed and dated
32 by the medicare beneficiary enrolling in the prescription
33 drug discount card program involved:

34 “(A) The authorization is on a separate piece of
35 paper.



1 “(B) The authorization is printed in a font size
2 and type suitable for medicare beneficiaries, as deter-
3 mined by the Secretary.

4 “(C) The authorization clearly states that enroll-
5 ment in the program or the receipt of benefits under
6 the program may not be conditioned upon signing the
7 authorization.

8 “(D) The authorization prohibits oral communica-
9 tion for the purpose of telemarketing by the entity.

10 “(E) The authorization specifically describes the
11 information that is to be used by the entity or disclosed
12 to another entity.

13 “(F) The authorization specifically describes the
14 purpose of the use or disclosure, including whether the
15 intended communication will concern health related
16 products or non-health related products and the precise
17 product or service or category of products or services
18 at issue.

19 “(G) The authorization includes the word mar-
20 keting if the purpose of the use or disclosure is referred
21 to in clauses (i) through (ix) of paragraph (4)(B).

22 “(H) The authorization specifies whether the enti-
23 ty offering the prescription drug discount card program
24 intends to use protected health information, disclose
25 protected health information to a business associate
26 acting on the entity’s behalf, or disclose protected
27 health information to an outside entity for the outside
28 entity’s own purposes.

29 “(I) The authorization identifies precisely any re-
30 cipient of the information.

31 “(J) The authorization states whether the entity
32 expects to receive direct or indirect remuneration for
33 the use or disclosure.

34 “(K) The authorization states that information,
35 once disclosed, may not be protected by any privacy
36 laws.



1 “(C) USE.—The term “use” has the meaning
2 given such term in section 164.501 of title 45, Code of
3 Federal Regulations.”.

