

**AMENDMENT TO THE AMENDMENT IN THE
NATURE OF A SUBSTITUTE TO H.R. 6357
OFFERED BY MR. MARKEY OF MASSACHUSETTS**

[Page and line numbers to H6357ANS_002, July 21, 2008,
6:45pm]

Page 94, after line 12, insert the following new paragraph and redesignate paragraph (8) as paragraph (9):

1 (8) MODEL INFORMED CONSENT.—

2 (A) IN GENERAL.—The Secretary, after
3 notice and opportunity for public comment in
4 accordance with section 553 of title 5, United
5 States Code, shall develop and disseminate
6 model consents of the type described in para-
7 graph (1).

8 (B) REQUIREMENTS OF MODEL INFORMED
9 CONSENT.—Each model consent developed
10 under subparagraph (A), with respect to the
11 protected health information of an individual,
12 shall inform such individual whether such infor-
13 mation may be disclosed to an entity in a for-
14 eign country, and in the case such information
15 may be so disclosed, whether the country is cer-

1 tified under subparagraph (D) as providing
2 adequate privacy protection.

3 (C) TREATMENT OF CONSENT OBTAINED
4 ON MODEL FORM.—Any consent obtained on a
5 model form developed under subparagraph (A)
6 shall be deemed to meet the requirement under
7 such subparagraph.

8 (D) CERTIFICATION OF COUNTRIES WITH
9 ADEQUATE PRIVACY PROTECTIONS.—

10 (i) IN GENERAL.—Not later than 6
11 months after the date of enactment of this
12 Act, the Federal Trade Commission, after
13 providing notice and opportunity for public
14 comment in accordance with section 553 of
15 title 5, United States Code, shall—

16 (I) certify those countries that
17 have legal systems that provide ade-
18 quate privacy protection for protected
19 health information; and

20 (II) make the list of countries
21 certified under subclause (I) available
22 to the general public.

23 (ii) CERTIFICATION CRITERIA.—

24 (I) IN GENERAL.—In deter-
25 mining whether a country should be

1 certified under this subparagraph, the
2 Federal Trade Commission shall con-
3 sider the adequacy of the country's in-
4 frastructure for detecting, evaluating,
5 and responding to privacy violations.

6 (II) PRESUMPTION.—The Com-
7 mission shall presume that a country's
8 privacy protections are inadequate if
9 they are any less protective of pro-
10 tected health information than those
11 afforded under Federal law or under
12 the laws of any State, or if the Com-
13 mission determines that such coun-
14 try's laws are not adequately enforced.

15 (iii) EUROPEAN UNION DATA PROTEC-
16 TION DIRECTIVE.—A country that has
17 comprehensive privacy laws that meet the
18 requirements of the European Union Data
19 Protection Directive shall be certified
20 under this subparagraph unless the Fed-
21 eral Trade Commission determines that
22 such laws are not commonly enforced with-
23 in such country.

