

**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—

13 (i) inform such individual about the
14 matter to which the individual is providing
15 consent;

1 (ii) inform such individual about the
2 specific purposes for which the information
3 may be used or disclosed;

4 (iii) explain what activities are consid-
5 ered health care operations; and

6 (iv) be in a form that is easily acces-
7 sible and understandable and allows the in-
8 dividual to make an informed decision.

9 (C) TREATMENT OF CONSENT OBTAINED
10 ON MODEL FORM.—Any consent obtained on a
11 model form developed under subparagraph (A)
12 shall be deemed to meet the requirement under
13 such subparagraph.

