

HB1059_L.001

HOUSE COMMITTEE OF REFERENCE REPORT

 Chairman of Committee

 Date
Committee on Health and Human Services.

After consideration on the merits, the Committee recommends the following:

HB09-1059 be amended as follows:

1 Amend printed bill, page 2, strike lines 9 through 21 and substitute the
2 following:

3 "(I) THE COVERED PERSON'S TREATING PHYSICIAN, WHO IS
4 PROVIDING COVERED HEALTH CARE SERVICES TO THE PERSON UNDER THE
5 HEALTH BENEFIT PLAN CONTRACT, RECOMMENDS PARTICIPATION IN THE
6 CLINICAL TRIAL AFTER DETERMINING THAT PARTICIPATION IN THE
7 CLINICAL TRIAL HAS A MEANINGFUL POTENTIAL TO BENEFIT THE COVERED
8 PERSON;

9 (II) THE CLINICAL TRIAL OR STUDY IS APPROVED UNDER THE
10 SEPTEMBER 19, 2000, MEDICARE NATIONAL COVERAGE DECISION
11 REGARDING CLINICAL TRIALS, AS AMENDED;

12 (III) THE PATIENT CARE IS PROVIDED BY A CERTIFIED, REGISTERED,
13 OR LICENSED HEALTH CARE PROVIDER PRACTICING WITHIN THE SCOPE OF
14 HIS OR HER PRACTICE AND THE FACILITY AND PERSONNEL PROVIDING THE
15 TREATMENT HAVE THE EXPERIENCE AND TRAINING TO PROVIDE THE
16 TREATMENT IN A COMPETENT MANNER;

17 (IV) PRIOR TO PARTICIPATION IN A CLINICAL TRIAL OR STUDY, THE
18 COVERED PERSON HAS SIGNED A STATEMENT OF CONSENT INDICATING
19 THAT THE COVERED PERSON HAS BEEN INFORMED OF THE PROCEDURE TO
20 BE UNDERTAKEN, ALTERNATIVE METHODS OF TREATMENT, THE GENERAL
21 NATURE AND EXTENT OF THE RISKS ASSOCIATED WITH PARTICIPATION IN
22 THE CLINICAL TRIAL OR STUDY, THE COVERAGE PROVIDED BY AN



1 INDIVIDUAL OR GROUP HEALTH BENEFIT PLAN WILL BE CONSISTENT WITH
2 THE COVERAGE PROVIDED IN THE COVERED PERSON'S HEALTH BENEFIT
3 PLAN, AND ALL OUT-OF-NETWORK RATES WILL APPLY; AND

4 (V) THE COVERED PERSON SUFFERS FROM A CONDITION THAT IS
5 DISABLING, PROGRESSIVE, OR LIFE-THREATENING."

6 Page 3, line 10, strike "OR";

7 line 12, strike "STUDY." and substitute "STUDY; OR";

8 after line 12, insert the following:

9 "(VI) HEALTH CARE SERVICES THAT, EXCEPT FOR THE FACT THAT
10 THEY ARE BEING PROVIDED IN A CLINICAL TRIAL, ARE OTHERWISE
11 SPECIFICALLY EXCLUDED FROM COVERAGE UNDER THE COVERED PERSON'S
12 HEALTH PLAN.";

13 line 27, strike "A MEDICAL SERVICE OR".

14 Page 4, strike lines 1 through 8 and substitute the following:

15 "ALL ITEMS AND SERVICES THAT ARE A BENEFIT UNDER A HEALTH
16 COVERAGE PLAN THAT WOULD BE COVERED IF THE COVERED PERSON WERE
17 NOT INVOLVED IN EITHER THE EXPERIMENTAL OR THE CONTROL ARMS OF
18 A CLINICAL TRIAL; EXCEPT THE INVESTIGATIONAL ITEM OR SERVICE,
19 ITSELF; ITEMS AND SERVICES PROVIDED SOLELY TO SATISFY DATA
20 COLLECTION AND ANALYSIS NEEDS AND THAT ARE NOT USED IN THE
21 DIRECT CLINICAL MANAGEMENT OF THE PATIENT; ITEMS AND SERVICES
22 CUSTOMARILY PROVIDED BY THE RESEARCH SPONSORS FREE OF CHARGE
23 FOR ANY ENROLLEE IN THE TRIAL; ROUTINE COSTS IN CLINICAL TRIALS
24 INCLUDE ITEMS OR SERVICES THAT ARE TYPICALLY PROVIDED ABSENT A
25 CLINICAL TRIAL; ITEMS OR SERVICES REQUIRED SOLELY FOR THE PROVISION
26 OF THE INVESTIGATIONAL ITEMS OR SERVICES, THE CLINICALLY
27 APPROPRIATE MONITORING OF THE EFFECTS OF THE ITEM OF SERVICE, OR
28 THE PREVENTION OF COMPLICATIONS; AND ITEMS OR SERVICES NEEDED
29 FOR REASONABLE AND NECESSARY CARE ARISING FROM THE PROVISION OF
30 AN INVESTIGATIONAL ITEM OR SERVICE, INCLUDING THE DIAGNOSIS OR
31 TREATMENT OF COMPLICATIONS."

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