

HOUSE COMMITTEE OF REFERENCE REPORT

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Chairman of Committee

February 2, 2009  
Date

Committee on Health and Human Services.

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

HB09-1059 be amended as follows, and as so amended, be referred to the Committee of the Whole with favorable recommendation:

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

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

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

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

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

9 after line 12, insert the following:

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

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

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

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

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