# Frequent Hemodialysis Network
# DETECTED THERAPY DEVIATION - FORM #310

This form should be completed following each calendar month in which the patient missed four or more dialysis sessions, or in which the actual treatment time averaged at least 30 minutes below the minimum allowable time over a period of 1 week or greater or received four or more treatments or greater as designated under the FHN protocol or for a nocturnal trial patient who dialyzed in-center rather than at home. Treatment deviations due to hospitalizations are not counted.

This form does not need to be completed if a Form 309 - Planned Therapy Deviation was completed for the given month.

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1. Participant ID # 2. Alpha Code 3a. Visit Type 3b. Visit Number 4. Date of 1st Detected Deviation: dd/mon/yyyy

5. This form is being completed because of the following reason(s): (For 5a-d: use 0=No, 1=Yes)
   a. The patient missed 4 or more treatments (from randomized treatment assignment) during the next month: .......... __
   b. The patient missed an average of at least 30 minutes or more treatment time for a period of at least 1 week: .......... __
   c. The patient had 4 or more extra treatments (from randomized treatment assignment) in a given month .......... __
   d. Nocturnal Trial only: the patient received some dialysis in-center this month instead of at home .......... __
6. Anticipated length of time until correction of deviation: .......... __
   1=1 month or less
   2=1-2 months
   3=2-4 months
   4=Remainder of study
   5=Indefinite
7. Was the deviation the result of a hospitalization or travel or some other life event that precluded adherence? (0=No, skip to Q9, 1=Yes, answer Q8) .......... __
8. If Q7 is Yes, indicate which of the following apply: (For 8a-b: use 0=No, 1=Yes)
   a. Hospitalization? (Be sure to complete Forms 302, 303) .......... __
   b. Travel? .......... __

*(Email the DCC at fhn-dcc@bio.ri.ccf.org if an additional reason is identified)*

9. Was deviation the result of a medical decision by a physician? .......... __
   (0=No, skip to Q11, 1=Yes, answer Q10)
10. If Q9 is Yes, indicate which of the following apply: (For 10 a-h, se 0=No, 1=Yes)
    a. Hypotension? .......... __
    b. Phosphate depletion? .......... __
    c. Patient fatigue? .......... __

*(Q10 d-h, Medical reasons continued on next page)*

***Q10 (deviation due to medical reason continued: Code 0=No, 1=Yes)***

d. Symptoms of under dialysis? .......... __

e. Problems controlling fluid intake and treating physician insists on additional dialysis sessions rather than hyperfiltration sessions .......... __

f. Vascular access problem made no hemodialysis possible .......... __

g. Moderate vascular access problem was judged to make dialysis possible no more than 3x per week .......... __

h. Other medical indication described in text field (Q17) .......... __
*(Email the DCC at fhn-dcc@bio.ri.ccf.org if an additional reason is identified)*

11. Was the deviation the result of patient non-adherence? .......... __
(0=No, skip to Q13, 1=Yes, answer Q12, 2=Yes, other reason explained in Q17)

12. If Q11 is Yes, indicate which of the following apply: (For 12a-g, use 0=No, 1=Yes)

a. Transportation difficulties? .......... __

b. Inadequate caregiver assistance? .......... __

c. Employment constraints? .......... __

d. Concern over vascular access? .......... __

e. Other time commitments? .......... __

f. Patient burn-out? .......... __

g. Patient symptoms suspected by patient to be due to over dialysis? .......... __
*(Email the DCC at fhn-dcc@bio.ri.ccf.org if an additional reason is identified)*

13. Was the deviation the result of logistical or scheduling issues with the dialysis unit? (0=No, skip to Q15, 1=Yes, answer Q14) .......... __

14. If Q13 is Yes, indicate which of the following apply: (For 14a-b: use 0=No, 1=Yes)

a. Staffing shortage? .......... __

b. Scheduling issues preclude the designated dialysis treatment schedule? .......... __
*(Email the DCC at fhn-dcc@bio.ri.ccf.org if an additional reason is identified)*

15. Was the deviation the result of logistical or other issues with performing dialysis in the home? (0=No, skip to Q17, 1=Yes, answer Q16) .......... __

16. If Q15 is Yes, indicate which of the following apply: (For 16a-c: use 0=No, 1=Yes)

a. Dialysis machine breakdown? .......... __

b. Water treatment breakdown or other plumbing issue? .......... __

c. Lack of dialysis supplies? .......... __
*(Email the DCC at fhn-dcc@bio.ri.ccf.org if an additional reason is identified)*

17. Other Comments: Please describe what is going on with this patient (Use the back of the paper form, if needed). (Database will allow up to 2000 characters)

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200. Date this form completed (dd/mon/yyyy)............................. __ __/__ __ __ /__ __ __ __

201. Username of person reviewing completeness of this form..........__ __ __ __ __ __ __ __

**For Clinical Center Use Only:**

**202. Username of person entering this form: __ __ __ __ __ __ __ __**

**203. Date Entered: (dd/mon/yyyy) __ __/__ __ __ /__ __ __ __**