IN-CENTER HEMODIALYSIS (HD) CLINICAL PERFORMANCE MEASURES DATA COLLECTION FORM 2006

[Before completing please read instructions at the bottom of this page and on pages 5 and 6]

PATIENT IDENTIFICATION

MAKE CORRECTIONS TO PATIENT INFORMATION ON LABEL IN THE SPACE BELOW

Place Patient Data Label Here

12. **If this patient is unknown or was not dialyzed in the facility at any time during OCT 2005-DEC 2005 return the blank form to the Network.**

13. Patient's Ethnicity (Check appropriate box). ☐ Not Hispanic or Latino

☐ Hispanic or Latino: Please specify country/area of origin or ancestry _____.

14. **Patient's height (MUST COMPLETE):** _____inches **OR** _____centimeters
(only for patients < 18 years old, provide date when height was measured: ____ / ___ / _____)
(mm) (dd) (yyyy)

Individual Completing Form (**Please print**):
First name: _____ Last name: _____ Title: _____
Phone number: (_____) _____ - _____ Fax number: (_____) _____ - _____

INSTRUCTIONS FOR COMPLETING THE IN-CENTER HEMODIALYSIS CLINICAL PERFORMANCE MEASURES DATA COLLECTION FORM 2006

The label on the top left side of this form contains the following patient identifying information (#'s 1-11). If the information is incorrect make corrections to the right of the label.

1. LAST and first name
3. SOCIAL Security Number (SSN)
5. GENDER (1=Male; 2=Female)
7. PRIMARY cause of renal failure by CMS-2728 code
9. ESRD Network number - Do not make corrections to this item.
2. DATE of birth (DOB) as MM/DD/YYYY
4. HEALTH Insurance Claim Number (HIC), (**same as Medicare number**)
6. RACE, check all that apply (1=American Indian/Alaska Native; 2=Asian; 3=Black or African American; 4=White; 6=Native Hawaiian or Other Pacific Islander)
8. DATE, as MM/DD/YYYY, that the patient FIRST began a regular course of dialysis
10. Facility's Medicare provider number
11. The most RECENT date this patient returned to hemodialysis following: transplant failure, an episode of regained kidney function, or switched modality.

12. If the patient is unknown or if the patient was not dialyzed in the facility at any time during OCT 2005 through DEC 2005, send the blank form back to the ESRD Network office. Provide the name and address of the facility providing services to this patient on December 31, 2005, if known.
13. Patient's Ethnicity. Please verify the patient's ethnicity with the patient and check appropriate box. If "Hispanic or Latino" is checked, please specify country/area of origin or ancestry.
14. Enter the patient's height in inches or centimeters. HEIGHT MUST BE ENTERED, do not leave this field blank. You may ask the patient his/her height to obtain this information. If the patient had both legs amputated, record pre-amputation height.

PLEASE COMPLETE ITEMS 15 AND 16 ON PAGE 2, ITEM 17 ON PAGE 3, AND ITEMS 18 AND 19 ON PAGE 4 OF THIS DATA COLLECTION FORM.
INSTRUCTIONS FOR COMPLETING THESE ITEMS ARE ON PAGES 5 AND 6.

IN-CENTER HEMODIALYSIS (HD) CLINICAL PERFORMANCE MEASURES DATA COLLECTION FORM 2006 (CONTINUED)

15. ANEMIA MANAGEMENT: For each lab question below, enter the 1st pre-dialysis lab value obtained for each month: OCT, NOV, DEC 2005. Include the date each lab was drawn. Enter NF/NP if the lab value cannot be located.

	OCT 2005	NOV 2005	DEC 2005
A. First pre-dialysis laboratory hemoglobin (Hgb) of the month:	____ ____ . ____ g/dL Date: ____/____/____ (If NF/NP go to 15C)	____ ____ . ____ g/dL Date: ____/____/____ (If NF/NP go to 15C)	____ ____ . ____ g/dL Date: ____/____/____ (If NF/NP go to 15C)
B.1.a. Did the patient have Epoetin prescribed at any time during the 28 days before the Hgb in 15A was drawn?	Epoetin ☐Yes ☐No ☐Unknown	Epoetin ☐Yes ☐No ☐Unknown	Epoetin ☐Yes ☐No ☐Unknown
B.1.b. Did the patient have Darbepoetin (Aranesp™) prescribed at any time during the 28 days before the Hgb in 15A was drawn?	Darbepoetin ☐Yes ☐No ☐Unknown	Darbepoetin ☐Yes ☐No ☐Unknown	Darbepoetin ☐Yes ☐No ☐Unknown
C. First pre-dialysis serum ferritin concentration of the month:	___ ___ ___ __ ng/mL Date: ____/____/____	___ ___ ___ __ ng/mL Date: ____/____/____	___ ___ ___ __ ng/mL Date: ____/____/____
D. First pre-dialysis % transferrin saturation (TSAT) of the month:	_____ _____ _____ % Date: ____/____/____	_____ _____ _____ % Date: ____/____/____	_____ _____ _____ % Date: ____/____/____
E. Was iron prescribed at any time during the month?	☐Yes ☐No (go to 16) ☐Unknown (go to 16)	☐Yes ☐No (go to 16) ☐Unknown (go to 16)	☐Yes ☐No (go to 16) ☐Unknown (go to 16)
F. If yes, what was the prescribed route of iron administration? (Check all that apply).	☐ IV ☐ PO ☐ Unknown	☐ IV ☐ PO ☐ Unknown	☐ IV ☐ PO ☐ Unknown

16. MINERAL METABOLISM MANAGEMENT: Enter the 1st pre-dialysis serum calcium, phosphorus, and albumin obtained for each month: OCT, NOV, DEC 2005. Include the date each lab was drawn. Enter NF/NP if the lab value cannot be located. Check the method used (16D) (BCG [bromcresol green] or BCP [bromcresol purple]) by the lab to determine serum albumin. If the lab method is unknown, please call lab to find out.

	OCT 2005	NOV 2005	DEC 2005
A. First pre-dialysis serum calcium of the month. Drawn on the same date as 16B and 16C:	___ ___.___ mg/dL Date: ____/____/____	___ ___.___ mg/dL Date: ____/____/____	___ ___.___ mg/dL Date: ____/____/____
B. First pre-dialysis serum phosphorus of the month. Drawn on the same date as 16A and 16C:	___ ___.___ mg/dL Date: ____/____/____	___ ___.___ mg/dL Date: ____/____/____	___ ___.___ mg/dL Date: ____/____/____
C. First pre-dialysis serum albumin of the month. Drawn on the same date as 16A and 16B:	___.___ gm/dL Date: ____/____/____	___.___ gm/dL Date: ____/____/____	___.___ gm/dL Date: ____/____/____
D. Check lab method used: BCG = bromcresol green; BCP = bromcresol purple	☐ BCG ☐ BCP	☐ BCG ☐ BCP	☐ BCG ☐ BCP

IN-CENTER HEMODIALYSIS (HD) CLINICAL PERFORMANCE MEASURES DATA COLLECTION FORM 2006 (CONTINUED)

17. ADEQUACY: Enter the information requested below for the dialysis session when the 1st labs of the month were drawn and used to measure adequacy for each month: OCT, NOV, DEC 2005. Include the date the labs were drawn. Enter NF/NP if the information cannot be located.

	OCT 2005	NOV 2005	DEC 2005
A. How many times per week was this patient prescribed to receive dialysis during the week prior to when the pre and post BUNs were drawn?	_____times per week	_____times per week	_____times per week
B. First pre-dialysis BUN value of the month:	_____ mg/dL Date: ____/____/____	_____ mg/dL Date: ____/____/____	_____ mg/dL Date: ____/____/____
C. First post-dialysis BUN value of the month: (both the pre & post dialysis BUN must be drawn on the same day)	_____ mg/dL Date: ____/____/____	_____ mg/dL Date: ____/____/____	_____ mg/dL Date: ____/____/____
D. Pre- & Post-dialysis weight at session when BUNs above drawn: (Circle either lbs or kgs)	Pre: _____.___ lbs/kgs Post: _____.___lbs/kgs	Pre: _____.___ lbs/kgs Post: _____.___lbs/kgs	Pre: _____.___ lbs/kgs Post: _____.___lbs/kgs
E. Actual DELIVERED time on dialysis at session when BUNs above drawn:	_____hrs ____ ____ min	_____hrs ____ ____ min	_____hrs ____ ____ min
F. First recorded URR of the month:	_____ _____._____ % Date: ____/____/____	_____ _____. _____ % Date: ____/____/____	_____ _____. _____ % Date: ____/____/____
G. First recorded single-pool Kt/V of the month:	_____ . _____ _____ Date: ____/____/____	_____ . _____ _____ Date: ____/____/____	_____ . _____ _____ Date: ____/____/____
H. Method used to calculate the single-pool Kt/V in 17G: (If unknown, please ask Medical Director)	☐Urea Kinetic Modeling ☐Daugirdas II ☐Depner ☐Derived from URR based on no pt. wts. ☐Other_____	☐Urea Kinetic Modeling ☐Daugirdas II ☐Depner ☐Derived from URR based on no pt. wts. ☐Other_____	☐Urea Kinetic Modeling ☐Daugirdas II ☐Depner ☐Derived from URR based on no pt. wts. ☐Other_____

IN-CENTER HEMODIALYSIS (HD) CLINICAL PERFORMANCE MEASURES DATA COLLECTION FORM 2006 (CONTINUED)

18. VASCULAR ACCESS: What type of access was used on the last hemodialysis session on or between 10/1/2005 and 12/31/2005 at the patient's primary in-center facility? **Check only one** of the following access types and follow the corresponding directions.

☐ AV Fistula
☐ Graft with AV Fistula
☐ Graft without AV Fistula

If you checked AV Fistula or Graft (with or without AV Fistula) please answer questions 1, 2, and 3 at the right.

If patient had AV Fistula or Graft:

1. Was surveillance for the presence of stenosis performed between 10/1/05 and 12/31/05?
   ☐ Yes ☐ No ☐ Unknown
2. If answer to question 1 is "Yes," please check all methods of surveillance (below) that were utilized. (See instructions on page 6).
   ☐ Color-Flow Doppler at least once between 10/1/05 and 12/31/05
   ☐ Static Venous Pressure at least once every 2 weeks between 10/1/05 and 12/31/05
   ☐ Dynamic Venous Pressure every HD session between 10/1/05 and 12/31/05
   ☐ Dilution Technique at least once between 10/1/05 and 12/31/05
   ☐ On-Line Clearance (OLC) Based Access Flow at least once between 10/1/05 and 12/31/05
   ☐ Other_____
3. Did the patient have an active AV Fistula or Graft (being used for hemodialysis) **AND** an inactive catheter or port access (not being used for hemodialysis) during the last hemodialysis session on or between 10/1/2005 and 12/31/2005?
   ☐ Yes ☐ No

☐ Catheter
☐ Port Access

If you checked Catheter or Port Access, please answer questions 1and 2 at the right.(check all that apply to reasons for catheter or port access at this time)

If patient had a catheter or port access: (check all boxes by the reasons that apply)

1. Reason for catheter or port access:
   ☐ Fistula maturing, not ready to cannulate (with two needles)
   ☐ Graft maturing, not ready to cannulate (with two needles)
   ☐ Temporary interruption of fistula due to clotting or revisions
   ☐ Temporary interruption of graft due to clotting or revisions
   ☐ No fistula or graft surgically created at this time
   ☐ No fistula or graft surgically planned (check all subcategories that apply)
   ○ Peripheral vascular disease
   ○ Patient size too small for AV fistula or graft
   ○ Renal transplantation scheduled
   ○ Patient preference
   ○ Physician/Surgeon preference
   ☐ Useable fistula or graft sites have been exhausted (check all subcategories that apply)
   ○ At least one failed fistula exists
   ○ A failed graft exists
   ○ Fistula history uncertain
   ☐ Other_____
2. Had a catheter or port access been used exclusively for the past 90 days or longer?
   ☐ Yes ☐ No ☐ Unknown

☐ Unknown

19. Did the patient FIRST start hemodialysis during January 1, 2005-August 31, 2005 (see date #8 on page 1)? DO NOT **include patients who transferred from peritoneal dialysis, had a newly failed transplant, or returned after an episode of regained kidney function** (See instructions on page 6). ☐ **Yes (answer 19A-B)** ☐ **No**

A. What type of access was in use at the **Initiation** of a maintenance course of hemodialysis (First hemodialysis was during JAN 1, 2005 - AUG 31, 2005.)? ☐ AV Fistula ☐ Graft ☐ Catheter ☐ Port Access ☐ Unknown

B. What type of access was in use 90 days later? ☐ AV Fistula ☐ Graft ☐ Catheter ☐ Port Access ☐ Unknown

IN-CENTER HEMODIALYSIS (HD) CLINICAL PERFORMANCE MEASURES DATA COLLECTION FORM 2006 (CONTINUED)

INSTRUCTIONS FOR COMPLETING QUESTIONS 15 THROUGH 19 (Continued from page 1): To answer questions 15 through 19, review the patient's clinic or facility medical record for OCT 1, 2005 through DEC 31, 2005. Do not leave any items blank. Enter NF/NP if the information cannot be located.

15A: Enter the patient's first pre-dialysis hemoglobin (Hgb) for each month OCT, NOV, DEC 2005. Include the date the lab was drawn. If not found or not performed during the month, enter NF/NP.

15B.1: Check the appropriate box to indicate if the patient had EPOETIN prescribed at any time during the 28 days BEFORE the date of the hemoglobin in 15A or had DARBEPOETIN (Aranesp™) prescribed at any time during the 28 days BEFORE the date of the hemoglobin value in 15A.

15C: Enter the patient's first pre-dialysis serum ferritin concentration for each month OCT, NOV, DEC 2005. Include the date the lab was drawn. If a serum ferritin concentration test was not found or not performed during the month, enter NF/NP.

15D: Enter the patient's first pre-dialysis % transferrin saturation (TSAT) for each month OCT, NOV, DEC 2005. Include the date the lab was drawn. If a % transferrin saturation (TSAT) test was not found or not performed during the month, enter NF/NP.

15E: Check either "Yes", "No", or "Unknown" to indicate if iron was prescribed at any time during the months of OCT, NOV, and DEC 2005. **If there was no prescription for iron go to question 16.**

15F: If the answer to 15E is "Yes", please check the appropriate box to indicate the route of iron administration (intravenous[IV] or by mouth [PO]) for OCT, NOV, and DEC 2005. If the patient received iron by mouth **and** IV during the month please check both boxes.

16A: Enter the patient's first pre-dialysis serum calcium for each month OCT, NOV, DEC 2005. Include the date the lab was drawn. If a serum calcium was not found or not performed during the month, enter NF/NP.

16B: Enter the patient's first pre-dialysis serum phosphorus for each month OCT, NOV, DEC 2005. Include the date the lab was drawn. If a serum phosphorus was not found or not performed during the month, enter NF/NP.

16C: Enter the patient's first pre-dialysis serum albumin for each month OCT, NOV, DEC 2005. Include the date the lab was drawn. If a serum albumin was not found or not performed during the month, enter NF/NP.

16D: Check the method used by the laboratory to determine the serum albumin value (bromcresol green or bromcresol purple). If you do not know what method the laboratory used, call the lab to find out this information.

17A: Enter the number of times per week the patient was **prescribed** to receive dialysis in OCT, NOV, and DEC 2005. If the prescription varied during a month, enter the prescription in effect the week prior to when the pre- and post-BUNs were drawn. Do not leave this question blank.

17B & C: Enter the patient's first pre- and post-dialysis BUNs for each month. Include the dates the labs were drawn. Both the pre- and post-dialysis BUN must be drawn on the same day. Enter NF/NP if not found or not performed during the month.

17D: Enter the patient's pre- and post-dialysis weight at the dialysis session when the pre- and post-dialysis BUNs in questions 17B&C were drawn. Circle either lbs or kgs as appropriate.

17E: Enter the patient's total treatment time (actual delivered time) on dialysis during the session when the BUNs in questions 17B&C were drawn for months OCT, NOV, DEC 2005. Do not enter the prescribed time on dialysis.

17F: Enter the patient's first URR recorded on the lab sheet for each month OCT, NOV, DEC 2005. Include the date the lab was drawn. If not found or not performed during a month, enter NF/NP.

17G: Enter the patient's first single-pool Kt/V recorded on the lab sheet for each month OCT, NOV, DEC 2005. Include the date the lab was drawn. If not found or not performed during a month, enter NF/NP.

17H: Check the box to indicate the method used to calculate the single-pool Kt/V in 17G. If you do not know what method was used, please ask the unit's Medical Director. Please check the "Other" box if you do not use any of the methods listed. If using another method and you know what it is, please write the method in the space provided.

IN-CENTER HEMODIALYSIS (HD) CLINICAL PERFORMANCE MEASURES DATA COLLECTION FORM 2006 (CONTINUED)

18: Check only one type of vascular access used on **last hemodialysis session on or between OCT 1, 2005 and DEC 31, 2005** at the patient's primary in-center facility and then complete the corresponding questions to the right of the access type. Exclude dialysis sessions performed at temporary facilities because of holiday travel or hospitalizations. If a fistula and catheter are being used simultaneously for vascular access, the patient's access type should be considered catheter. ("Port Access" is considered a vascular access device which consists of a valve and cannula that is subcutaneously implanted and is accessed by dialysis needles).

AV Fistula or Graft:

If the vascular access marked for question 18 was an AV fistula or graft (with or without AV fistula) indicate if routine surveillance for the presence of stenosis between Oct 1, 2005 and Dec 31, 2005 was done. Routine surveillance is the sequential measurement of access flow OR of venous pressure.

- Indicate "**YES**" for this question if you measure access flow OR venous pressure using any of the following:
  Techniques and frequencies used to measure access flow include:
  a. one of the dilution methods in which the needles are reversed and recirculation is deliberately induced on a regular basis, **OR**
  b. conventional Color-Flow Doppler at a minimum of once every three months.
  Techniques and frequencies used to measure venous pressure include:
  a. dynamic venous pressure measured at every hemodialysis session; uses low blood pump flow rates usually set at 200mL/min., **OR**
  b. static venous pressure measured at a minimum of once every two weeks; performed at zero blood pump flow.
- Indicate "**NO**" for this question if you only conduct (or note) the following clinical assessments:
  a. Prolonged bleeding after needle withdrawal.
  b. Altered characteristics of thrill or bruit.
  c. Adequacy measurements using Kt/V or URR.
  d. Recirculation methods.

Continue with question 2 if answered "yes" above and check all surveillance methods utilized based on the definitions and intervals given above. If other techniques and/or corresponding intervals were used check "other" and write in the technique and corresponding intervals.

Continue with question 3 and answer "yes" if patient had a catheter or port access that was being used previously for hemodialysis but had not been removed on last hemodialysis session on or between 10/1/2005 and 12/31/2005.

Catheter or Port Access:
If the vascular access marked for question 18 was a catheter or port access, indicate in the appropriate space the **reason for the catheter or port access.**

Continue with question 2 and indicate in the appropriate space **if one or more catheters or port accesses** had been used **continuously** in this patient for the past **90 days or longer** between OCT 1, 2005 and DEC 31, 2005.

Unknown:
If the vascular access in question 18 is unknown indicate by checking the "unknown" box and then continue to question 19.

19: Check the appropriate space to indicate if the patient FIRST started hemodialysis during January 1, 2005-August 31, 2005 (see date #8 on page 1). These patients would have begun a regular maintenance course of hemodialysis during January 1, 2005 - August 31, 2005. **DO NOT** include patients who have transferred from peritoneal dialysis, had a newly failed transplant, or returned after an episode of regained kidney function, and were placed on maintenance hemodialysis during the time frame January 1, 2005-August 31, 2005. If "Yes", answer questions 19A-B. If "No", questions 19A-B should be left blank and the form has been completed.

19A: Check the appropriate space to indicate type of vascular access in use upon **Initiation** of a maintenance course of hemodialysis. Patient's FIRST hemodialysis would be during the time frame January 1, 2005-August 31, 2005. Exclude patients who have received intermittent dialysis treatments for volume overload or congestive heart failure. ("Port Access" is considered a vascular access device which consists of a valve and cannula that is subcutaneously implanted and is accessed by dialysis needles)

19B: Check the appropriate space to indicate type of vascular access, for the patient identified in 19A, **in use 90 days after** the patient first started hemodialysis. ("Port Access" is considered a vascular access device which consists of a valve and cannula that is subcutaneously implanted and is accessed by dialysis needles).