IN-CENTER HEMODIALYSIS (HD) CLINICAL PERFORMANCE MEASURES DATA COLLECTION FORM 2004

[Before completing please read instructions at the bottom of this page and on pages 4, 5 and 6]

PATIENT IDENTIFICATION

Place Patient Data Label Here

MAKE CORRECTIONS TO PATIENT INFORMATION ON LABEL IN THE SPACE BELOW

12. **If this patient is unknown or was not dialyzed in the facility at any time during OCT 2003-DEC 2003 return the blank form to the Network.**

13. Patient's Ethnicity (Check appropriate box). ❑ non-Hispanic ❑ Hispanic, Mexican American (Chicano) ❑ Hispanic, Puerto Rican ❑ Hispanic, Cuban American ❑ Hispanic, Other _____ ❑ Unknown

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

15. **Did patient have limb amputation(s) prior to Dec. 31, 2003:** ❑ Yes ❑ No ❑ Unknown

16. Has the patient ever been diagnosed with any type of diabetes?
❑ Yes (go to 17) ❑ No (go to 18) ❑ Unknown (go to 18)

17. If question 16 was answered **YES**, was the patient taking medications to control the diabetes during the study period?
❑ Yes ❑ No ❑ Unknown If **YES**, was the patient using insulin during the study period? ❑ Yes ❑ No ❑ Unknown

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 2004

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.
2. DATE of birth (DOB) as MM/DD/YYYY.
3. SOCIAL Security Number (SSN).
4. HEALTH Insurance Claim Number (HIC), (**same as Medicare number**).
5. GENDER (1=Male; 2=Female).
6. RACE (1=American Indian/Alaska Native; 2=Asian; 3=Black; 4=White; 5=Unknown; 6=Pacific Islander; 7=Mid East Arabian; 8=Indian Subcontinent; 9=Other Multiracial).
7. PRIMARY cause of renal failure by CMS-2728 code.
8. DATE, as MM/DD/YYYY, that the patient began a regular course of dialysis.
9. ESRD Network number. Do not make corrections to this item.
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 2003 through DEC 2003, 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, 2003, if known.
13. Patient's Ethnicity. Please verify the patient's ethnicity with the patient and check appropriate box.
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 and check YES for item 15.
15. For the purpose of this study, check NO if this patient has had toe(s), finger(s), or mid-foot (Symes) amputation; but **check YES if this patient has had a below-knee, below-elbow, or more proximal (extensive) amputation prior to Dec. 31, 2003.**
16. Check either "Yes", "No", or "Unknown" to indicate if the patient has ever been diagnosed with any type of diabetes. If **YES**, proceed to question 17.
17. Check either "Yes", "No", or "Unknown" to indicate if the patient was taking medications to control the diabetes during the study period. If the answer to 17 is **YES**, please check either "Yes", "No", or "Unknown" to indicate if the patient was using insulin during the study period. Study period is OCT 2003-DEC 2003.

IN-CENTER HEMODIALYSIS (HD) CLINICAL PERFORMANCE MEASURES DATA COLLECTION FORM 2004 (CONTINUED)

18. ANEMIA MANAGEMENT: For each lab question below, enter the lab value obtained from the monthly lab draw for each month: OCT, NOV, DEC 2003. Enter NF/NP if the lab value cannot be located.

	OCT 2003	NOV 2003	DEC 2003
A. Pre-dialysis laboratory hemoglobin (Hgb) from the monthly lab draw:	____ ____ . ____ g/dL (If NF/NP go to 18C)	____ ____ . ____ g/dL (If NF/NP go to 18C)	____ ____ . ____ g/dL (If NF/NP go to 18C)
B.1.a. Did the patient receive Epoetin at any time during the 30 days before the Hgb in 18A was drawn?	Epoetin: ❑ Yes ❑ No ❑ Unknown	Epoetin: ❑ Yes ❑ No ❑ Unknown	Epoetin: ❑ Yes ❑ No ❑ Unknown
B.1.b. Did the patient receive Darbepoetin (Aranesp™) at any time during the 30 days before the Hgb in 18A was drawn?	Darbepoetin: ❑ Yes ❑ No ❑ Unknown	Darbepoetin: ❑ Yes ❑ No ❑ Unknown	Darbepoetin: ❑ Yes ❑ No ❑ Unknown
B.2.a. What was the PRESCRIBED Epoetin dose in units for each treatment during the 7 days immediately BEFORE the Hgb in 18A was drawn? (See instructions on page 4)	Epoetin: _____ units/tx _____ units/tx _____ units/tx	Epoetin: _____ units/tx _____ units/tx _____ units/tx	Epoetin: _____ units/tx _____ units/tx _____ units/tx
B.2.b. What was the PRESCRIBED Darbepoetin dose in micrograms for the MONTH immediately BEFORE the Hgb in 18A was drawn? (See instructions on page 4)	Darbepoetin: _____ mcg/month	Darbepoetin: _____ mcg/month	Darbepoetin: _____ mcg/month
B.3. a. How many times per week was Epoetin prescribed? Check box if prescribed < 1 x per week.	Epoetin: _____ x per week ❑ < 1 x per week	Epoetin: _____ x per week ❑ < 1 x per week	Epoetin: _____ x per week ❑ < 1 x per week
B.3.b. How many times per month was Darbepoetin prescribed?	Darbepoetin: _____ x per month	Darbepoetin: _____ x per month	Darbepoetin: _____ x per month
B.4. a. What was the prescribed route of administration for Epoetin? (Check all that apply)	Epoetin: ❑ IV ❑ SC ❑ Unknown	Epoetin: ❑ IV ❑ SC ❑ Unknown	Epoetin: ❑ IV ❑ SC ❑ Unknown
B.4.b. What was the prescribed route of administration for Darbepoetin? (Check all that apply)	Darbepoetin: ❑ IV ❑ SC ❑ Unknown	Darbepoetin: ❑ IV ❑ SC ❑ Unknown	Darbepoetin: ❑ IV ❑ SC ❑ Unknown
C. Serum ferritin concentration from the monthly lab draw:	___ ___ ___ ___ ng/mL	___ ___ ___ ___ ng/mL	___ ___ ___ ___ ng/mL
D. % transferrin (iron) saturation from the monthly lab draw:	_____ _____ _____ %	_____ _____ _____ %	_____ _____ _____ %
E. Was iron prescribed at any time during the month?	❑ Yes ❑ No (go to 19) ❑ Unknown (go to 19)	❑ Yes ❑ No (go to 19) ❑ Unknown (go to 19)	❑ Yes ❑ No (go to 19) ❑ Unknown (go to 19)
F. If yes, what was the prescribed route of iron administration? (Check all that apply).	❑ IV ❑ PO ❑ Unknown	❑ IV ❑ PO ❑ Unknown	❑ IV ❑ PO ❑ Unknown
G. If the patient was prescribed IV iron, what was the total dose of IV iron **administered** during the month?	_____ mg/month	_____ mg/month	_____ mg/month

IN-CENTER HEMODIALYSIS (HD) CLINICAL PERFORMANCE MEASURES DATA COLLECTION FORM 2004 (CONTINUED)

19. SERUM ALBUMIN: Enter the serum albumin obtained from the monthly lab draw for each month: OCT, NOV and DEC 2003. Enter NF/NP if the lab value cannot be located. Check the method used (BCG/bromcresol green or BCP/bromcresol purple) by the lab to determine serum albumin. If lab method unknown, please call lab to find out.

	OCT 2003	NOV 2003	DEC 2003
A. Serum albumin from the monthly lab draw:	_____ . _____ g/dL	_____ . _____ g/dL	_____ . _____ g/dL
B. Check lab method used: BCG = bromcresol green; BCP = bromcresol purple	❑ BCG ❑ BCP	❑ BCG ❑ BCP	❑ BCG ❑ BCP

20. ADEQUACY: Enter the information requested below for the dialysis session when the monthly labs were drawn and used to measure adequacy for each month: OCT, NOV, DEC 2003. Enter NF/NP if the information cannot be located.

	OCT 2003	NOV 2003	DEC 2003
A. How many times per week was this patient prescribed to receive dialysis?	_____times per week	_____times per week	_____times per week
B. Recorded URR from the monthly lab draw:	_____ _____ . _____%	_____ _____ . _____%	_____ _____ . _____%
C. Recorded single-pool Kt/V from the monthly lab draw:	_____ . _____	_____ . _____	_____ . _____
D. Method used to calculate the single-pool Kt/V in 20C: (If unknown, please ask Medical Director)	❑ UKM ❑ Daugirdas II ❑ Depner ❑ Derived from URR based on no pt. wts. ❑ Other _____	❑ UKM ❑ Daugirdas II ❑ Depner ❑ Derived from URR based on no pt. wts. ❑ Other _____	❑ UKM ❑ Daugirdas II ❑ Depner ❑ Derived from URR based on no pt. wts. ❑ Other _____
E. Was residual renal function used to calculate the single-pool Kt/V in 20C on this patient?	❑ Yes ❑ No ❑ Unknown	❑ Yes ❑ No ❑ Unknown	❑ Yes ❑ No ❑ Unknown
F. Pre-dialysis BUN value from the monthly lab draw:	_____ mg/dL	_____ mg/dL	_____ mg/dL
G. Post-dialysis BUN value from the monthly lab draw: (both the pre & post dialysis BUN must be drawn on the same day)	_____ mg/dL	_____ mg/dL	_____ mg/dL
H. 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
I. Actual DELIVERED time on dialysis at session when BUNs above drawn:	_____hrs ____ ____ min	_____hrs ____ ____ min	_____hrs ____ ____ min
J. Delivered blood pump flow rate @ 60 minutes after start of dialysis session when BUNs above drawn:	____ ___ ___ mL/min	____ ___ ___ mL/min	____ ___ ___ mL/min
K. Code for dialyzer used for dialysis session when BUNs above drawn: (see chart)	_____	_____	_____

IN-CENTER HEMODIALYSIS (HD) CLINICAL PERFORMANCE MEASURES DATA COLLECTION FORM 2004 (CONTINUED)

21. VASCULAR ACCESS: What type of access was used on the last hemodialysis session on or between 10/1/2003 and 12/31/2003 at the patient's primary in-center facility? **Check only one** of the following access types and follow the corresponding directions.

❑ AV Fistula
❑ Synthetic Graft
❑ Bovine Graft

If you checked AV Fistula or Synthetic or Bovine Graft, please answer questions 1 and 2 at the right.

1. Was routine surveillance for the presence of stenosis performed between 10/1/03 and 12/31/03?
❑ 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 10/1/03 and 12/31/03
❑ Static Venous Pressure at least once every 2 weeks between 10/1/03 and 12/31/03
❑ Dynamic Venous Pressure every HD session between 10/1/03 and 12/31/03
❑ Dilution Technique at least once between 10/1/03 and 12/31/03
❑ Other_____

❑ Catheter
❑ Port Access

If you checked Catheter or Port Access, please answer questions 1 and 2 at the right.

1. Reason for catheter or port access:
❑ Fistula or graft maturing, not ready to cannulate
❑ Temporary interruption of fistula or graft due to clotting or revisions
❑ All fistula or graft sites have been exhausted
❑ No fistula or graft surgically created at this time
❑ No fistula or graft surgically planned (check all that apply)
❍ Peripheral vascular disease
❍ Patient size too small for AV fistula or graft
❍ Renal transplantation scheduled
❍ Patient preference
❍ Physician/Surgeon preference
❑ Other_____

2. Had a catheter or port access been used exclusively for the past 90 days or longer?
❑ Yes ❑ No ❑ Unknown

❑ Unknown

22. Did the patient FIRST start hemodialysis during January 1, 2003-August 31, 2003 (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 22A-B)** ❑ **No**

A. What type of access was in use at the **Initiation** of a maintenance course of hemodialysis (See date #8 on page 1)?
❑ AV Fistula ❑ Synthetic Graft ❑ Bovine Graft ❑ Catheter ❑ Port Access ❑ Unknown

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

INSTRUCTIONS FOR COMPLETING QUESTIONS 18 THROUGH 22 (Continued from page 1): To answer questions 18 through 22, review the patient's clinic or facility medical record for OCT 1, 2003 through DEC 31, 2003. Do not leave any items blank. Enter NF/NP if the information cannot be located.

18A: Enter the patient's pre-dialysis hemoglobin (Hgb) from the monthly lab draw (or first time during the month if not done with the monthly lab draw) for each month OCT, NOV, DEC 2003. If not found or not performed during the month, enter NF/NP.

18B.1: Check the appropriate box to indicate if the patient received EPOETIN at anytime during the 30 days BEFORE the date of the hemoglobin in 18A or for DARBEPOETIN (Aranesp™) at anytime during the 30 days BEFORE the date of the hemoglobin value in 18A. If the answer is NO to both, skip to question 18C.

18.B.2: If **Epoetin** was prescribed, enter the **PRESCRIBED** Epoetin dose, **not the administered dose**, in units given at each dialysis treatment during the 7 days immediately before the date of the hemoglobin value in 18A, even if the patient did not receive the dose. This includes any prescribed dose not given because of an error or the patient missed a treatment, etc. Enter "0" if the patient was on "Hold" for a treatment. (For the purposes of this collection, a "Hold" order will be considered a 0 unit prescribed dose.) If Epoetin is prescribed less frequently than every dialysis treatment, leave the unit/tx space blank to indicate one or two doses per the 7-day period.

If **Darbepoetin** (Aranesp™) was prescribed, enter the **PRESCRIBED MONTHLY** Darbepoetin dose, **not the administered dose**, in micrograms per month during the month immediately before the date of the hemoglobin value in 18A, even if the patient did not receive the dose. This includes any prescribed dose not given because of an error or the patient missed a treatment, etc. Enter "0" if the patient was on "Hold". (For the purposes of this collection, a "Hold" order will be considered a 0 mcg/month prescribed dose.)

18.B.3: Enter the number of times per week that Epoetin was prescribed (check the box if Epoetin was prescribed less than once per week) **OR** the number of times per month Darbepoetin was prescribed.

IN-CENTER HEMODIALYSIS (HD) CLINICAL PERFORMANCE MEASURES DATA COLLECTION FORM 2004 (CONTINUED)

18B.4: Check the appropriate box to indicate the prescribed route of administration for Epoetin or for Darbepoetin (intravenous [IV] or subcutaneous [SC]). If the patient was prescribed Epoetin or Darbepoetin IV and SC during the month, please check both boxes.

18C: Enter the patient's serum ferritin concentration from the monthly lab draw (or first time during the month if not done with the monthly lab draw) for each month OCT, NOV, DEC 2003. If a serum ferritin concentration test was not found or not performed during the month, enter NF/NP.

18D: Enter the patient's % transferrin (iron) saturation from the monthly lab draw (or first time during the month if not done with the monthly lab draw) for each month OCT, NOV, DEC 2003. If a % transferrin (iron) saturation test was not found or not performed during the month, enter NF/NP.

18E: Check either "Yes", "No", or "Unknown" to indicate if iron was prescribed at any time during the months of OCT, NOV, and DEC 2003. **If there was no prescription for iron go to question 19.**

18F: If the answer to 18E 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 2003. If the patient received iron by mouth **and** IV during the month please check both boxes.

18G: If the patient was prescribed IV iron, add together all doses that were given during the month and enter the TOTAL dose of IV iron (in mg) **administered** per month during OCT, NOV, and DEC 2003.

19A: Enter the patient's serum albumin from the monthly lab draw (or first time during the month if not done with the monthly lab draw) for each month OCT, NOV, DEC 2003. If a serum albumin was not found or not performed during the month, enter NF/NP.

19B: 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.

20A: Enter the number of times per week the patient was **prescribed** to receive dialysis in OCT, NOV, and DEC 2003. If the prescription varied during a month, enter the prescription in effect the week the monthly labs were drawn. Do not leave this question blank.

20B: Enter the patient's URR recorded on the lab sheet from the monthly lab draw for each month OCT, NOV, DEC 2003. If not found or not performed during a month, enter NF/NP.

20C: Enter the patient's single-pool Kt/V recorded on the lab sheet from the monthly lab draw for each month OCT, NOV, DEC 2003. If not found or not performed during a month, enter NF/NP.

20D: Check the box to indicate the method used to calculate the single-pool Kt/V in 20C. 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.

20E: Check the appropriate box to indicate whether residual renal function was used to calculate the single-pool Kt/V in 20C. If you do not know, please ask the unit's Medical Director.

20F & G: Enter the patient's pre- and post-dialysis BUNs from the monthly lab draw (or the BUNs used to measure adequacy for the month, if there was a blood drawing error when the monthly labs were drawn). Enter NF/NP if not found or not performed during the month.

20H: Enter the patient's pre- and post-dialysis weight at the dialysis session when the pre- and post-dialysis BUNs in question 20F&G were drawn. Circle either lbs or kgs as appropriate.

20I: Enter the patient's total treatment time (actual delivered time) on dialysis during the session when the BUNs in question 20F&G were drawn for months OCT, NOV, DEC 2003. Do not enter the prescribed time on dialysis.

20J: Enter the delivered blood pump flow rate in mL/minutes at 60 minutes after the start of the dialysis session when the BUNs in questions 20F&G were drawn for months OCT, NOV, DEC 2003. Do not enter the prescribed blood pump flow rate or the highest achieved blood pump flow rate.

IN-CENTER HEMODIALYSIS (HD) CLINICAL PERFORMANCE MEASURES DATA COLLECTION FORM 2004 (CONTINUED)

20K: Using the enclosed Dialyzer Code Chart, enter the code for the dialyzer used at the dialysis session when the pre- and post-dialysis BUNs in question 20F&G were drawn for OCT, NOV, DEC 2003. If the dialyzer used is not listed on the chart, enter the code for "other" (9999).

21: Check only one type of vascular access used on **last hemodialysis session on or between OCT 1, 2003 and DEC 31, 2003** 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. ("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, Synthetic Graft, Bovine Graft:

If the vascular access marked for question 21 was an AV fistula, synthetic graft or bovine graft, indicate if routine surveillance for the presence of stenosis between Oct 1, 2003 and Dec 31, 2003 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 200 mL/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.

Catheter or Port Access:

If the vascular access marked for question 21 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, 2003 and DEC 31, 2003.

Unknown:

If the vascular access in question 21 is unknown indicate by checking the "unknown" box and then continue to question 22.

22: Check the appropriate space to indicate if the patient FIRST started hemodialysis during January 1, 2003-August 31, 2003 (see date #8 on page 1). These patients would have begun a regular maintenance course of hemodialysis during January 1, 2003-August 31, 2003. **DO NOT** include patients who have transferred from peritoneal dialysis, had a newly failed trans plant, or returned after an episode of regained kidney function, and were placed on maintenance hemodialysis during the time frame January 1, 2003-August 31, 2003. If "Yes", answer questions 22A-B. If "No", questions 22A-B should be left blank and the form has been completed.

22A: Check the appropriate space to indicate type of vascular access in use upon **Initiation** of a maintenance course of hemodialysis (see date #8 on page 1) during the time frame January 1, 2003-August 31, 2003. 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).

22B: Check the appropriate space to indicate type of vascular access, for the patient identified in 22A, **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).