CMS Manual System

Pub. 100-20 One-Time Notification

Department of Health & Human Services (DHHS)
Centers for Medicare & Medicaid Services (CMS)

Transmittal 145 **Date: MARCH 11, 2005**

CHANGE REQUEST 3730

SUBJECT: **Frequent Hemodialysis Network Payment Changes for Approved Clinical Trial Costs**

I. SUMMARY OF CHANGES: CMS is jointly sponsoring two clinical trials evaluating the benefits of more frequent hemodialysis with the National Institute of Diabetes and Digestive and Kidney Diseases. One of these trials compares conventional, thrice weekly hemodialysis to 6-times per week hemodialysis in a dialysis center and the other compares conventional, thrice weekly in-center hemodialysis to 6-times per week nocturnal hemodialysis performed at home. For Medicare beneficiaries enrolled in the experimental arm (more frequent dialysis) of these trials, CMS authorizes payment for one additional composite rate per week for the duration of the trial. The duration of the daily in-center hemodialysis trial will be 12 months after patient enrollment. The duration of the nocturnal hemodialysis trial will be 14 months after patient enrollment. For patients enrolled in the experimental arm of the nocturnal hemodialysis trial, CMS also authorizes additional home dialysis training payment at the composite payment rate plus $20 for each training session incurred up to a maximum of 30 training session payments per patient. This CR was originally communicated on February 18, 2005, as Transmittal 142, which was rescinded on February 23, 2005.

NEW MATERIAL - EFFECTIVE DATE*: June 1, 2005
IMPLEMENTATION DATE: July 5, 2005

II. CHANGES IN MANUAL INSTRUCTIONS (*N/A if manual not updated*):

R/N/D	CHAPTER/SECTION/SUBSECTION/TITLE
N/A	

III. FUNDING: No additional funding will be provided by CMS; Contractor activities are to be carried out within their FY 2005 operating budgets.

IV. ATTACHMENTS:

	Business Requirements
	Manual Instruction
	Confidential Requirements
X	**One-Time Notification**
	Recurring Update Notification

***Unless otherwise specified, the effective date is the date of service.**

Attachment – One-Time Notification

Pub. 100-20	Transmittal: 145	Date: March 11, 2005	Change Request 3730

SUBJECT: Frequent Hemodialysis Network Payment Changes for Approved Clinical Trial Costs

I. GENERAL INFORMATION

A. Background: The Centers for Medicare and Medicaid Services (CMS) is jointly sponsoring with the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) two clinical trials to evaluate the effectiveness of more frequent hemodialysis sessions compared with conventional thrice-weekly hemodialysis. One of these trials compares daily in-center hemodialysis (6 times per week) with conventional in-center hemodialysis (3-times per week). The other compares nocturnal hemodialysis (6 times per week in the home) with conventional in-center hemodialysis. CMS has agreed to pay for covered patient care-related expenses for Medicare beneficiaries enrolled in these trials. For patients enrolled in the experimental arms of these trials (more frequent in-center or nocturnal hemodialysis), CMS also authorizes payment for one additional composite for the duration of the trial. The duration of the daily in-center hemodialysis trial will be 12 months after patient enrollment. The duration of the nocturnal hemodialysis trial will be 14 months after patient enrollment. For patients enrolled in the experimental arm of the nocturnal hemodialysis trial, CMS also authorizes additional home dialysis training payment at the composite payment rate plus $20 for each training session incurred not to exceed 30 training session payments per patient. The standard Medicare deductibles and co-payments will apply to both composite rate payments and training session payments.

B. Policy: Authority to enter into this agreement is contained in Section 601 of the Economy Act of 1932 as amended (31 USC 1535). CMS' program authority is CFR 42 USC 1310. The program authority for NIDDK is the Economy Act, as amended (31 USC 1535).

II. BUSINESS REQUIREMENTS

"Shall" denotes a mandatory requirement
"Should" denotes an optional requirement

Requirement Number	Requirements	Responsibility ("X" indicates the columns that apply)								
		FI	RHHI	Carrier	DMERC	Shared System Maintainers				Other
						FISS	MCS	VMS	CWF	
3730.1	The FIs shall collect from provider demonstration sites attestation for all beneficiaries qualified and enrolled in the ESRD Daily Trial (Attachments 1 and 2).	X								Provider Demonstration Sites

Requirement Number	Requirements	Responsibility ("X" indicates the columns that apply)								
		FI	RHHI	Carrier	DMERC	Shared System Maintainers				Other
						FISS	MCS	VMS	CWF	
3730.2	The FIs shall instruct the provider demonstration site (listed in Attachment 3) to populate Form Locator (FL) 63 or the 837I equivalent on the 72X Type of Bill (TOB) with "Trial 49" for dialysis services provided to the trial beneficiaries.	X								Provider Demonstration Sites
3730.2.1	The FIs shall process claims for payment, with Trial 49 populated in FL 63 in accordance with standard Medicare claims processing rules.	X								
3730.2.2	For home hemodialysis patients enrolled in Trial 49, FIs shall follow the normal procedures in place to bill under Temporary Method I. This allows payment for home dialysis items and services on behalf of patients that have not filed a Form CMS-382 selection form.	X								
3730.3	FISS shall design and create a process for creating a file of all demonstration claims paid each month and transmit it in FSSCPDCP/FSSCPDCR record format monthly to a file address (to be designated) at the CMS data center. See Attachment 4 for record layout and description.	X				X				CMS Data Center
3730.3.1	FISS shall make available a printable version of the report to a designated CMS staff person containing the following design and create a report containing the following information to a designated file address at the CMS data center (CMS/DC): a. dialysis provider number; b. beneficiary Medicare health insurance identification number with alphanumeric suffix; c. beneficiary name; d. date of service; e. bill type; and f. document control number.	X				X				

Requirement Number	Requirements	Responsibility ("X" indicates the columns that apply)								
		FI	RHHI	Carrier	DMERC	Shared System Maintainers				Other
						FISS	MCS	VMS	CWF	
3730.3.2	A CMS designated staff person shall access the Trial 49 CMS/DC file address to print out the report and shall review the report to ensure program integrity.									CMS staff person in ORDI
3730.4	FISS shall allow the maximum number of hemodialysis composite rates billed for a 30/31 day billing cycle to exceed the 13/14 limit when Trial 49 is populated in FL 63 on the 72X TOB. The limits allowed will be 17/18 for the 30/31 day billing cycle. Standard Medicare co-payments and deductibles will apply.	X				X				
3730.5	When Trial 49 is populated in FL 63 on the 72X TOB, FISS shall allow the maximum number of hemodialysis composite rates with Condition Code 73 present for training to be 30 over three 30/31 day billing cycles. Standard Medicare co-payments and deductibles will apply.	X				X				
3730.6	FISS shall transmit a special processing number 49 to CWF when Trial 49 is populated in FL 63.					X			X	

III. PROVIDER EDUCATION

Requirement Number	Requirements	Responsibility ("X" indicates the columns that apply)								
		FI	RHHI	Carrier	DMERC	Shared System Maintainers				Other
						FISS	MCS	VMS	CWF	
	None									

IV. SUPPORTING INFORMATION AND POSSIBLE DESIGN CONSIDERATIONS

A. Other Instructions: N/A

X-Ref Requirement #	Instructions

B. Design Considerations: N/A

X-Ref Requirement #	Recommendation for Medicare System Requirements

C. Interfaces: N/A

D. Contractor Financial Reporting /Workload Impact: N/A

E. Dependencies: N/A

F. Testing Considerations: N/A

V. SCHEDULE, CONTACTS, AND FUNDING

Effective Date*: June 1, 2005 **Implementation Date:** July 5, 2005 **Pre-Implementation Contact(s):** Penny Mohr e-mail: pmohr@cms.hhs.gov telephone: 410-786-6502 **Post-Implementation Contact(s):** Regional Offices	**No additional funding will be provided by CMS; Contractor activities are to be carried out within their FY 2005 operating budgets.**

***Unless otherwise specified, the effective date is the date of service.**

4 Attachments.

ATTACHMENT 1.

FREQUENT HEMODIALYSIS NETWORK (FHN)
NOCTURNAL HEMODIALYSIS ATTESTATION FORM

I hereby attest that the patients listed below have been enrolled in the Centers for Medicare and Medicaid Services (CMS) and National Institute of Diabetes and Digestive and Kidney Disorders (NIDDK) FHN clinical trial (Trial 49) in the nocturnal hemodialysis arm. I also attest these patients are Medicare-eligible and qualify for Medicare payments for their hemodialysis treatments. Their enrollment in the nocturnal hemodialysis arm of this trial qualifies them by reason of medical necessity for up to 4 hemodialysis composite rate payments per week for up to 14 months after enrollment (projected disenrollment date). In addition, these payments qualify for a maximum number of dialysis composite rates with Condition Code 73 present for training to be billed at 4 hemodialysis training session composite rates per week up to a maximum of 30 training session payments. I will include "Trial 49" on Form Locator 63 or the 837I equivalent on the 72X Type of Bill for hemodialysis services provided to the trial beneficiaries.

Patient name	HIC number	Enrollment date	Projected disenrollment date

_____
Chief executive officer

_____
Facility name

_____
CMS Provider ID

_____
Date

ATTACHMENT 2.

FREQUENT HEMODIALYSIS NETWORK (FHN)
DAILY IN-CENTER HEMODIALYSIS ATTESTATION FORM

I hereby attest that the patients listed below have been enrolled in the Centers for Medicare and Medicaid Services (CMS) and National Institute of Diabetes and Digestive and Kidney Disorders (NIDDK) FHN clinical trial (Trial 49) in the daily in-center hemodialysis arm. I also attest these patients are Medicare-eligible and qualify for Medicare payments for their hemodialysis treatments. Their enrollment in the more frequent dialysis arm of this trial qualifies them by reason of medical necessity for up to 4 hemodialysis composite rate payments per week for up to 12 months after enrollment (projected disenrollment date). I will include "Trial 49" on Form Locator 63 or the 837I equivalent on the 72X Type of Bill for dialysis services provided to the trial beneficiaries.

Patient name	HIC number	Enrollment date	Projected disenrollment date

_____
Chief executive officer

_____
Facility name

_____
CMS Provider ID

_____
Date

Attachment 3: PI's Centers, Core Centers, Participating Dialysis Units for the Frequent Hemodialysis Network			
Data through Monday, January 11, 2005 * Indicates location of MRI imaging sites			
Clinical Center Consortium Center #, name	Core Center Number	Participating Dialysis Unit Number and CMS Provider Number	
Center #1 RRI, Dr. Levin (DAILY)	Core Centers	Participating Dialysis Units	CMS Provider Number
	11: RRI New York City *5 MRI sites in NYC Martin Kuhlmann, M.D.	1101 Harlem Dialysis Center 1102 City Dialysis Center-Midtown Manhattan 1103 Nephrocare, Inc. 1104 Southern Manhattan Dialysis Center 1105 Mt. Sinai Dialysis Centers (Joseph Vassalotti) 1105 Mt. Sinai Dialysis Centers (Joseph Vassalotti) 1106 Queens Artificial Kidney Center 1107 Yorkville Dialysis Center	332564 332524 332534 332530 330024 333511 332517 333506
	12: London, Ontario Robert Lindsay, MD	1201 LHSC - WC (Westminster Campus) 1202 LHSC - SSC (South Street Campus) 1203 LHSC - UC (University Campus) 1204 LHSC - LS (London Satellite)	Canada N/A
	13 RRI CT Fredrick Finkelstein, MD	1301 Branford 1302 Milford 1303 St. Raphael	072522 072513 072512
	14 RRI Michigan Joseph Messana, MD	1401 Ann Arbor (Rajiv Saran) 1402 Livonia	232576 232577
	15 – RRI Rochester, Strong Health Dialysis Jeremy G. Taylor, MD	1501 Finger Lakes 1502 Highlands Living Center 1503 Clinton Crossing 1504 Strong Memorial Hospital 1505 Highlands SelfCare	332631 332630 332629 332626 332628
	16 RRI NC, Carolina Dialysis *1 MRI site at UNC Philip Klemmer, MD	1601 Carrboro 1602 Sanford	342622 342620
	17. RRI Wake Forest/Baptist Michael Rocco, MD	1701 - Wake Forest /Baptist	

Center #2, UCSF, Dr. Chertow (DAILY)			
	21: San Francisco, Marin, Sonoma, Contra Costa Glenn Chertow, MD *Will have all MRIs at UCSF Medical Center	2101 UCSF-Mt. Zion (adult) 2102 UCSF (pediatrics) 2103 San Francisco General 2104 CPMC Pacific 2105 CPMC Davis 2106 Kaiser San Francisco 2107 Davita Ocean Garden 2108 Davita Community (Haight) 2109 Davit Potrero Hill 2110 Gambro San Francisco 2111 Gambro Chinatown 2112 Satellite Larkspur 2113 Satellite Santa Rosa 2114 Davita Antioch 2115 Davita Walnut Creek 2116 FMC Santa Rosa 2117 FMC Ukiah 2118 FMC Antioch 2119 FMC Pittsburg 2120 FMC Pleasant Hill 2121 FMC Walnut Creek 2122 FMC Brentwood 2123 Gambro Daly City	
	22: Sacramento Tom Depner, MD	2201 DCI University 2202 DCI Southgate 2203 DCI Madison 2204 DCI Rancho Cordova	
	23: Peninsula, Satellite George Ting, MD *Will have all MRIs at UCSF Medical Center	2301 El Camino Hospital 2302 Satellite Redwood City 2303 Satellite Sunnyvale 2304 El Camino Rose Garden 2305 El Camino Evergreen 2306 Satellite San Jose (East) 2307 Satellite San Jose (South) 2308 Satellite San Jose (West) 2309 Satellite Santa Cruz 2310 Satellite Watsonville 2311 Satellite Gilroy 2312 Satellite Modesto 2313 Satellite Sonora 2314 Satellite Turlock 2315 Satellite Windsor	

	24: Los Angeles Allen Nissenson, MD UCLA Med Center (Adult) will be the site of all MRIs for this core.	2401 UCLA Medical Center (adult) 2402 UCLA Medical Center (pediatrics) 2403 UC Irvine Medical Center 2404 Davita North Hollywood 2405 Davita Van Nuys 2406 Davita Beverly Hills 2407 Davita Los Angeles 2408 Davita Encino 2409 USC Medical Center	
	25: San Diego Ravindra Mehta, MD UCSD Medical Centers (2501 and 2502) will be the site of all MRIs for this core	2501 UCSD Medical Center (adult) 2502 UCSD Medical Center (pediatrics) 2503 San Diego VA Medical Center 2504 Davita San Diego 2505 Davita Chula Vista 2506 Davita Oceanside 2507 Gambro Chula Vista 2508 Gambro Encintas 2509 Gambro La Jolla 2510 Gambro Escondido	
Center #3, Wake Forest, Dr. Michael Rocco, M.D. (Nocturnal)			
	31: Barnes-Jewish/Washington University	3101 Barnes-Jewish	262565
	32: Indiana University	3201 Indiana University	
	33 Kidney Associates KC	3301 DCI Kansas City	262517
	34: Lynchburg Nephrology	3401 Lynchburg Nephrology UVA Amherst Dialysis UVA Lynchburg Dialysis UVA Page Dialysis UVA Augusta Dialysis UVA Renal Services (hospital) UVA Renal Services (dialysis) UVA Orange Dialysis UVA Zions Crossroad Dialysis	 493512 493513 493511 493509 490009 492301 493507 493505
	35: Rogosin Institute	3501 Rogosin Institute	
	36: Rubin Dialysis *1 MRI site	3601 Clifton Park 3602 Saratoga Springs (Rubin Dialysis)	332632 332557
	37: U of Iowa	3701 University of Iowa	160058
	38: U of Toronto	3801 U of Toronto 3802 Humber River Regional Hospital	Canada NA
	39: U of Vancouver Vancouver General Hospital will be the site for all MRIs for this core	3901 SPH - Vancouver 3902 VGH - Vancouver 3903 Fraser - Royal Columbian 3904 Vancouver Island - Royal Jubilee	Canada NA

	40: U of W Ontario	4001 LHSC - WC (Westminster Campus) 4002 LHSC - SSC (South Street Campus) 4003 LHSC - UC (University Campus) 4004 LHSC - LS (London Satellite)	Canada NA
	41: Wake Forest University	4101 Piedmont Dialysis Center	342505

Attachment 4 – Trial 49 Claims Paid Report File Layout

	File Position	Format	Title	Description
1.	1-6	6 CHAR	Provider Number	The identification number of the institutional provider certified by Medicare to provide services to the beneficiary.
2.	7-17	11 CHAR	Health Insurance Code	Concatenated variable comprised of Beneficiary Claim Account Number and the NCH Category Equatable Beneficiary Identification Code
3.	18-23	6 CHAR	Claim Patient 6 POS Surname	The first 6 positions of the Medicare patient's surname (last name) as reported by the provider on the claim.
4.	24	1 CHAR	Claim Patient 1st Initial Given Name	The first initial of the Medicare patient's given name (first name) as reported by the provider on the claim.
5.	25	1 CHAR	Claim Patient 1st Initial Middle Name	The first initial of the Medicare patient's middle name as reported by the provider on the claim.
6.	26-33	8 NUM	Beneficiary Birth Date	The beneficiary's date of birth. EDIT RULES = YYYYMMDD
7.	34-41	8 NUM	Claim from Date	The first day on the billing statement covering services rendered to the beneficiary. EDIT RULES = YYYYMMDD
8.	42-49	8 NUM	Claim through Date	The last day on the billing statement covering services rendered to the beneficiary. EDIT RULES = YYYYMMDD
9.	50-51	2 NUM	Bill type	1 = Composite rate payment as identified by the Revenue Center Code 82X for outpatient hemodialysis for field location 42 in bill type 72X and condition code is not = 73 2 = Training session payment as identified by condition code 73 on bill type 72X
10.	52-56	5 NUM	Document control number	Sequential number of reports created for Trial 49 EDIT RULES = 1 - 99999