

CMS Manual System

Pub 100-20 One-Time Notification

Transmittal 206

Department of Health & Human Services (DHHS)

Centers for Medicare & Medicaid Services (CMS)

Date: FEBRUARY 1, 2006

Change Request 4138

SUBJECT: Modifications/Additions to CR 3730, Frequent Hemodialysis Network (FHN) Payments 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.

NEW/REVISED MATERIAL

EFFECTIVE DATE: February 1, 2006

IMPLEMENTATION DATE: March 3, 2006

Disclaimer for manual changes only: The revision date and transmittal number apply only to red italicized material. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.

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

R = REVISED, N = NEW, D = DELETED

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 2006 operating budgets.

IV. ATTACHMENTS:

One-Time Notification

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

Attachment – One-Time Notification

Pub. 100-20	Transmittal: 206	Date: February 1, 2006	Change Request 4138
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SUBJECT: Modifications/Additions to CR 3730, Frequent Hemodialysis Network (FHN) Payments 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)								
		F I	R H I	C a r r i e r	D M E R C	Shared System Maintainers				Other
						F I S S	M C S	V M S	C W F	
4138.1	The FIs shall collect attestation forms from provider demonstration sites for all beneficiaries qualified and enrolled in the ESRD Daily Trial. This requirement is the same	X							Provider Demonstration Sites	

III. PROVIDER EDUCATION

Requirement Number	Requirements	Responsibility (“X” indicates the columns that apply)								
		F I	R H I	C a r r i e r	D M E R C	Shared System Maintainers				Other
						F I S S	M C S	V M S	C W F	
4138.3	Contractors shall post this entire instruction, or a direct link to this instruction, on their Web site and include information about it in a listserv message within 1 week of the release of this instruction. In addition, the entire instruction must be included in your next regularly scheduled bulletin and incorporated into any educational events on this topic.	X								

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

<p>Effective Date*: February 1, 2006</p> <p>Implementation Date: March 3, 2006</p> <p>Pre-Implementation Contact(s): Brady Augustine e-mail: brady.augustine@cms.hhs.gov telephone: 410-786-5323</p> <p>Post-Implementation Contact(s): Regional Offices</p>	<p>No additional funding will be provided by CMS; Contractor activities are to be carried out within their FY 2006 operating budgets.</p>
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3 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 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 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 Friday, August 19, 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	
	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 South Queens Dialysis Center 1108 Yorkville Dialysis Center 1109 Place Dialysis Center 1110 Upper Manhattan Dialysis Center	332564 332524 332534 332530 330024 333511 332517 332531 333506 333524 333539
	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 Missouri Brent Miller, MD	1701 Chromalloy American Kidney Center	
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 Davita Potrero Hill 2110 Gambro San Francisco 2111 Gambro Chinatown 2112 Satellite Larkspur 2113 Satellite Santa Rosa 2114 Davita Antioch 2115 Davita Walnut Creek 2123 Gambro Daly City	053523 053501 052813 050047 050008 050076 052728 052507 052775 052719 052769 052526 052630 052841 052689 052546
	22: Sacramento Tom Depner, MD	2201 DCI University 2202 DCI Southgate 2203 DCI Madison 2204 DCI Rancho Cordova	052676 052711 052796 052774
	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	050308 052793 052870 053520 053514 052572 052600 052514 052555 052629 052751 052531 052609 052647 052887

	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 Hollywood 2405 Davita Valley Dialysis 2406 Davita Beverly Hills 2407 Davita Los Angeles 2408 South Valley Regional 2409 USC Medical Center	052865 052865 052589 052801 052554 052599 052695 052744 052794
	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 Mission Dialysis 2505 Davita Chula Vista 2506 Davita Oceanside 2507 Gambro Chula Vista 2508 Gambro Encintas 2510 Gambro Escondido	052818 052818 05114F 052779 052835 052834 052731 052756 052525
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	153510
	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
	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 4102 Salem Dialysis 4103 Northside Dialysis	342505 On hold On hold