

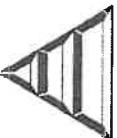
DEPARTMENT OF HEALTH AND HUMAN SERVICES  
OFFICE OF DIRECTOR

ACTION REFERRAL

TO <i>Hess</i>	DATE  <i>4-27-12</i>
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DIRECTOR'S USE ONLY	ACTION REQUESTED
1. LOG NUMBER  <div style="text-align: center; font-size: 1.2em;"><i>00416</i></div>	<input type="checkbox"/> Prepare reply for the Director's signature DATE DUE _____
2. DATE SIGNED BY DIRECTOR  <div style="text-align: center;"> <i>*Check # 0006211729 Enclosed for \$2,811.36</i>  </div>	<input type="checkbox"/> Prepare reply for appropriate signature DATE DUE _____  <input type="checkbox"/> FOIA DATE DUE _____  <input checked="" type="checkbox"/> Necessary Action

APPROVALS <small>(Only when prepared for director's signature)</small>	APPROVE	* DISAPPROVE <small>(Note reason for disapproval and return to preparer.)</small>	COMMENT
1.			
2.			
3.			
4.			



## Fresenius Medical Care

April 23, 2012

Mr. Bill Prince, Medicaid Director  
Department of Health and Human Services  
P.O. Box 8206  
Columbia, SC 29202-8206

Re: Hemoglobin A1c laboratory testing  
Fresenius Medical Care North America (FMCNA)

Dear Mr. Prince:

The purpose of this letter is to provide you with information on payments received by FMCNA related to Hemoglobin A1c testing.

The management of diabetes mellitus requires regular determinations of blood glucose levels. Hemoglobin A1C or glycated hemoglobin/protein testing is an appropriate test for monitoring a patient for management and control of diabetes and to assess hyperglycemia, a history of hyperglycemia or dangerous hypoglycemia. Measurement may be necessary every 3 months. More frequent assessments may be appropriate in the patient whose care has been altered to improve control or in whom evidence is present that intercurrent events may have altered a previously satisfactory level of control (for example, post-major surgery or as a result of glucocorticoid therapy). A review of our Hemoglobin A1c testing has determined that in some instances, testing occurred at frequencies greater than recommended and in some instances resulted in overpayments.

We have developed an audit protocol (attached as Exhibit A) to determine overpayments relating to this issue. We have completed our review for calendar years 2007 to 2010 and repayment for this time frame is attached. We used the results from a random sample of claims to extrapolate an overall repayment obligation due to your program. The check included with this correspondence is due to your organization to cover estimated overpayments for services furnished to members of your program

**Fresenius Medical Care North America**

Corporate Headquarters: 920 Winter Street Waltham, MA 02451-1457


(781) 699-9000

In these instances, we are unable to directly refund the payments through the normal channels since specific beneficiary names, dates of service, and insurance plan are not available. For these audits, we provide an explanation of the audit, and repay the funds by check. A list of FMCNA providers in your state is enclosed (attached as Exhibit B).

FMCNA is reviewing our policies and procedures relating to Hemoglobin A1c testing. In addition we will include in our annual compliance audit program a review of Hemoglobin A1c testing for the next two years to ensure that any applicable preventive measures are being properly implemented. We expect to complete our review of 2011 by May 31, 2012.

Should you have any specific questions, please contact Karen Lopes, Director FMS Operations Monitoring at 781-699-4092. In addition, (1) FMCNA is not waiving attorney-client privilege, or any other potential privilege, by providing this information; and (2) this document and its attachments, if any, contain trade secrets and/or confidential commercial and financial information subject to exemption b(4) of the Freedom of Information Act.

Sincerely,

A handwritten signature in black ink, appearing to read "C. Dubinsky", written in a cursive style.

Catherine Dubinsky  
Vice President, FMS Operations Integrity  
Fresenius Medical Care – North America

Enclosure

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**Fresenius Medical Care North America**

Corporate Headquarters: 920 Winter Street Waltham, MA 02451-1457 (781) 699-9000

FMCNA Facility Name	Address 1	Address 2	City	ST	Medicaid Provider #	TAX ID#
FRESENIUS MEDICAL CARE CHESTER COUNTY	501 HEALTHWAY DRIVE		CHESTER	SC	42-5187 - SC	04-2944532
FMC DIALYSIS SERVICES LOW COUNTRY DIALYSIS	10 JOHNNY MORRALL CIRCLE	TWO PROFESSIONAL DRIVE	PORT ROYAL	SC	42-5141 - SC	04-2944532
FRESENIUS MEDICAL CARE GEORGETOWN	712 NORTH FRASER STREET		GEORGETOWN	SC	42-5196 - SC	04-2944532
FRESENIUS MEDICAL CARE BENNETTSTVILLE	1104 FRANK EVANS WAY		BENNETTSTVILLE	SC	42-2520 - SC	04-2944532
DARLINGTON DIALYSIS CENTER	103 SALEEBY LOOP		DARLINGTON	SC	42-5301 - SC	04-2944532
FRESENIUS MEDICAL CARE DILLON	1304 HIGHWAY 301 SOUTH		DILLON	SC	42-5329 - SC	04-2944532
FRESENIUS MEDICAL CARE KINGSTREE	215 N. BROOKS STREET		KINGSTREE	SC	42-5212 - SC	04-2944532
FRESENIUS MEDICAL CARE MARION	109 MERRITT COURT		MARION	SC	42-5454 - SC	04-2944532
FRESENIUS MEDICAL CARE FORT MILL	535 RIVER CROSSING DRIVE		FORT MILL	SC	425382 - SC	04-2944532
FRESENIUS MEDICAL CARE SUMTER	615 WEST WESMARK BLVD.		SUMTER	SC	42-5105 - SC	04-2944532
FRESENIUS MEDICAL CARE MANNING	3107 SUMTER HIGHWAY		MANNING	SC	42-5374 - SC	04-2944532
CONWAY DIALYSIS CENTER	838 FARRAR DRIVE		CONWAY	SC	42-5427 - SC	04-2944532
LORIS DIALYSIS CENTER	3827 BELL STREET		LORIS	SC	42-5356 - SC	04-2944532
FMC DIALYSIS SERVICES THE MARSHLANDS	28 RICE POND ROAD-RIVERWALK	ROUTE 1, BOX 615	RIDGELAND	SC	42-5703 - SC	04-2944532
FMC DIALYSIS SERVICES MURRELLS INLET	5011 HIGHWAY 17 BYPASS		MURRELLS INLET	SC	42-5712 - SC	04-2944532
FRESENIUS MEDICAL CARE FLORENCE DIALYSIS CENTER	435 NORTH CASHUA DRIVE		FLORENCE	SC	42-2505 - SC	04-2944532
FMC DIALYSIS SERVICES LAKE MARION	20 BUFF BOULEVARD		SUMMERTON	SC	42-5730 - SC	04-2944532
FMC DIALYSIS SERVICES PEE DEE DIALYSIS CENTER	331 ELIZABETH ANN COURT		LAKE CITY	SC	42-2576 - SC	04-2944532
FMC DIALYSIS SERVICES NORTH MYRTLE BEACH	710-A HIGHWAY 17 SOUTH		NORTH MYRTLE BEACH	SC	42-5696 - SC	04-2944532
FMC DIALYSIS SERVICES ANDREWS	102 COUNTY LINE ROAD		ANDREWS	SC	ERD115 - SC	04-2944532
FRESENIUS MEDICAL CARE LEE COUNTY	289 FAIRVIEW AVENUE		BISHOPVILLE	SC	42-5669 - SC	04-2944532
FMC-FREEDOM DIALYSIS CENTER	1520 FREEDOM BLVD.		FLORENCE	SC	42-5749 - SC	04-2944532
FMC DIALYSIS SERVICES OF HARTSVILLE	1308 SOUTH FOURTH STREET		HARTSVILLE	SC	422586 - SC	04-2944532
ANDERSON DIALYSIS CLINIC	416 EAST CALHOUN STREET	SUITE A	ANDERSON	SC	422506 - SC	04-2944532
OONEE DIALYSIS CENTER	685 S. OAK STREET		SENECA	SC	425365 - SC	04-2944532
FRESENIUS MEDICAL CARE ROCK HILL	1560 HEALTHCARE DRIVE		ROCK HILL	SC	422589 - SC	04-2944532
FMC HILTON HEAD DIALYSIS CENTER	25 HOSPITAL CENTER BOULEVARD	SUITE 108, HOSPITAL MEDICAL PAVILION	HILTON HEAD ISLAND	SC	42-5481 - SC	04-2944532
FMC SERVICES OF BELTON-HONEA PATH	200 CHURCH STREET		HONEA PATH	SC	422600 - SC	04-2944532
FMC OF PENDLETON	908 SOUTH MECHANIC STREET		PENDLETON	SC	ERD145 - SC	04-2944532
FRESENIUS MEDICAL CARE YORK	1440 ALEXANDER LOVE HWY		YORK	SC	422613 - SC	04-2944532

FMCNA Facility Name	Address 1	Address 2	City	ST	Medicaid Provider #	TAX ID#
RCG GREENVILLE	605 S. ACADEMY STREET		GREENVILLE	SC	42-5674 - SC	62-1555316
RCG PALMETTO	317 PROFESSIONAL PARK ROAD		CLINTON	SC	ERD126 - SC	62-1555316
RCG SIMPSONVILLE	16 POWDERHORN ROAD		SIMPSONVILLE	SC	ERD127 - SC	62-1555316
RCG GREER	3254 BRUSHY CREEK ROAD		GREER	SC	ERD162 - SC	62-1555316
FRESENIUS MEDICAL CARE CHERAW	104 GRACE LANE		CHERAW	SC	CCN42-2614 - SC	04-2944532
FRESENIUS MEDICAL CARE JOHNSONVILLE	200 STUCKEY STREET		JOHNSONVILLE	SC	ERD180 - SC	04-2944532
FRESENIUS MEDICAL CARE CHURCH STREET	406 SOUTH CHURCH STREET		FLORENCE	SC	ERD178 - SC	04-2944532
FRESENIUS MEDICAL CARE WEST CONWAY	1702 MILLPOND ROAD		CONWAY	SC	ERD182 - SC	04-2944532
FRESENIUS MEDICAL CARE FORT LAWN	5707 WILLOWBROOK STREET		FORT LAWN	SC	422621 - SC	04-2944532
FRESENIUS MEDICAL CARE MYRTLE BEACH	4592 OLEANDER DRIVE		MYRTLE BEACH	SC	REG0017 - SC	04-2944532
FRESENIUS MEDICAL CARE CAMDEN	7 HAILE LANE		CAMDEN	SC	42-2582 - SC	26-2270347
FRESENIUS MEDICAL CARE COLUMBIA	2125 ADAMS GROVE RD.		COLUMBIA	SC	42-5043 - SC	26-2270347
FRESENIUS MEDICAL CARE SOUTH COLUMBIA	2139 ADAMS GROVE RD.		COLUMBIA	SC	42-5436 - SC	26-2270347
FRESENIUS MEDICAL CARE LOWER RICHLAND	1840 PINEVIEW DR.		COLUMBIA	SC	42-5841 - SC	26-2270347
FRESENIUS MEDICAL CARE IRMO	1012 LYKES LANE		IRMO	SC	ERD117 - SC	26-2270347
FRESENIUS MEDICAL CARE LUGOFF-ELGIN	909 CAROLINA DR.		LUGOFF	SC	ERD158 - SC	26-2270347
FRESENIUS MEDICAL CARE LEXINGTON	131 WHISPERING WINDS DR.		LEXINGTON	SC	42-5721 - SC	26-2270347
FRESENIUS MEDICAL CARE NEWBERRY	2041 MEDICAL PARK DR.		NEWBERRY	SC	42-5310 - SC	26-2270347
FRESENIUS MEDICAL CARE MIDTOWN	1301 TAYLOR ST., STE 4-M		COLUMBIA	SC	42-5463 - SC	26-2270347
FRESENIUS MEDICAL CARE WEST COLUMBIA	105 SUM MOR DR.		WEST COLUMBIA	SC	42-5503 - SC	26-2270347
FRESENIUS MEDICAL CARE MEADOWLAKE	7631 WILSON BLVD.		COLUMBIA	SC	RE0005 - SC	26-2270347
FRESENIUS MEDICAL CARE FAIRFIELD COUNTY	1126 US HWY 321 BUS S.	SUITE A	WINNSBORO	SC	ERD114 - SC	26-2270347
FRESENIUS MEDICAL CARE BATESBURG - LEESVILLE	303 VILLAGE SQUARE DR.		LEESVILLE	SC	ERD161 - SC	26-2270347
FRESENIUS MEDICAL CARE WINYAH	2623 SOUTH FRASER STREET		GEORGETOWN	SC	REG0018 - SC	04-2944532
FRESENIUS MEDICAL CARE CNA KIDNEY CENTERS, LLC	121 PARK CENTRAL DR.	SUITE 101	COLUMBIA	SC	PENDING - SC	26-2270347
SPECTRA LABORATORIES			Rockleigh NJ / Milpitas CA		L00107 / 041200	043455945 / 942825915

Inc.

**Fresenius Medical Care**

DATE \_\_\_\_\_

CHECK NO.

03/29/2012

000621172

NOT VALID AFTER 90 DAYS

NOT VALID AFTER 60 DAYS

**PAY**

Two thousand eight hundred eleven and 36/100 Dollars

TO  
THE  
ORDER  
OF

DEPT OF HEALTH & HUMAN SERVICES  
PO Box 8206  
COLUMBIA SC 29202-8206

Wells Fargo Bank, N.A.

110006211729

1:0531015611

20799011-53



**VENDOR NO.# 190986**

**PLEASE DETACH BEFORE DEPOSITING**

PAGE 1 OF 1

0006211729

INVOICE#	INVOICE DATE	DESCRIPTION	GROSS AMOUNT	DISCOUNT AMT	NET AMOUNT
HGB AIC	03/20/2012	HGB AIC AUDIT ALL 2007-2010	2,811.36	0.00	2,811.36
TOTALS			\$2,811.36		\$2,811.36

**BACKGROUND**

The management of diabetes mellitus requires regular determinations of blood glucose levels. Hemoglobin A1c (HgbA1c) is an appropriate test for monitoring a patient. Measurement may be medically necessary every three months. More frequent assessment may be appropriate in the patient whose care has been altered to improve control or in whom evidence is present that intercurrent events may have altered a previously satisfactory level of control (for example, post-major surgery or as a result of glucocorticoid therapy).

**DATA CAPTURED**

The years covered are 2007 through 2010. Identify all patients by year having at least one HBG A1c test resulted in said calendar year. Ascertain if the identified patients have a diabetic co-morbid in the medical records. The following Universes by year will be obtained from "Custom Reporting and Data Analysis":

- Universe A: Patient has at least one resulted Hgb A1c.
- Universe B: Unique patients with a Diabetes Co-morbid.
- Universe C: Patients active for 12 months.
  - C1: Patients  $\leq 4$  tests
  - C2: Patients with 5 or 6 tests
  - C3: Patients  $> 6$  tests
- Universe D: Patients active for  $< 12$  months.
  - D1: Patients  $\leq 4$  tests
  - D2: Patients with 5 or 6 tests
  - D3: Patients  $> 6$  tests
- Universe E: Unique patients with no diabetes co-morbid.
- Universe F: Patients active for 12 months.
  - F1: Patients  $\leq 4$  tests
  - F2: Patients with 5 or 6 tests
  - F3: Patients  $> 6$  tests
- Universe G: Patients active for  $< 12$  months.
  - G1: Patients  $\leq 4$  tests
  - G2: Patients with 5 or 6 tests
  - G3: Patients  $> 6$  tests

Additional Universes will be created based upon the number of Hgb A1c performed in a calendar year. Once all Universes have been determined for testing, each Universe identified as "to be tested" will be further stratified into:

- Veterans Administration (VA). Both Spectra and FMS facilities may have billed for the same lab services. Spectra refunded all monies received from the VA under a separate audit.
- Medicare patients serviced by Spectra East (Rockleigh). Medicare has edits in their system to identify Hgb A1c tests performed more frequently than every 90 days.
- Spectra West Government payors and Spectra East Government payors minus Medicare patients.
- Commercial/Other payors.

## AUDIT METHODOLOGY

For universes identified with patients having a diabetes co-morbid diagnosis (Universes C and D), split into the following Universes: Veterans Administration Patients; Spectra East Medicare Patients; Spectra West Government/Spectra East Non-Medicare Government Patients; and Commercial/Other Patients. (NOTE: For Veterans Administration Patients, combine all patients found in Universes C and D and test as one Universe using the criteria outlined below.) Randomly select 30 samples for each Universe and perform the following analysis:

- UNIV C1: (Patients with a diabetic co-morbid with  $\leq 4$  tests and active 12 months)
  - Ascertain the tests performed are not done more frequently than every 90 days. Any test not meeting the above criteria would be an error unless additional documentation is available to support more frequent assessments (every 1-2 months). For example:
    - Questionable HGB A1c results (MD requested repeat analysis).
    - A patient whose diabetes regimen has been altered to improve control.
    - A patient in who evidence is present that intercurrent events may have altered a previously satisfactory level of control (for example post major surgery).
    - A pregnant woman.
- UNIV C2: (Patients with a diabetic co-morbid with 5 or 6 tests and active 12 months)
  - Ascertain the tests performed are not done more frequently than every three months. Exceptions are the same as C1.
- UNIV C3: (Patients with a diabetic co-morbid with  $> 6$  tests and active 12 months)
  - Further stratify UNIV C3 into UNIV C4 (7 – 13 tests) and UNIV C5 ( $>13$  tests). For each universe, ascertain the tests performed are not done more frequently than every three months. Exceptions are the same as C1.
- UNIV D1: (Patients with a diabetic co-morbid with  $\leq 4$  tests and active less than 12 months)
  - Ascertain the tests performed are not done more frequently than every three months. Exceptions are the same as C1.
- UNIV D2: (Patients with a diabetic co-morbid with 5 or 6 tests and active less than 12 months)
  - Ascertain the tests performed are not done more frequently than every three months. Exceptions are the same as C1.
- UNIV D3: (Patients with a diabetic co-morbid with  $> 6$  tests and active less than 12 months)
  - Further stratify UNIV D3 into UNIV D4 (7 – 13 tests) and UNIV D5 ( $>13$  tests). For each universe, ascertain the tests performed are not done more frequently than every three months. Exceptions are the same as C1.



## HGB A1c AUDIT PLAN

Exhibit A

For universes identified with patients **not** having a diabetes co-morbid diagnosis (Universes F and G) in the clinical information system record, split into the following Universes: Veterans Administration Patients; Spectra East Medicare Patients; Spectra West Government/Spectra East Non-Medicare Government Patients; and Commercial/Other Patients. (NOTE: For Veterans Administration Patients, combine all patients found in Universes F and G and test as one Universe using the criteria outlined below.) Randomly select 30 samples for each Universe and perform the following analysis:

1. If patient is a diabetic, perform the following analysis:
  - UNIV F1: (Patients with  $\leq 4$  tests and active 12 months)
    - Ascertain the tests performed are not done more frequently than every three months. Any test not meeting the above criteria would be an error unless additional documentation is available to support more frequent assessments (every 1-2 months). For example:
      - Questionable HGB A1c results.
      - A patient whose diabetes regimen has been altered to improve control
      - A patient in who evidence is present that intercurrent events may have altered a previously satisfactory level of control (for example post major surgery).
      - A pregnant woman.
  - UNIV F2: (Patients with 5 or 6 tests and active 12 months)
    - Ascertain the tests performed are not done more frequently than every three months. Exceptions are the same as F1.
  - UNIV F3: (Patients with  $> 6$  tests and active 12 months)
    - Further stratify UNIV F3 into UNIV F4 (7 – 13 tests) and UNIV F5 ( $>13$  tests). For each universe, ascertain the tests performed are not done more frequently than every three months. Exceptions are the same as F1.
  - UNIV G1: (Patients with  $\leq 4$  tests and active less than 12 months)
    - Ascertain the tests performed are not done more frequently than every three months. Exceptions are the same as F1.
  - UNIV G2: (Patients with 5 or 6 tests and active less than 12 months)
    - Ascertain the tests performed are not done more frequently than every three months. Exceptions are the same as F1.
  - UNIV G3: (Patients with  $> 6$  tests and active less than 12 months)
    - Further stratify UNIV G3 into UNIV G4 (7 – 13 tests) and UNIV G5 ( $>13$  tests). For each universe, ascertain the tests performed are not done more frequently than every three months. Exceptions are the same as F1.

HGB A1c  
AUDIT PLAN

Exhibit A

2. If the patient is not a diabetic, ascertain the presence of an extraordinary clinical condition/event or a glucose test result of  $> 125$ , along with a physician order. If these criteria exist, the occasional HgbA1c (1 or 2 per year), is accepted as appropriate. One of these criteria must exist for each HgbA1c test performed on a non-diabetic patient. If no such criteria, said test was performed in error. Use these standards for all patients selected for review under universes F and G.

**REPAYMENT CALCULATIONS**

From billing data, determine any applicable repayment based on payments received and extrapolate results for each universe.