

DEPARTMENT OF HEALTH AND HUMAN SERVICES  
OFFICE OF DIRECTOR

ACTION REFERRAL

TO <i>Wells</i>	DATE <i>1-6-11</i>
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DIRECTOR'S USE ONLY	ACTION REQUESTED
1. LOG NUMBER  <i>1011296</i>	<input type="checkbox"/> Prepare reply for the Director's signature DATE DUE _____
2. DATE SIGNED BY DIRECTOR  <i>Check # 00057194487 for \$4,546.96 enclosed.</i>	<input type="checkbox"/> Prepare reply for appropriate signature DATE DUE _____
	<input type="checkbox"/> FOIA DATE DUE _____
	<input checked="" type="checkbox"/> Necessary Action

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



**RECEIVED**

JAN 06 2011

Department of Health & Human Services  
OFFICE OF THE DIRECTOR

January 3, 2011

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

Re: Overpayment relating to Activase in FMCNA Dialysis Facilities

To Whom It May Concern:

The purpose of this letter is to provide you with an update to the issue described in our letter of December 15, 2010 (attached as Exhibit A) regarding information of overpayments received by Fresenius Medical Care North America (FMCNA) dialysis facilities relating to the facilities' administration of the drug Activase.

Activase is a tissue plasminogen activator produced by recombinant DNA technology, and is used in the dialysis setting.

A process review of our dialysis facility Activase billings has found two error types that have resulted in overpayments.

1. Keystroke errors. In some instances, data entry keystroke errors have resulted in claim and payment errors. The normal dose of Activase is 2 mg. and we have discovered instances where keystroke errors have resulted in billings inconsistent with this dose size. As a result, we have received overpayments because of these keystroke errors.
2. Dose Administered/Dose billed errors. In the dialysis facility setting, Activase is furnished as a powder, which must be reconstituted with 2.2ml of sterile water for injection to a final concentration of 1mg. /ml. We have found two billing errors associated with the use of this vial size.

First, we have found that in some instances staff is able to obtain and utilize more than 2ml from the vial. The nurse properly enters into the medical record the actual amount administered.

However, because the CPT procedure code for Activase is in 2mg. increments, when the staff member utilizes more than 2mg. of Activase (for example 2.1 mg.) and enters that amount into the medical record, the procedure code crosswalk in our billing system rounds up the dose to the next billable increment of drug (in this instance, 4mg.) and bills that amount. Since the proper billing increment is the 2mg. vial actually used, we have received overpayments in instances where 4mg. was billed.

**Fresenius Medical Care North America**

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

Second, we have found that in some instances the physician instructs the staff to insert additional saline into the access after the administration of Activase. We have found that our billing system bills according to the volume of both Activase and saline administered, rather than only the 2mg. of Activase administered.

We have developed an audit protocol (attached as Exhibit B) to determine overpayments relating to these two issues. We have completed our review for calendar years 2002-2008, and repayment for this timeframe for two of our three billing systems is attached. We expect to complete the review of all three billing systems, including calendar year 2010, by March 31, 2011.

We are implementing modifications to our billing systems to ensure that these types of errors do not occur in the future. In addition, we are reviewing our policies and procedures relating to the administration of Activase to determine whether additional process changes would prevent future errors. Next, when the policy/procedure review is completed, we will develop and implement an in-service to provide staff with the new policies and procedures. Finally, we will include in our annual compliance audit program a review of Activase billings for the next two years to ensure that these preventive measures are being properly implemented.

When the audit and policy modifications are completed, we will provide you with information relating to the full overpayment amount, the policies and procedures modified, the training program implemented, and the ongoing compliance audit to ensure the modifications are effective.

Should you have any specific questions, please contact me directly. 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,



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



## Fresenius Medical Care

December 15, 2010

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

Re: Overpayment relating to Activase in FMCNA Dialysis Facilities

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A process review of our dialysis facility Activase billings has found two error types that have resulted in overpayments.

1. Keystroke errors. In some instances, data entry keystroke errors have resulted in claim and payment errors. The normal dose of Activase is 2 mg. and we have discovered instances where keystroke errors have resulted in billings inconsistent with this dose size. As a result, we have received overpayments because of these keystroke errors.
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We have developed an audit protocol (attached) to determine overpayments relating to these two issues. We have completed our review for calendar 2009, and repayment for 2009 for two of our three billing systems is attached. We are continuing our review, which will include the years from 2002 through the present. We expect to complete the review of all years and all three billing systems by December 31, 2010.

We are implementing modifications to our billing systems to ensure that these types of errors do not occur in the future. In addition, we are reviewing our policies and procedures relating to the administration of Activase to determine whether additional process changes would prevent future errors. Next, when the policy/procedure review is completed, we will develop and implement an in-service to provide staff with the new policies and procedures. Finally, we will include in our annual compliance audit program a review of Activase billings for the next two years to ensure that these preventive measures are being properly implemented.

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(781) 699-9000

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Sincerely,



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

Enclosure

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## Fresenius Medical Care

### CATHFLO ACTIVASE AUDIT WORK PLAN

#### **BACKGROUND:**

Cathflo™ Activase® (Activase) is used to restore patency in a central venous dialysis catheter in order to provide sufficient blood flow to achieve the prescribed dialysis prescription.

#### **DATA CAPTURED:**

Obtain from the Knowledge Center administrations of Activase from May 1, 2002 to December 31, 2009. Summarize data by calendar year. Calendar year 2010 will be audited in 2011.

#### **UNIVERSES DEVELOPED:**

The minimum billable dose for Activase is 2 mg, one vial. Any dose entered greater than 2 mg will result in the billing of two or more vials. No single catheter limb administration should exceed 2 mg's, per FMS Policy. From UNIVERSE A, identify all single catheter limb administrations that exceed 2 mg's. This is identified as a dose between 2.1 to 2.9 mg and over 4 mg. All other doses are considered either a single or double catheter limb administration and would not result in an incorrect vial use billing. This audit will exclude calendar year 2005, as this year was previously audited by FMCNA Office of Ethics and Compliance. UNIVERSE B (2002-2004; 2006-2009). Convert Universe B from one administration per line to multiple administrations per day by unique patient. This will allow for the testing of all administrations on the same day for a unique patient. Draw sample of 30 for Universe B.

#### **UNIVERSE TO BE AUDITED FOR EXTRAPOLATION:**

**UNIVERSE B:** Improper dosage entered per catheter limb, all insurers.



## Fresenius Medical Care

### SAMPLING METHODOLOGY:

For the Universe, for each year, select 30 lines for review. A line represents administrations for a specific date. Review only the line (administrations) randomly selected to determine if more than one vial was billed for a single catheter limb administration.

### SAMPLING DETAIL BY YEAR

YEAR	UNIVERSE B
2009	X
2008	X
2007	X
2006	X
2005	-
2004	X
2003	X
2002	X

### DOCUMENTATION REVIEW:

The documentation requested from the field will be the hemodialysis treatment sheet.

### REPAYMENT CALCULATION:

1. Review information from the facilities to determine whether a billing error occurred.
2. Obtain financial data to review charges and payments.
3. Extrapolate results.
4. Determine methodology for repayment.
5. Determine what follow up is necessary including education/training.





**Fresenius Medical Care**

Fresenius Management Services, Inc.

920 Winter St.

(800) 662-1237

Waltham, MA 02451-1457

DATE

12/29/2010

CHECK NO.

0005719427

66-158  
531

NET AMOUNT

PAY \*\*\*\*\*4,546.96\*

NOT VALID AFTER 90 DAYS

PAY

Four thousand five hundred forty six and 96/100 Dollars

TO  
THE  
ORDER  
OF

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

Wachovia Bank, N.A.  
of North Carolina  
Chapel Hill, North Carolina 27514

*Michael Brennan*

⑈0005719427⑈ ⑆053101561⑆ 2079900011555⑈

VENDOR NO. # 190986

PLEASE DETACH BEFORE DEPOSITING

PAGE 1 OF 1

0005719427

INVOICE#	INVOICE DATE	DESCRIPTION	GROSS AMOUNT	DISCOUNT AMT	NET AMOUNT
ACTIVASE-PROTON	12/22/2010	ACTIVASE AUDIT-2002-2008 PROTON	4,546.96	0.00	4,546.96
TOTALS			\$4,546.96		\$4,546.96