



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Inspector General

Office of Audit Services, Region V  
233 North Michigan Avenue  
Suite 1360  
Chicago, IL 60601

October 7, 2011

Report Number: A-05-11-00027

Chris Roberson  
Director of Compliance and Community Programs  
Indiana Hemophilia and Thrombosis Center, Inc.  
8402 Harcourt Road, Suite 500  
Indianapolis, IN 46260

Dear Mr. Roberson:

Enclosed is the U.S. Department of Health and Human Services (HHS), Office of Inspector General (OIG), final report entitled *Review of Medicare Payments for NovoSeven Coagulation Factor VIIa to Indiana Hemophilia and Thrombosis Center, Inc. From January 1, 2008, Through December 31, 2009*. We will forward a copy of this report to the HHS action official noted on the following page for review and any action deemed necessary.

The HHS action official will make final determination as to actions taken on all matters reported. We request that you respond to this official within 30 days from the date of this letter. Your response should present any comments or additional information that you believe may have a bearing on the final determination.

Section 8L of the Inspector General Act, 5 U.S.C. App., requires that OIG post its publicly available reports on the OIG Web site. Accordingly, this report will be posted at <http://oig.hhs.gov>.

If you have any questions or comments about this report, please do not hesitate to call me, or contact Dave Markulin, Audit Manager, at (312) 353-1644 or through email at [David.Markulin@oig.hhs.gov](mailto:David.Markulin@oig.hhs.gov). Please refer to report number A-05-11-00027 in all correspondence.

Sincerely,

/Sheri L. Fulcher/  
Regional Inspector General  
for Audit Services

Enclosure

**Direct Reply to HHS Action Official:**

Nanette Foster Reilly  
Consortium Administrator  
Consortium for Financial Management and Fee for Service Operations  
Centers for Medicare & Medicaid Services  
601 East 12<sup>th</sup> Street, Room 235  
Kansas City, Missouri 64106

Department of Health and Human Services

**OFFICE OF  
INSPECTOR GENERAL**

**REVIEW OF MEDICARE PAYMENTS  
FOR NOVOSEVEN COAGULATION  
FACTOR VIIA TO INDIANA  
HEMOPHILIA AND THROMBOSIS  
CENTER, INC.  
FROM JANUARY 1, 2008, THROUGH  
DECEMBER 31, 2009**



Daniel R. Levinson  
Inspector General

October 2011  
A-05-11-00027

# ***Office of Inspector General***

<http://oig.hhs.gov>

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# *Notices*

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Section 8L of the Inspector General Act, 5 U.S.C. App., requires that OIG post its publicly available reports on the OIG Web site.

## **OFFICE OF AUDIT SERVICES FINDINGS AND OPINIONS**

The designation of financial or management practices as questionable, a recommendation for the disallowance of costs incurred or claimed, and any other conclusions and recommendations in this report represent the findings and opinions of OAS. Authorized officials of the HHS operating divisions will make final determination on these matters.

## **EXECUTIVE SUMMARY**

### **BACKGROUND**

Pursuant to Title XVIII of the Social Security Act (the Act), the Medicare program provides health insurance for people age 65 and over and those who are disabled or have permanent kidney disease. The Centers for Medicare & Medicaid Services, which administers the program, contracts with Medicare contractors to process and pay Medicare Part B claims submitted by providers for outpatient services. Medicare Part B helps cover medically-necessary services, such as doctors' services, outpatient care, and certain drugs.

NovoSeven (Coagulation Factor VIIa Recombinant) is a drug used to treat people suffering from blood clotting disorders. Section 1861(s)(2)(I) of the Act provides Medicare coverage of blood clotting factors, such as NovoSeven, for hemophilia patients competent enough to use such factors to control bleeding without medical supervision.

Indiana Hemophilia and Thrombosis Center, Inc. (the Center) is the only federally recognized comprehensive hemophilia treatment center in the state of Indiana. The Center, located in Indianapolis, Indiana, provides healthcare and pharmacy services to patients with bleeding and clotting disorders. A NovoSeven dispensation may consist of various dosages of the drug, which are distributed to a patient for home use or administered at the Center. For calendar years (CY) 2008 and 2009, National Government Services, the Medicare Part B carrier for Indiana, processed and paid the Center's Medicare Part B claims.

We reviewed 171 NovoSeven dispensations made to six beneficiaries, with payments totaling \$46,783,961, that account for all Medicare Part B payments to the Center for NovoSeven dispensed during CYs 2008 and 2009.

### **OBJECTIVE**

Our objective was to determine whether the Medicare Part B payments made to the Center for NovoSeven dispensed during CYs 2008 and 2009, were allowable.

### **SUMMARY OF FINDINGS**

Of the 171 dispensations paid by Medicare Part B to the Center for NovoSeven dispensed during CYs 2008 and 2009, payments for 169 were allowable. For the unallowable payments for one dispensation, the Center claimed Medicare payments for double the amount of units actually dispensed. For the unallowable payments for the second dispensation, the Center received duplicate payments. As a result, the Center received net overpayments totaling \$434,935, which the Center had not refunded to Medicare by the beginning of our audit.

The overpayments occurred because the Center did not have policies and procedures in place to ensure the correct number of units dispensed were claimed for payment and to ensure Medicare payments for drug dispensations were appropriate, based on claimed amounts.

## **RECOMMENDATIONS**

We recommend that the Center:

- ensure the \$434,935 of overpayments has been refunded to Medicare,
- establish policies and procedures to ensure that the correct number of units for drug dispensations are claimed, and
- establish policies and procedures to ensure that Medicare payments for drug dispensations are appropriate based on claimed amounts.

## **INDIANA HEMOPHILIA AND THROMBOSIS CENTER, INC. COMMENTS**

In written comments on our draft report, the Center concurred with our recommendations. The Center stated that it has ensured and verified that the overpayments were refunded to Medicare and described additional policies and procedures that it implemented or planned to implement. The Center's written comments also included statements that were unrelated to our recommendations; therefore, we did not verify those statements. The Center's comments are included in their entirety as the Appendix.

## TABLE OF CONTENTS

|  | <u>Page</u> |
|--|-------------|
| <b>INTRODUCTION</b> .....  | 1           |
| <b>BACKGROUND</b> .....  | 1           |
| NovoSeven .....  | 1           |
| Indiana Hemophilia and Thrombosis Center, Inc. ....                  | 1           |
| <b>OBJECTIVE, SCOPE, AND METHODOLOGY</b> .....                       | 1           |
| Objective .....  | 1           |
| Scope .....  | 1           |
| Methodology .....  | 2           |
| <b>FINDINGS AND RECOMMENDATIONS</b> .....                            | 2           |
| <b>MEDICARE PART B BILLING REQUIREMENT</b> .....                     | 3           |
| <b>INCORRECT NUMBER OF UNITS CLAIMED</b> .....                       | 3           |
| <b>DUPLICATE PAYMENTS</b> .....                                      | 3           |
| <b>RECOMMENDATIONS</b> .....   | 3           |
| <b>OTHER MATTER</b> .....  | 4           |
| <b>INDIANA HEMOPHILIA AND THROMBOSIS CENTER, INC. COMMENTS</b> ..... | 4           |
| <b>APPENDIX</b>  |             |
| <b>INDIANA HEMOPHILIA AND THROMBOSIS CENTER, INC. COMMENTS</b>       |             |

## **INTRODUCTION**

### **BACKGROUND**

Pursuant to Title XVIII of the Social Security Act (the Act), the Medicare program provides health insurance for people age 65 and over and those who are disabled or have permanent kidney disease. The Centers for Medicare & Medicaid Services (CMS), which administers the program, contracts with Medicare contractors to process and pay Medicare Part B claims submitted by providers for outpatient services. Medicare Part B helps cover medically-necessary services, such as doctors' services, outpatient care, and certain drugs.

#### **NovoSeven**

NovoSeven<sup>1</sup> (Coagulation Factor VIIa Recombinant) is a drug used to treat people suffering from blood clotting disorders. Section 1861(s)(2)(I) of the Act provides Medicare coverage of blood clotting factors, such as NovoSeven, for hemophilia patients competent enough to use such factors to control bleeding without medical supervision. A NovoSeven dispensation may consist of various dosages of the drug, which are distributed to a patient for home use or administered at a hemophilia treatment center. During the audit period (calendar years (CY) 2008 and 2009), Medicare required providers to bill one unit for every microgram of NovoSeven dispensed.

#### **Indiana Hemophilia and Thrombosis Center, Inc.**

Indiana Hemophilia and Thrombosis Center, Inc. (the Center) is the only federally recognized comprehensive hemophilia treatment center in the state of Indiana. The Center, located in Indianapolis, Indiana, provides healthcare and pharmacy services to patients with bleeding and clotting disorders. For CYs 2008 and 2009, National Government Services, the Medicare Part B carrier for Indiana, processed and paid the Center's Medicare Part B claims.

### **OBJECTIVE, SCOPE, AND METHODOLOGY**

#### **Objective**

Our objective was to determine whether the Medicare Part B payments made to the Center for NovoSeven dispensed during CYs 2008 and 2009, were allowable.

#### **Scope**

We reviewed 171 NovoSeven dispensations<sup>2</sup> made to six beneficiaries, with payments totaling \$46,783,961, that account for all Medicare Part B payments to the Center for NovoSeven dispensed during CYs 2008 and 2009.

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<sup>1</sup> NovoSeven<sup>®</sup> is a registered trademark of Novo Nordisk Health Care AG.

<sup>2</sup> A dispensation may result in multiple Medicare payments.

We limited our review of internal controls to gaining an understanding of the Center's policies and procedures related to the purchasing, inventorying, handling, and dispensing of drugs, and the preparation and submission of claims to Medicare.

We conducted our fieldwork from February through April 2011.

## **Methodology**

To accomplish our objective, we:

- reviewed applicable Medicare laws, regulations, and guidance,
- identified Medicare paid claims to the Center for NovoSeven dispensations using CMS's National Claims History file,
- interviewed the Center's officials to gain an understanding of the Center's policies and procedures,
- reviewed the Center's purchasing and dispensation records for NovoSeven during CYs 2008 and 2009,
- reviewed Medicare beneficiary medical records related to the Center's Medicare claims for NovoSeven, and
- interviewed five Medicare beneficiaries who received NovoSeven for home use<sup>3</sup> and verified their receipt of NovoSeven from the Center.

We conducted this performance audit in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objective.

## **FINDINGS AND RECOMMENDATIONS**

Of the 171 dispensations paid by Medicare Part B to the Center for NovoSeven dispensed during CYs 2008 and 2009, payments for 169 were allowable. For the unallowable payments for one dispensation, the Center claimed Medicare payments for double the amount of units actually dispensed. For the unallowable payments for the second dispensation, the Center received duplicate payments. As a result, the Center received net overpayments totaling \$434,935, which the Center had not refunded to Medicare by the beginning of our audit.

The overpayments occurred because the Center did not have policies and procedures in place to ensure the correct number of units dispensed were claimed for payment and to ensure Medicare payments for drug dispensations were appropriate, based on claimed amounts.

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<sup>3</sup> For one beneficiary, NovoSeven was only administered at the Center.

## **MEDICARE PART B BILLING REQUIREMENT**

Pursuant to Section 1833(e) of the Act (42 U.S.C. § 1395l (e)):

No payment shall be made to any provider of services or other person under this part unless there has been furnished such information as may be necessary in order to determine the amounts due such provider or other person under this part for the period with respect to which the amounts are being paid or for any prior period.

## **INCORRECT NUMBER OF UNITS CLAIMED**

During CY 2008, the Center claimed Medicare payment for an incorrect number of units for one NovoSeven dispensation. The Center claimed payments for double the amount of units actually dispensed. As a result, the Center received payments of \$232,000, resulting in overpayments totaling \$116,000.

The overpayments occurred because the Center did not have policies and procedures in place to ensure the correct number of units dispensed were claimed for payment. As a result of our audit, the Center issued checks to refund the \$116,000 of overpayments to Medicare.

## **DUPLICATE PAYMENTS**

During CY 2008, the Center received duplicate Medicare payments for one dispensation, resulting in overpayments totaling \$318,935.

The overpayments were not identified because the Center did not have policies and procedures in place to ensure Medicare payments for drug dispensations were appropriate based on claimed amounts. As a result of our audit, the Center issued checks to refund the \$318,935 of overpayments to Medicare.

## **RECOMMENDATIONS**

We recommend that the Center:

- ensure the \$434,935 of overpayments has been refunded to Medicare,
- establish policies and procedures to ensure that the correct number of units for drug dispensations are claimed, and
- establish policies and procedures to ensure that Medicare payments for drug dispensations are appropriate based on claimed amounts.

## **OTHER MATTER**

The Center states that patient's home infusion records will become a part of the patient's medical record. The Center considers an infusion record to be a very important part in developing the best possible care for a patient. The Center states that an infusion record is an accurate way to document bleeding episodes and treatment. Having accurate information assists in the development of the best treatment plan.

Our review of the Center's Medicare beneficiary medical records disclosed that the medical records did not consistently include the patient's home infusion records. In interviews with the Medicare beneficiaries, it was noted that in some instances they, in fact, had kept detailed infusion records, during the audit period, and had provided those records to the Center.

## **INDIANA HEMOPHILIA AND THROMBOSIS CENTER, INC. COMMENTS**

In written comments on our draft report, the Center concurred with our recommendations. The Center stated that it has ensured and verified that the overpayments were refunded to Medicare and described additional policies and procedures that it implemented or planned to implement. The Center's written comments also included statements that were unrelated to our recommendations; therefore, we did not verify those statements. The Center's comments are included in their entirety as the Appendix.

# **APPENDIX**

APPENDIX: INDIANA HEMOPHILIA AND THROMBOSIS CENTER, INC. COMMENTS



Indiana  
Hemophilia &  
Thrombosis  
Center, Inc.

August 31, 2011

Stephen F. Slamar  
Acting Regional Inspector General for Audit Services  
Office of Audit Services, Region V  
233 North Michigan Avenue  
Suite 1360  
Chicago, IL 60601

Re: Office of Inspector General (OIG) Review of Medicare Payments for NovoSeven Coagulation Factor VIIa to Indiana Hemophilia and Thrombosis Center from January 1, 2008, through December 31, 2009 Report Number A-05-11-00027

Dear Mr. Slamar:

Thank you for the opportunity to review and comment on the OIG Draft Report entitled "Review of Medicare Payments for NovoSeven Coagulation Factor VIIa to Indiana Hemophilia and Thrombosis Center from January 1, 2008, through December 31, 2009" (A-05-11-00027).

**Background on the Indiana Hemophilia & Thrombosis Center, Inc.**

The Indiana Hemophilia & Thrombosis Center, Inc. ("IHTC") is a 501(c)(3) non-profit, multidisciplinary treatment center and safety net provider dedicated to providing the highest quality comprehensive healthcare for persons with bleeding and clotting disorders.

IHTC is Indiana's only federally recognized comprehensive hemophilia center and receives its designation by its receipt of grant funding from the Maternal & Child Health Bureau and the Centers for Disease Control and Prevention (CDC).

Today there are approximately 140 Hemophilia Treatment Centers (HTCs) in the United States that provide comprehensive services to over 20,000 individuals with bleeding disorders. Services include, but are not limited to, expertise in coagulation disorders, individual treatment plans, preventative medicine, and access to a multidisciplinary team. These services maximize both the effectiveness and efficiency of the HTC model of care.<sup>1</sup>

**Hemophilia Background**

Hemophilia is a rare bleeding disorder characterized by a deficiency or absence of clotting factor VIII (Hemophilia A, or FVIII deficiency) or clotting factor IX (Hemophilia B, or FIX deficiency). The most common type of hemophilia, FVIII deficiency, occurs in about one in 5,000 male births, while FIX deficiency occurs in about one in 25,000 male births.

<sup>1</sup> Soucie J, Nuss R, Evatt B, et al. Mortality among males with hemophilia: relations with source of medical care. *Blood* 2000; 96:437-42.

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The primary signs and symptoms of hemophilia are excessive/prolonged bleeding and easy bruising. In general, musculoskeletal bleeding is the hallmark of hemophilia. The extent of these symptoms depends on the type of hemophilia, the severity of the underlying deficiency, and the presence or absence of an inhibitor.

### **Treatment of Hemophilia**

There is currently no cure for hemophilia. However, treatment of the condition has advanced remarkably in the past 30 years such that children with hemophilia that receive comprehensive treatment can now look forward to a near-normal life expectancy. Hemophilia is managed effectively with infusion of manufactured clotting factor concentrates to replace the factor protein that is missing from the blood. This is called clotting factor replacement therapy. Clotting factor concentrates can be manufactured using human plasma or through recombinant technology.

Clotting factor concentrates are typically provided to patients through HTC pharmacy programs or through private homecare companies. As Indiana's federally recognized comprehensive treatment center, IHTC operates a Public Health Service (PHS) Pharmacy Program, which allows IHTC to dispense clotting factor concentrates at reduced prices.

The amount of factor and the frequency of administration depend on several variables such as the severity and site of the bleeding, the size/weight of the patient, and the presence/absence of an inhibitor. Treatment with clotting factor concentrate is expensive, accounting for up to 90% of the cost of care in hemophilia and is significantly higher for patients that are being treated with an inhibitor.<sup>2,3</sup>

### **Inhibitor Development and Treatment**

The development of an inhibitor is one of the most serious complications in the treatment of hemophilia. An inhibitor is an antibody against the clotting factor concentrate used in replacement therapy. Antibody formation is the body's immune response toward foreign proteins. Because individuals with hemophilia are deficient or lacking in a specific clotting factor protein, replacing the clotting factor can result in an immune response in some individuals, as their bodies identify the clotting factor concentrate as "non-self" and thus destroy the infused clotting factor. Up to 30% of individuals with severe FVIII deficiency and 1% to 6% of individuals with severe FIX deficiency develop inhibitors.<sup>4</sup>

Development of an inhibitor represents a grave consequence of the disease and significantly alters patient treatment, risk of development of joint disease, cost of therapy, and overall morbidity experienced. The presence of inhibitors reduces or eliminates the efficacy of standard clotting factor replacement therapy. For all patients with hemophilia and inhibitors, prompt treatment with a bypassing agent such as NovoSeven® (Coagulation Factor VIIa Recombinant) is imperative to achieve bleed control and resolution, and prevention of sequela. This is especially important in inhibitor patients using bypassing therapy as overall bleed control is less reliable with these therapies and requires prompt, individually tailored and appropriate therapy.

### **Savings Resulting from IHTC's PHS Pharmacy Program**

The Medicare payment allowance limit for NovoSeven® (J7189) during the OIG's audit period ranged

<sup>2</sup> Smith P, Teutsch S, Shaffer P, et al. Episodic versus prophylactic infusions for hemophilia A: a cost-effectiveness analysis. *The Journal of Pediatrics* 1996;129:424-31.

<sup>3</sup> Globe D, Curtis R, Koerper M. Utilization of care in haemophilia: a resource-based method for cost analysis from the Haemophilia Utilization Group Study (HUGS). *Haemophilia* 2004;10:63-70.

<sup>4</sup> DiMichele D. Inhibitors in Hemophilia: A Primer. In: *Treatment in Hemophilia: World Federation of Hemophilia (WFH); 2004.*

from \$1.173 to \$1.308 per microgram. Because the Medicare beneficiaries whose claims were included in this review chose to receive their medications from the IHTC's PHS Pharmacy Program, IHTC was able to save Medicare approximately \$4.5 million during the two-year audit period, by billing below the allowable for NovoSeven®.

\* \* \*

### OIG Recommendations

1. Ensure the \$434,935 of overpayments has been refunded to Medicare.

**Response:** IHTC has ensured and verified that the inadvertent overpayments were refunded to Medicare and were processed by Indiana's Medicare Part B contractor.

2. Establish policies and procedures to ensure that the correct number of units for drug dispensations are claimed.

**Response:** The IHTC pharmacy program has several policies and procedures regarding the dispensation and billing of pharmacy claims. Medicare claims for NovoSeven® represent a unique challenge. The Indiana Medicare Part B Contractor is National Government Services ("NGS"). NGS's claims adjudications software restricts the "units of service" field, and the total claim amount for each claim. Additionally, the units of service field on the required CMS 1500 claim form is limited to three digits (i.e. 999). Therefore, all claims submitted to NGS for clotting factor claims in excess of 999 units of service must be specially processed. The NGS system identifies claims submitted in excess of 999 units and modifies the claim submission to be one unit of service and forwards the claim to be manually priced for payment. The NGS system also has a per claim limit of \$100,000. Therefore, NGS has instructed IHTC that all claims resulting in a billed charge in excess of \$100,000 must be manually split into separate claims reflecting the aggregate dispensation. In order to prevent the NGS system from denying a claim as a duplicate, NGS has instructed the IHTC to submit a varying total billed charge and mcg/unit of service for each claim. In previous correspondence with NGS regarding this matter, we were informed that the number of clotting factor claims submitted to them is small in relation to the total number of claims processed and would require significant restructuring. NGS has also stated that the limitations with the CMS 1500 claim form are beyond their control. Therefore, although IHTC's pharmacy dispensation system is capable of submitting claims electronically to payers, NGS requires IHTC to manually modify claims to meet NGS system requirements.

Pursuant to the OIG's recommendation, IHTC has implemented additional policies and procedures to ensure that manually submitted claims to Medicare are verified by two individuals at IHTC for accuracy prior to submission. Additionally, IHTC contracted with its pharmacy billing and dispensation system provider in March 2011 to create a reporting mechanism allowing for reconciliation of the units dispensed by the pharmacy against the units of service billed to payers. We anticipate this reporting mechanism to be complete in September 2011, allowing us to electronically verify all dispensations.

3. Establish policies and procedures to ensure that Medicare payments for drug dispensations are appropriate based on claimed amounts.

**Response:** IHTC has established additional policies and procedures to ensure that payments for drug dispensation are appropriate based on claimed amounts. Reconciliations of the entire claim are performed when an explanation of benefits is received from a payer. When a claim (manual or

system generated) is created, the original amount billed is recorded within the electronic billing system and future transactions are reconciled against the original amount whether they are payment in full, partial payments, overpayments, contractual adjustments or notification of patient responsibility.

**Other Matter**

The OIG also noted that the medical records did not consistently include the patients' home infusion records documenting bleeding episodes and treatment.

**Response:** While not required by most insurance companies or all HTC's, IHTC has consistently made efforts to have patients complete home infusion records. IHTC currently has two options available to complete these records; ATHNadvoy or a paper infusion calendar. ATHNadvoy is a secure electronic treatment record system that enables patients to log bleeding events and treatments online through a computer. IHTC also developed and offers an infusion calendar. This paper calendar is specifically designed by the IHTC team to document bleeding episodes and infusions in an easy-to-document and read format. Despite offering multiple methods for log completion and encouraging patients to complete these, the number of patients maintaining an accurate, up-to-date bleeding and infusion log remains less than optimal - consistent with that reported at HTC's across the country. When patients bring treatment logs to clinic, they are reviewed and discussed with the patient/family and, if possible and practical, the records are copied into the patients Electronic Medical Record (EMR). Regardless of whether patients complete treatment logs, all IHTC patients utilizing clotting factor concentrate are clinically evaluated and followed by IHTC's physicians and medical staff to ensure optimal medication utilization. If treatment logs are incomplete or documented in a format which make them difficult to scan into an EMR, physicians and care providers document relevant trends and/or treatment decisions in the patient's chart. IHTC is committed to continue efforts to obtain, review and record this important documentation.

We appreciate the cooperation of your staff and the professional manner in which this audit was conducted. If you have any further questions, please feel free to contact me at (317) 871-0011.

Sincerely,

/Nancy F. Hoard/

Nancy F. Hoard  
Executive Director

cc: Nicki Stauffacher