DEPARTMENT OF HEALTH & HUMAN SERVICES

OFFICE OF INSPECTOR GENERAL

Office of Audit Services
Region I
John F. Kennedy Federal Building
Boston, MA 02203
(617) 565-2684

August 5, 2002

CIN: A-01-01-00510

Mr. John Markus
Senior Vice President Corporate Compliance
Fresenius Medical Care North America
Corporate Headquarters
Business Practices and Corporate Compliance
95 Hayden Avenue
Lexington, Massachusetts 02420-9192

Dear Mr. Markus:

Enclosed are two copies of the U.S. Department of Health and Human Services, Office of Inspector General (OIG), Office of Audit Services' (OAS) report entitled "Review of EPOGEN Internal Control Procedures at Fresenius Massachusetts Providers for Calendar Year 1999."

Final determination as to actions taken on all matters reported will be made by the HHS action official named on page 2. We request that you respond to the HHS action 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.

In accordance with the principles of the Freedom of Information Act (5 U.S.C. 552, as amended by Public Law 104-231), OIG, OAS reports issued to the Department's grantees and contractors are made available to members of the press and general public to the extent information contained therein is not subject to exemptions in the Act which the Department chooses to exercise. (See 45 CFR Part 5.) As such, within 10 business days after the final report is issued, it will be posted on the world wide web at http://oig.hhs.gov/.

To facilitate identification, please refer to Common Identification Number A-01-01-00510 in all correspondence relating to this report.

Sincerely,

Michael J. Armstrong
Regional Inspector General
for Audit Services

Enclosures - as stated
cc: w/enclosure - Lynda Silva, Acting Regional Administrator, CMS
- Donald W. Sirois, Executive Director of Government Programs, AHS

Direct Reply to HHS Action Official:

Ms. Lynda Silva
Acting Regional Administrator
Centers for Medicare and Medicaid Services - Region I
U.S. Department of Health and Human Services
Room 2325
JFK Federal Building
Boston, Massachusetts 02203-0003

Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

REVIEW OF EPOGEN INTERNAL CONTROL PROCEDURES AT FRESENIUS MASSACHUSETTS PROVIDERS FOR CALENDAR YEAR 1999

JANET REHNQUIST
Inspector General

AUGUST 2002
A-01-01-00510

Office of Inspector General

http://oig.hhs.gov/

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The OIG's Office of Audit Services (OAS) provides all auditing services for HHS, either by conducting audits with its own audit resources or by overseeing audit work done by others. Audits examine the performance of HHS programs and/or its grantees and contractors in carrying out their respective responsibilities and are intended to provide independent assessments of HHS programs and operations in order to reduce waste, abuse, and mismanagement and to promote economy and efficiency throughout the Department.

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EXECUTIVE SUMMARY

Background

Health Insurance for the Aged and Disabled (Medicare), Title XVIII of the Social Security Act, as amended, is a broad program of health insurance that is administered by the Centers for Medicare and Medicaid Services (CMS), formerly the Health Care Financing Administration. Medicare includes coverage for eligible persons suffering from kidney failure under its End Stage Renal Disease (ESRD) program. One type of coverage includes the use of EPOGEN (EPO), which is used as a substitute for the protein erythropoietin. The EPO stimulates the production and development of red blood cells. Low levels of erythropoietin often result in anemia, with symptoms including rapid heartbeat, chest pain, fatigue, and limitations in performance of daily activities.

The ESRD facilities are reimbursed by Medicare based on the number of EPO units administered to each ESRD patient. Medicare is responsible for paying $8 per 1,000 units of EPO.

Fresenius Medical Care North America (Fresenius) operates the nation's largest network of dialysis clinics and is a leading manufacturer of dialysis products. It is a division of Fresenius Medical Care AG, formed by the joining of Fresenius Worldwide Dialysis and National Medical Care in 1996. Fresenius has operations in approximately 100 countries. The company is the world's leading provider of dialysis services and treats approximately 81,200 patients in nearly 1,100 dialysis clinics. In Massachusetts, there were 27 Fresenius providers that submitted claims that contained services for EPO equal to or greater than 90,000 billed and reimbursed units in calendar year 1999 to the Associated Hospital Service (AHS).

Objective

The objective of our review was to determine if Fresenius' Massachusetts providers have established adequate internal controls and procedures to ensure that claims for EPO are supported and billed in accordance with Medicare rules and regulations. Our review covered about 4,600 claims that contained services for EPO equal to or greater than 90,000 units and submitted by 27 Massachusetts Fresenius providers during calendar year 1999.

Summary of findings

We employed a simple random sample of 200 Fresenius claims and the value of the sampled claims EPO amounts totaled $249,528. We reviewed the billing and medical records for the 200 claims to determine whether the EPO services billed and reimbursed were supported by the medical records. As a basis for a Medicare payment, federal regulations require that the provider, supplier or beneficiary, as appropriate, must furnish to the intermediary or carrier sufficient information to determine whether payment is due. As part of our review, we requested, obtained and reviewed beneficiaries' records for (1) written physician orders prescribing the number of units of EPO to be administered per patient treatment, (2) dialysis treatment records to determine the amount of EPO administered per treatment, and (3) CMS' common working file records to determine the number of units billed to the Medicare program.

We found that Massachusetts Fresenius providers have generally established adequate internal controls and procedures to ensure that claims submitted for EPO are supported and billed in accordance with Medicare rules and regulations. However, based on a random sample of 200 claims valued at $249,528, we did identify portions of 23 claims totaling $3,585 not eligible for Medicare reimbursement. Specifically, we identified 14 claims totaling $2,102 in which the facility clinician administered more EPO than was called for under the protocol ordered by the physician. We also identified 9 claims totaling $1,483 in which the facility could not provide sufficient documentation to support the amount of the EPO payment.

In addition, we addressed our concerns with respect to the use of EPO protocols as standing physician orders and with physicians not signing off EPO dosage changes. We believe that the documentation of the physician's signature for dose changes provides a quality of care and utilization control mechanism as to the amount of EPO administered and billed by the facility.

Recommendations

We recommend that Fresenius

(1) strengthen their internal controls and procedures to ensure that claims submitted for EPO are supported and billed in accordance with Medicare rules and regulations, and

(2) resolve with CMS and AHS as to what physician documentation is required when using a protocol containing an algorithm as a standing physician order for a nurse to administer EPO.

Auditee Response

In comments to our first draft report recommendation, Fresenius stated they have strengthened their internal controls and procedures since the 1999 OIG audit period. In regards to our second recommendation, Fresenius believes that the OIG and AHS's concerns expressed in the report requiring physician approval of individual EPO dosage changes is misplaced, and that requiring a separate physician order for each change would frustrate the purpose of the algorithm.

Additional OIG Comments

In regards to the Fresenius's response to the second recommendation, we have concerns with physicians not signing off EPO dosage changes, and are not convinced this is a widespread practice. Further, as Fresenius disagrees with OIG and AHS, we believe our second recommendation to resolve with CMS and AHS as to what physician documentation is required when using a protocol containing an algorithm as a standing physician order for a nurse to administer EPO is still applicable. It is important for there to be a clear understanding of what physician documentation is required for Medicare reimbursement.

We will provide the AHS and CMS with the results of our review for appropriate consideration and corrective action.

INTRODUCTION

BACKGROUND

Health Insurance for the Aged and Disabled (Medicare), Title XVIII of the Social Security Act, as amended, is a broad program of health insurance that is administered by the Centers for Medicare and Medicaid Services (CMS), formerly the Health Care Financing Administration. Medicare includes coverage for eligible persons suffering from kidney failure under its End Stage Renal Disease (ESRD) program.

The Food and Drug Administration approved the generic drug epoetin commonly known as EPO on June 1, 1989. The drug EPO is used as a substitute for the protein erythropoietin, which is secreted by the kidneys and stimulates the production and development of red blood cells. Low levels of erythropoietin often result in anemia with symptoms including rapid heartbeat, chest pain, fatigue, and limitations in performance of daily activities. Prior to the development of EPO, ESRD beneficiaries with low levels of erythropoietin required frequent blood transfusions, an expensive procedure that could have introduced significant medical risk.

The CMS authorized Medicare contractors to pay for EPO as of June 1, 1989. The EPO, when provided to a patient determined to have ESRD, shall not be included as a dialysis service for purposes of payment under any prospective payment amount or comprehensive fee, and payment shall be made separately in the amount equal to $10 per 1,000 units of EPO (rounded to the nearest 100 units). Medicare is responsible for paying $8 per 1,000 units of EPO, as the Medicare payment amount is subject to the Medicare Part B deductible and coinsurance.

Fresenius Medical Care North America (Fresenius) operates the nation's largest network of dialysis clinics and is a leading manufacturer of dialysis products. The company is based in Lexington, Massachusetts. It is a division of Fresenius Medical Care AG, formed by the joining of Fresenius Worldwide Dialysis and National Medical Care in 1996.

Fresenius has operations in approximately 100 countries. The company is the world's leading provider of dialysis services and treats approximately 81,200 patients in nearly 1,100 dialysis clinics.

In Massachusetts, there were 27 Fresenius providers that submitted claims that contained services for EPO equal to or greater than 90,000 billed and reimbursed units in calendar year 1999 to the fiscal intermediary, Associated Hospital Service (AHS).

OBJECTIVE, SCOPE AND METHODOLOGY

Our review was conducted in accordance with generally accepted government auditing standards. The objective of our review was to determine if Massachusetts Fresenius providers have established adequate internal controls and procedures to ensure that claims for EPO are supported and billed in accordance with Medicare rules and regulations.

We limited consideration of the internal control structure to those controls concerning claims submission because the objective of our review did not require an understanding or assessment of the complete internal control structure of Fresenius. We concluded, however, that our consideration of the internal control structure could be conducted more efficiently by expanding substantive audit tests, thereby placing limited reliance on the providers internal control structure.

To accomplish our objective, we:

- researched applicable laws and regulations related to EPO.

- used CMS's National Claims History (NCH) to identify 4,598 Massachusetts Fresenius claims that contained services for EPO equal to or greater than 90,000 billed and reimbursed units. The 4,598 claims EPO amounts were valued at $5,414,434, and were submitted by 27 Massachusetts Fresenius providers to the AHS during calendar year 1999.

- employed a simple random sample of 200 Massachusetts Fresenius claims from the 27 providers for those claims containing charges for EPO services equal to or greater than 90,000 units during the period January 1, 1999 through December 31, 1999. The EPO value of the sampled claims totaled $249,528.

- reviewed the billing and medical records for the 200 claims to determine whether the billed and reimbursed EPO services were supported by the medical records. The billed and reimbursed charges associated with the EPO claims were reviewed and discussed with the AHS and Office of Inspector General (OIG) medical review staff to determine whether claims complied with Medicare rules and regulations. Our audit did not include determining whether the beneficiary's medical condition warranted the need for the EPO administered.

- interviewed the 27 Fresenius providers' officials concerning internal controls pertaining to the submission of Medicare claims for EPO.

- discussed our results with CMS officials in Boston, Massachusetts and Baltimore, Maryland.

Our fieldwork was conducted from June 2001 to November 2001 at the 27 Massachusetts Fresenius providers, AHS in Quincy, Massachusetts; CMS offices in Boston, Massachusetts and Baltimore, Maryland; and the Boston Regional OIG Office.

FINDINGS AND RECOMMENDATIONS

We found that Massachusetts Fresenius providers have generally established adequate internal controls and procedures to ensure that claims submitted for EPO are supported and billed in accordance with Medicare rules and regulations. However, based on a random sample of 200 claims valued at $249,528, we did identify portions of 23 claims totaling $3,585 not eligible for

Medicare reimbursement:

- 14 claims totaling $2,102 in which the facility clinician administered more EPO than was called for under the protocol ordered by the physician.

- 9 claims totaling $1,483 in which the facility could not provide sufficient documentation to support the amount of the EPO payment.

In addition, we also addressed our concerns with respect to the use of EPO protocols as standing physician orders.

Administering EPO In Accordance With Established Protocol/Algorithms

As part of Fresenius's Continuous Quality Improvement Initiative, the Fresenius Medical Director developed a sample EPO protocol with dosing algorithms and recommended its use at Fresenius facilities. The algorithms were based on medical studies the National Kidney Foundation Dialysis Outcomes Quality Initiative, the experience in clinical trials conducted by the drug manufacturer, Amgen, and the clinical experience of the Fresenius Medical Director. The facility's medical director and the patients' attending physician can either adopt, adapt or reject the sample protocol. While many Fresenius facilities and attending physicians use protocols, it should be noted that not all Fresenius facilities use the same protocols. The protocols can vary by patient and facility.

The protocol is a tool the dialysis facility's medical staff formulated and approved, in conjunction with the attending physician, to make timely decisions regarding a patient's anemia management. The protocols contain algorithms that monitor the patient's hemoglobin blood levels to determine an EPO dose. The attending physician would issue a standing order in the medical record directing the nurse to administer EPO dosage according to a protocol. The algorithm is a formula that requires the nurse on duty to gather requisite data elements for the algorithm and make appropriate calculations. The result is a recommendation to decrease, increase, maintain or temporarily hold the current EPO dose.

As part of our review, we obtained and reviewed beneficiaries' medical records for (1) written physician orders prescribing the number of units of EPO to be administered per patient treatment, and (2) dialysis treatment records to determine the amount of EPO administered per treatments billed to the Medicare program. Our analysis identified inconsistencies between the number of units of EPO prescribed in the written physician order (i.e., protocol), administered by the facility to the patient, and billed to the Medicare program. For example:

> One claim billed for 104,000 units of EPO totaling $832 and the treatment forms indicate the provider's staff administered 104,000 units of EPO; however, based on the physician's order the EPO dose was to be reduced 20 percent to 6,400 units per treatment if the hemoglobin was greater than 12. The patient's hemoglobin was 13.5 prior to the claim period and remained greater than 12 throughout the month. Therefore, the patient's EPO dosage should have decreased 20 percent to 6,400 units per treatment for all 13 treatments in the month. Therefore, we are questioning 20,800 units of EPO totaling $166.

As a basis for a Medicare payment, Title 42 Code of Federal Regulations (CFR) Section 424.5 (a)(6) provides:

Overall, we identified portions of 14 claims where the facilities' staff did not follow the physician order to decrease the EPO dosage based on the established protocol. As a result, we are questioning $ 2,102.

Maintaining Sufficient Documentation To Support Payment

Fresenius policy for administering medications requires the nurse to sign and date, as to when EPO was administered to each patient. This is documented in the patient's medical record to provide evidence as to the amount of EPO provided. This policy is consistent with Medicare reimbursement rules. However, we found portions of 7 claims where the medical records did not contain sufficient information that EPO was administered to the beneficiary. In this regard, the patient's chart did not contain the nurse's signature and the time that EPO was administered. We also found 2 additional claims involving a physician order not being updated and a billing error.

Overall, we identified portions of 9 claims where the facilities could not provide us adequate supporting documentation for payment purposes. As a result, we are questioning $1,483.

The Use of EPO Protocols

Prior to the use of protocols, physicians prepared a new order for all EPO dose changes. With the use of EPO protocols, this process has changed. As previously mentioned, Fresenius facilities use the protocol as a standing physician order for a nurse to administer EPO. However, physician involvement with documenting dose changes varies among the Massachusetts Fresenius facilities. In our review of the documentation for the claims in our sample, we noted that some protocols required a physician to sign off EPO dose changes, while other protocols were silent about physician sign offs when EPO doses were adjusted**.** We also found physicians signed off on EPO dose changes, even when the protocols were silent about sign offs. In other cases, we noted that the attending physician did not sign off on the standing order for over a year, even though the EPO dose had almost doubled.

While the EPO protocol is an effective manner of treatment for individuals, we have concerns with physicians not signing off EPO dosage changes. Under Medicare reimbursement regulations, a physician has a major role in ensuring quality of care and in determining utilization of health services furnished by providers. The documentation of the physician's signature for dose changes, whether by telephone, facsimile, or electronic messaging, provides a quality of care and utilization control mechanism as to the amount of EPO administered and billed by the facility. Moreover, as a condition of participation, the ESRD facility is required to ensure that all medical records are properly documented.

The average EPO dose for the 200 sampled claims at the 27 Massachusetts Fresenius facilities was 12,600 units per treatment. At a reimbursement rate of $8 per 1,000 units of EPO, the increase in EPO dosages can result in a significant cost to the Medicare program.

Based on our discussions with the Fresenius and AHS officials, there exist significant differences with respect to the documentation requirements pertaining to the physician EPO protocol orders. Fresenius officials believe that a physician order directing nurses to follow an EPO dosing algorithm is a valid physician order in which physicians do not need to sign off on any changes as long as the nurse administers the EPO in accordance with the algorithm. The AHS applies the Commonwealth of Massachusetts Nurse's Practice Act requirements and believes claims involving dosage changes should have physician signoffs for EPO dose changes.

RECOMMENDATIONS

We recommend that Fresenius:

(1) strengthen their internal controls and procedures to ensure that claims for EPO are supported and billed in accordance with Medicare rules and regulations.

(2) resolve with CMS and AHS as to what physician documentation is required when using a protocol containing an algorithm as a standing physician order for a nurse to administer EPO.

AUDITEE RESPONSE

In its comments to our first draft report recommendation, Fresenius stated they have strengthened their internal controls and procedures since the 1999 OIG audit period.

In regards to our second recommendation, Fresenius:

- believes that the concerns expressed in the report requiring physician approval of individual EPO dosage changes is misplaced, and that requiring a separate physician order for each change would frustrate the purpose of the algorithm. They state that the value of an algorithm lies in its ability to direct the nursing staff to adjust medication dosing according to fixed medical criteria established by the treating physician without requiring a specific physician order for each change in dose. Fresenius believes this practice has been widely accepted in the medical community.

- stated that the reference in the Report to reliance by AHS on the Massachusetts Nurses Practice Act to require a separate physician order for each dose change made pursuant to a physician-directed algorithm is misplaced, and nothing in the Nurse Practice Act supports such a conclusion.

See APPENDIX for complete text of Auditee comments.

ADDITIONAL OIG COMMENTS:

In regards to the Fresenius's response to the second recommendation, we provide the following additional comments.

First, we do not question the benefit and use of physician-directed algorithms. However, we have concerns with physicians not signing off EPO dosage changes, and are not convinced this

practice is as widespread as Fresenius suggests. Based on audits of other Massachusetts dialysis providers, we found that the dialysis providers required that physicians sign off on changes in which nurses adjusted EPO dosages utilizing algorithms. We even found that some of the Massachusetts Fresenius ESRD providers selected in our sample required physicians to sign off on all changes in which nurses adjusted EPO dosages based on algorithms. The documentation of the physician's signature for dose changes, whether by telephone, facsimile, or electronic messaging, provides a quality of care and utilization control mechanism as to the amount of EPO administered and billed by the facility. Moreover, as a condition of participation, the ESRD facility is required to ensure that all medical records are properly documented.

In the absence of a national policy, a local intermediary is responsible for establishing local medical review policies. In the case of this audit, the local intermediary, AHS, utilizes the Nurse Practice Act while reviewing and adjudicating Medicare claims. However, officials from AHS stated they do not question the benefit and use of physician-directed algorithms. The AHS officials believe claims involving EPO dosage changes should have evidence that the physician reviewed the nurse's adjustments and concurred with the adjusted dosage amount. Since as Fresenius disagrees with AHS's interpretation of the Nurses Practice Act, we believe our second recommendation to resolve with CMS and AHS as to what physician documentation is required when using a protocol containing an algorithm as a standing physician order for a nurse to administer EPO is still applicable. It is important for there to be a clear understanding of what physician documentation is required for Medicare reimbursement.

We will provide the AHS and CMS with the results of our review for appropriate consideration and corrective action.

APPENDIX

July 15, 2002

Mr. Michael J. Armstrong
Regional Inspector General for Audit Services
Office of Inspector General
Office of Audit Services, Region 1
John F. Kennedy Federal Building
Boston, MA 02203

RE: CIN A-01-01-00510

Dear Mr. Armstrong:

We have reviewed the draft audit report entitled "Review of EPOGEN Internal Control Procedures at Fresenius Massachusetts Providers for Calendar Year 1999," dated June 27, 2002 and wish to offer the following comments.

1. We are pleased that the Report found that Fresenius-owned dialysis units in Massachusetts

> "have generally established adequate internal controls and procedures to ensure that claims submitted for EPO are supported and billed in accordance with Medicare rules and regulations."

This finding reflects the results of a coordinated effort by Fresenius employees in Massachusetts and across the country to implement effective clinical quality and billing programs. The results are consistent with other Medicare claims audits conducted by Fresenius staff and by PricewaterhouseCoopers under the terms of the Company's Corporate Integrity Agreement with the OIG. They reflect a conscious commitment to a high standard of clinical and billing integrity by the Company and its employees.

2. We believe that the $3,585 identified by the audit as not eligible for Medicare reimbursement (1.4% of the reimbursement associated with the sampled claims) would be reduced if the claims were to be reviewed through the full Medicare administrative process. We believe that at least $985.60 of this amount (affecting portions of 6 claims) reflects charges for services properly administered in accordance with a physician's order. Although we recognize that a full adjudication of these claims lies outside the scope of the present audit, we believe that given an opportunity to present additional testimonial and documentary evidence, through the established Medicare appeals process, we would be able to successfully defend these claims.

For example, the draft audit report cites a case where "the nurse failed to reduce the EPOGEN dose by 20% when the hemoglobin was greater than 12 gm/dl." In this instance, there is a monthly medical summary note that outlines a co-morbid condition of systemic lupus erythematosus, recent

thrombosis of the arterial venous shunt used for dialysis, recent removal of fluid from the knee, as well as treatment with steroids. A medical progress note in the patient's chart for the prior month indicates that the hemoglobin is "on target." During this period it was standard practice for the physician and his associates to review patient status during weekly rounds at this dialysis facility. We believe that testimonial evidence from the attending physician and the nursing staff on the condition of the patient at the time and their treatment objectives would be highly relevant to an Administrative Law Judge reviewing the case on a *de novo* basis.

3. We are pleased that the Report acknowledges that the use of EPOGEN algorithms is an effective manner of treatment for dialysis patients. We believe, however, that the concerns expressed in the Report regarding physician approval of individual EPOGEN dosage changes is misplaced, and that requiring a separate physician order for each change would frustrate the purpose of algorithms. The value of an algorithm lies in its ability to direct the nursing staff to adjust medication dosing according to fixed medical criteria established by the treating physician without requiring a specific physician order for each change in dose. This practice has been widely accepted in the medical community for dialysis and other health care settings with measurable benefits to patients.

Ironically, Fresenius has relied upon the common and accepted practice of using physician-directed algorithms to maintain patient hemoglobin levels within the range recommended by the National Kidney Foundation Dialysis Outcomes Quality Initiative (DOQI) as Medicare contractors have begun to use the DOQI guidelines to assess the medical necessity of EPOGEN services. A concerted effort by the Company to monitor and provide optimal EPOGEN dosing for patients with hemoglobin levels within the DOQI recommended range has improved anemia management for patients and saved millions of dollars for the Medicare program through tighter dose management. Requiring physicians to write a separate order for each dose adjustment would undercut the effectiveness of physician-directed EPOGEN dosing algorithms and negate the medical and cost-effectiveness gains of the last several years. It would also have the effect of creating a rule that does not apply elsewhere in healthcare.

As you know, we have discussed these issues with senior officials at CMS and have found them to be fully aware of the use of physician-directed algorithms in a variety of clinical settings. For this reason, and because of the widespread and long-standing use of algorithms in a number of clinical settings, we strongly suggest that the OIG consult with an expert panel of medical practitioners who have experience in the use of medication algorithms before advocating any changes to current practice, both for its impact on patient care and the additional expense to the healthcare system.

4. The reference in the Report to reliance by Associated Hospital Services (AHS) on the Massachusetts Nurse Practice Act to require a separate physician order for each dose change made pursuant to a physician-directed algorithm in misplaced. Nothing in the Nurse Practice Act supports such a conclusion. In fact, implementing regulations and Advisory Rulings from the Board of Registration in Nursing (the "Board") confirm an opposite view.

The Code of Massachusetts Regulations defines the Standards of Conduct for nurses licensed by the Board at 244 CMR 9.00. Section 9.03 (38) entitled "Administration of Drugs," provides that:

> "A nurse licensed by the Board shall not administer any prescription drug or non-prescription drug to any person in the course of nursing practice except as directed by an authorized prescriber."

Where a medication algorithm is ordered by an authorized prescriber (i.e., a physician) the regulation does not require an additional physician order for each change in dose within the parameters of the physician-prescribed algorithm. This is confirmed by discussions with officials at the Board and by Advisory Ruling 9903, issued by the Board on August 12, 1998, which specifically authorizes nurses to follow the instructions of physician-prescribed medication dosing parameters in the administration of certain analgesic medications to non-pregnant patients. It requires that orders from an authorized prescriber must include "the drug name, diluent type, concentration, and dose parameters." It provides that patient management by a registered nurse may include "adjusting the drug dose as prescribed, by altering the infusion rate" consistent with the medication order. This intent is further confirmed by Advisory Ruling 9904, issued on the same day, which creates an exception to the general rule for pregnant patients. Such an explicit exception would not be necessary if the Board intended to limit nursing practice as suggest by AHS. (See Attachments)

5. Since the OIG found the Company has "generally established adequate internal controls and procedures," and in light of the small percentage of claims payments that the OIG found to be in question, the Company believes the Report recommendation that Fresenius strengthen its internal controls and procedures relating to the administration of EPOGEN is not consistent with these audit results. The Company has, in fact, initiated a number of internal clinical and billing improvement projects since the 1999 audit period through its continuous quality improvement initiatives, compliance efforts, and through improved clinical practice and documentation policies. If the auditors have any additional specific suggestions, we will, of course, be willing to consider them.

Thank you for the opportunity to comment on the draft audit report.

Sincerely yours,

John Markus
Senior Vice President
Corporate Compliance and Administration

Advisory Rulings

Advisory Ruling 9903

Management of the Patient Receiving Analgesia by Catheter Techniques

(Epidural, Intrathecal, Intrapleural or Peripheral Nerve Catheters)

Purpose:

The Board of Registration in Nursing issues this Advisory Ruling to direct the practice of Registered Nurses whose practice includes the nursing management of patients receiving analgesic medications via epidural, intrathecal, intrapleural or peripheral nerve catheter techniques to alleviate acute or chronic pain.

Date Adopted: August 12, 1998

Advisory Ruling:

Registered Nurses (R.N.s) with the appropriate knowledge, skills and abilities may manage the nursing care of ***nonpregnant*** patients receiving analgesic medications via epidural, intrathecal, intrapleural or peripheral nerve catheters for acute or chronic pain.

Orders from an authorized prescriber must include the drug name, diluent type, concentration and dose parameters.

The R.N. shall assume responsibility for patient care only after the provider who has placed the catheter/infusion device has verified correct catheter placement and the patient's vital signs are stable.

When agency policies permit, and there is a specific order from an authorized prescriber, patient management by an R.N. may include: preparing the medication for administration using an infusion device; replacing empty infusion syringes or bags; adjusting the drug dose as prescribed, by altering the infusion rate; administering a

prescribed re-bolus of the medication by increasing the rate of a continuous infusion, when the patient has received a previous dose by an anesthesiologist or CRNA; stopping the infusion; and removing the catheter.

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The Board of Registration in Nursing

Advisory Rulings

Advisory Ruling 9904

Management of the Pregnant Patient Receiving Analgesia by Catheter Techniques

(Epidural, Intrathecal, Intrapleural or Peripheral Nerve Catheters)

Purpose:

The Board of Registration in nursing issues this Advisory Ruling to direct the practice of Registered Nurses whose practice includes the nursing management of a pregnant patient receiving analgesic/anesthetic medications via epidural, intrathecal, intrapleural or peripheral nerve catheter techniques.

Date Adopted: August 12, 1998

Advisory Ruling:

When a licensed anesthesia care provider is readily available, an R.N. with the appropriate knowledge, skills and abilities may monitor the care of a ***pregnant*** patient receiving analgesic/anesthetic medications via epidural, intrathecal, intrapleural or peripheral nerve catheters or devices, following stabilization of vital signs after either bolus injection or establishment of a continuous infusion by a physician or a Certified Registered Nurse Anesthetist. When agency policies permit, and there is a specific order, an R.N. may replace empty infusion syringes or bags; stop the infusion; and remove the catheter. Initiating an infusion, administering an initial dose, adjusting the dose/infusion rate and administering a rebolus of analgesic/anesthetic medication via such catheters for a ***pregnant*** patient is not within the scope of R.N. practice.

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