DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Inspector General
Office of Audit Services

REGION IV
61 Forsyth Street, S.W., Suite 3T41
Atlanta, Georgia 30303

June 18, 2004

Report Number: A-04-03-01000

Ms. Debra Minton
Vice President of Human Resources and Compliance
The Lifeline Group
600 Clifty Street
Somerset, Kentucky 42502-0938

Dear Ms. Minton:

Enclosed are two copies of the Office of Inspector General reports entitled *Review of Home Health Services Provided By The Lifeline Health Group Inc.* This review was requested by the Office of Counsel to the Inspector General that has responsibility over providers subject to corporate integrity agreements.

Our objective was to determine whether Medicare payments to Lifeline for home health services met Medicare eligibility and reimbursement requirements. Our review covered the period of October 26, 2001 through June 30, 2002. Based on the results of a review of medical records documentation of a sample of 100 claims conducted by a Program Safeguard Contractor, it was determined that during this period, Lifeline was paid for services that did not meet Medicare eligibility and reimbursement requirements resulting in overpayments of about $1,173,330.

Final determination as to action taken on all matters reported will be made by the Department of Health and Human Services (HHS) action official. 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 United States Code 552, as amended by P.L.104-231, Office of Inspector General reports are made available to members of the public to the extent information contained therein is not subject to exemptions in the Act (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.

If you have any questions or comments about this report, please contact Mr. Donald Czyzewski, Audit Manager, at (305) 536-5309, extension 10.

To facilitate identification, please refer to report number A-04-03-01000 in all correspondence relating to this report.

Sincerely,

Charles J. Curtis
Regional Inspector General
for Audit Services, Region IV

Enclosure

Direct Reply to HHS Action Official:

Mr. Dale Kendrick
Associate Regional Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
61 Forsyth Street, Suite 4T20
Atlanta, Georgia 30303-8909

Department of Health and Human Services

OFFICE OF
INSPECTOR GENERAL

REVIEW OF HOME HEALTH SERVICES PROVIDED BY THE LIFELINE HEALTH GROUP INC.

Inspector General

June 2004
A-04-03-01000

Office of Inspector General

http://oig.hhs.gov

The mission of the Office of Inspector General (OIG), as mandated by Public Law 95-452, as amended, is to protect the integrity of the Department of Health and Human Services (HHS) programs, as well as the health and welfare of beneficiaries served by those programs. This statutory mission is carried out through a nationwide network of audits, investigations, and inspections conducted by the following operating components:

Office of Audit Services

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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The OIG's Office of Evaluation and Inspections (OEI) conducts short-term management and program evaluations (called inspections) that focus on issues of concern to the department, the Congress, and the public. The findings and recommendations contained in the inspections reports generate rapid, accurate, and up-to-date information on the efficiency, vulnerability, and effectiveness of departmental programs.

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Office of Counsel to the Inspector General

The Office of Counsel to the Inspector General (OCIG) provides general legal services to OIG, rendering advice and opinions on HHS programs and operations and providing all legal support in OIG's internal operations. The OCIG imposes program exclusions and civil monetary penalties on health care providers and litigates those actions within the department. The OCIG also represents OIG in the global settlement of cases arising under the Civil False Claims Act, develops and monitors corporate integrity agreements, develops model compliance plans, renders advisory opinions on OIG sanctions to the health care community, and issues fraud alerts and other industry guidance.

Notices

THIS REPORT IS AVAILABLE TO THE PUBLIC
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In accordance with the principles of the Freedom of Information Act (5 U.S.C. 552, as amended by Public Law 104-231), Office of Inspector General, Office of Audit Services reports are made available to members of the public to the extent the information is not subject to exemptions in the act. (See 45 CFR Part 5.)

OAS FINDINGS AND OPINIONS

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

OBJECTIVE

The objective of the review was to determine whether Medicare payments to Lifeline for home health services met Medicare eligibility and reimbursement requirements.

FINDINGS

For the period of October 26, 2001 through June 30, 2002, Lifeline was paid for home health services that did not meet Medicare eligibility and reimbursement requirements resulting in Medicare overpayments of about $1,173,330. We contracted with a Program Safeguard Contractor to conduct a medical review of a statistical random sample of 100 paid home health claims for services rendered by Lifeline. The medical reviewers determined that Lifeline billed for: beneficiaries who were either not homebound or whose homebound status was not adequately documented (nine claims); beneficiaries who had no need for qualifying skilled services (five claims); services that were not reasonable or necessary for the beneficiary's condition (one claim); services not properly authorized by a physician (two claims); and services not supported by documentation (two claims).

We believe that Lifeline billed for these services because Lifeline may not have effective admission and financial controls in place to ensure that every beneficiary admitted to the home health program met the eligibility criteria and every service provided met the Medicare reimbursement requirements.

Therefore, we are recommending that Lifeline:

- Examine the errors identified by our contracted medical review, and develop additional admission controls, financial controls, and training to ensure that these types of errors do not occur in the future.

- Work with the Fiscal Intermediary (FI) to reimburse the Medicare program the estimated overpayment of $1,173,330. Any refunds made after June 30, 2002 relating to claims during the period of review should be considered as reductions to the estimated overpayment of $1,173,330.

AUDITEE COMMENTS

In a written response to our draft report dated April 20, 2004, Lifeline expressed its disagreement with the medical review results, with the exception of three claims. However, Lifeline's internal review had detected a claim, identified as an overpayment that was previously refunded to the Medicare program, and requested that this claim not be used to calculate any refund to Medicare. They also provided numerous copies of supporting medical records documentation and the

results of their own medical reviews. Additionally, Lifeline requested information regarding the sampling methodology utilized by the Office of Inspector General (OIG).

OFFICE OF INSPECTOR GENERAL RESPONSE

Denials of home health services relate to conflicting conclusions reached by medical review experts, therefore the OIG will make Lifeline's attachments available to the action official for appropriate consideration in the audit resolution process.

The refund by Lifeline in October 2002, corresponding to a sample claim, was made after the period of audit. Therefore, it was correctly included in estimating the $1,173,330 overpayment. Any refunds made by Lifeline after the period of our review, for claims included in the review period, should be used to offset the estimated overpayment. We have adjusted our recommendations accordingly.

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BACKGROUND

Home Health Services

A home health agency (HHA) is a public or private organization that is primarily engaged in providing skilled nursing care and other therapeutic services in the home on a visiting basis. Home health services allow people with limited mobility to receive professional health care services in their homes.

Home Health Legislation

The Balanced Budget Act of 1997, P.L. 105-33, enacted on August 5, 1997, and amended by the Balanced Budget Refinement Act of 1999, significantly changed the way Medicare pays for home health services. Prior to October 1, 2000, HHAs received payment under a cost-based reimbursement. Section 4603(a) of the Balanced Budget Act required the implementation of the home health prospective payment system (PPS) to be effective October 1, 2000.

Implementing Regulations

Title 42 Code of Federal Regulation (CFR) §484, Subpart E implements the home health PPS, and §409 and § 424 govern beneficiary eligibility.

Under the home health PPS, Medicare makes payments for home health services on the basis of a national standardized 60-day episode payment, adjusted for case-mix and wage-index. Medicare requires HHAs to use the outcomes and information assessment set to assess potential patients, and re-assess existing patients. The outcomes and assessment information set is a patient assessment data set designed to measure the patient status and functioning, and outcomes of home health care. The outcomes and assessment information set is electronically transmitted to State agencies via the home assessment validation entry software. Within the home assessment, validation entry software is a grouper that determines the appropriate home health resource group and the 5-character health insurance PPS code, which the provider of services enters on the Medicare claim.

In order for home health services to be covered by Medicare, beneficiaries generally must be confined to their home; under the care of a physician; under an established plan of care; and in need of skilled nursing services on an intermittent basis, or skilled physical, speech or occupational therapy.

FI Responsibility

The FI responsibilities are defined in 42 CFR § 421.100. CMS contracts with FIs, usually large insurance companies to assist them in administering the home health benefits program. The FI for Lifeline is Palmetto Government Benefit Administrator (Palmetto).

Among other responsibilities, FIs are responsible for processing claims, assisting in the application of safeguards against unnecessary utilization of services, conducting provider audits and resolving provider disputes.

Lifeline Corporate Integrity Agreement

The United States, through, the United States Attorney's Office for the Middle District of Florida and the OIG of the Department of Health and Human Services (HHS), entered into a Settlement Agreement (Agreement) with Lifeline. As part of the Agreement, the OIG and Lifeline entered into a comprehensive 5-year corporate integrity agreement beginning on October 26, 2001. The corporate integrity agreement covers all of Lifeline's operations and subsidiaries. In addition to other requirements, the corporate integrity agreement requires that an independent review organization perform annual claim reviews of a sample of Lifeline's Medicare claims.

OBJECTIVE, SCOPE AND METHODOLOGY

Objective

The objective of this review was to determine whether Medicare payments to Lifeline for home health services met Medicare eligibility and reimbursement requirements.

Scope and Methodology

Our review covered service dates from October 26, 2001 through June 30,2002. For this period, Medicare payments to Lifeline for 4,617 home health claims totaled $10,876,845.

To accomplish our objective we:

- reviewed applicable laws, regulations, Medicare guidelines, and FI guidance for home health services

- extracted from the Data Extraction System user interface, all Lifeline home health PPS claims for the period of our audit

- selected a random sample of 100 paid claims totaling $255,217 (See Appendix A for our sampling methodology)

- obtained supporting medical and financial records documentation from Lifeline for each sample claim

- obtained supporting medical records documentation for each sampled claim and interviewed the ordering physician

- whenever possible, interviewed the beneficiary, a family member, or an acquaintance familiar with their health condition

- obtained the assistance of a Program Safeguard Contractor to review all documentation obtained and determine whether the home health services rendered by Lifeline met Medicare eligibility and reimbursement requirements

- reviewed the Program Safeguard Contractor's reported results

- utilized an unrestricted variable appraisal program to estimate overpayments to Lifeline (see Appendix B for the results and projections of our sample.)

- conducted an exit conference with members of Lifeline management to provide them with the preliminary results of our review

We did not review the overall internal control structure of HHA or of the Medicare program. We did not test the internal controls because the objective of our review was accomplished through substantive testing.

Our review was made in accordance with Generally Accepted Government Auditing Standards. Fieldwork was performed in the States of Kentucky and Florida and included visits to Lifeline's provider locations, their home offices, physicians' offices, and beneficiaries' residences. Although we initiated fieldwork in December 2002, we suspended work from March through June 2003. We worked primarily with the Program Safeguard Contractor from July through October 2003.

We issued a draft report to Lifeline on March 12, 2004 and received Lifeline's comments on April 20, 2004. Lifeline officials attached to their response numerous copies of supporting medical records documentation and the results of their reviews. The entire text of the auditee response, excluding attachments, is included in Appendix C.

For the period of October 26, 2001 through June 30, 2002, Lifeline received payment for home health services that did not meet Medicare eligibility and reimbursement requirements resulting in overpayments of about $1,173,330. Medical reviewers determined from our random sample of 100 claims that Lifeline received payment for: beneficiaries who were either not homebound or whose homebound status was not adequately documented (9 claims); beneficiaries who had no need for qualifying skilled services (5 claims); services that were not reasonable or necessary for the beneficiary's condition (1 claim); services not properly authorized by a physician (2 claims); and services not supported by documentation (2 claims).

We believe that Lifeline billed for these services because they may not have effective admission and financial controls in place to ensure that every beneficiary admitted to the home health program met the eligibility criteria and every service billed met the Medicare reimbursement requirements.

The following chart summarizes the medical review results of our sample (See Appendix A).

Reason Claim Not Accepted	No. of Claims	Reimbursed Amount for Claims Not Accepted
Beneficiaries not Homebound or for whom Homebound Status was not Adequately Documented	9	$26,530.37
No Need for Qualifying Skilled Service	5	8,280.64
Services not Reasonable or Necessary	1	926.35
Services not Authorized by a Physician	2	5,865.59
Services not Supported by Documentation	2	2,341.28
Total Not Accepted	19	$43,944.23

Services to Beneficiaries Who Were Not Homebound or Whose Homebound Status Was Not Adequately Documented

Nine claims were for services provided to beneficiaries who were not homebound or for whom Lifeline did not document the homebound status. For one claim, the beneficiary was not homebound and not confined to the home as required by 42 CFR § 424.22. This beneficiary independently managed activities of daily living and could independently ambulate to the vehicle when in need of transportation. For the remaining eight claims, the skilled care providers did not substantiate the homebound status of the beneficiaries in the outcomes and assessment information set as required by regulations at 42 CFR § 484.55.

Services to Beneficiaries With No Need for Skilled Services

Five claims were for services provided to beneficiaries with no need for skilled services. The information contained in the medical records documentation did not substantiate the beneficiary's need for qualifying skilled services as required by 42 CFR § 409.32.

Some of the reasons cited by the medical reviewers include: (1) a skilled nurse was to assess nutritional status of a beneficiary. The beneficiary could have reported this information to their treating physician, rather than a skilled nurse; (2) a beneficiary was able to feed self independently via feeding tube and maintain the feeding tube at the start of the episode and did not require intermittent skilled nursing; (3) a beneficiary received occupational therapy services however they are only covered when the eligibility for home health services are established by the prior need for intermittent skilled nursing, speech-language pathology, or physical therapy services; (4) a family member was able to perform the procedures to achieve a beneficiary's health goal from the start of care, and therefore skilled care services were not required; and (5) skilled nursing services were provided to a beneficiary prior to discharge from an acute care

hospitalization, and the beneficiary was able to prepare meals, complete light housekeeping duties, and transfer herself.

Services Not Reasonable And Necessary

One claim contained a skilled nurse visit that did not meet Medicare reimbursement requirements because the services covered by the visit were not reasonable and necessary as required by 42 CFR § 409.44. Services were not reasonable and necessary because medical records documentation showed that a family member was willing, capable and, in fact, performing the services covered by that visit. As billed by Lifeline, this claim contained five visits and qualified for reimbursement under the standardized 60-day episode payment. Disallowance of one visit changed this claim to a low utilization payment adjustment claim reimbursable on a national per-visit amount.

Services Not Properly Authorized By a Physician

Two claims contained services that were not authorized by a physician as required by 42 CFR § 409.43. In both instances, the physicians who ordered the home health services did not sign a plan of care authorizing physical therapy services. Although a physical therapy assessment was performed there were no subsequent physician orders authorizing these or any physical therapy services. Removal of the unauthorized services required both claims to be recalculated. One of the claims still qualified for the standardized 60-day episode but the utilization supported a different home health resource group. Because of the reduction of the services, the other claim no longer qualified for the 60-day episode and became a low utilization payment adjustment reimbursable on a national per-visit amount.

Services Not Supported By Documentation

Two claims were for services not supported by Lifeline medical records documentation. The medical records documentation did not include the outcomes and assessment information set for the periods under review as required by 42 CFR § 484.55.

Results of Services Not Meeting Medicare Eligibility and Reimbursement Requirements

We estimate that Lifeline received Medicare payments for services that did not meet Medicare eligibility and reimbursement requirements totaling about $1,173,330 out of a universe of $10,876,845 (see Appendix B).

Lack of Effective Administrative and Financial Controls

We believe that the unallowable home health services identified by medical review occurred because Lifeline may not have effective admission and financial controls in place to ensure that every beneficiary admitted to the home health program met the eligibility criteria and every service billed met the Medicare reimbursement requirements.

Recommendations

We are recommending that Lifeline:

- Examine the errors identified by our contracted medical review, and develop additional admission controls, financial controls, and training to ensure that these types of errors do not occur in the future.

- Work with the FI to reimburse the Medicare program the estimated overpayment of $1,173,330. Any refunds made after June 30, 2002 relating to claims during the period of review should be considered as reductions to the estimated overpayment of $1,173,330.

Auditee Comments

In a written response to our draft report, dated April 20, 2004, Lifeline expressed its disagreement with the medical review results and requested information regarding the sampling methodology utilized by the OIG. Lifeline also requested that the OIG review their response and make appropriate revisions to the draft report.

Lifeline's disagreement with the medical review results was based on reviews conducted by Lifeline personnel and an outside consulting firm. Lifeline stated that neither their review nor the outside consulting firm's found the vast majority of the denied claims to be substantiated. However, they did agree with three findings regarding the (not-homebound) status of two patients and one patient whose services were not authorized by a physician. In one case, Lifeline's internal review had detected the problem and already refunded $1,722.72 to the Medicare program on October 31, 2002.

Lifeline officials attached to their response numerous copies of supporting medical records documentation and the results of their reviews. The entire text of Lifeline's response, excluding attachments, is included in Appendix C.

Office of Inspector General Response

Regarding Lifeline's issues with the sampling methodology, we provided them with information relating to the methodology utilized to select the sample and project the results of the medical review. In a telephone call on May 13, 2004, Lifeline indicated that they had no additional comments, at this time, regarding this matter.

The remaining issue concerning denials of home health services relate to conflicting conclusions reached by medical review experts. Chapter 1-105 of the HHS Grants Administration Manual sets forth Department policy for the resolution of audit findings, by stating the Department's Operating Division (in this case – the Centers for Medicare & Medicaid Services) is responsible for resolving all audit findings. Considering Lifeline's response includes numerous attachments requiring further medical review; we will make the attachments available to the named action official as well as the FI for appropriate consideration in the audit resolution process.

The refund by Lifeline in October 2002, corresponding to a sample claim, was made after the period of audit. Therefore, it was correctly included in estimating the $1,173,330 overpayment. Any refunds made by Lifeline after the period of our review, for claims included in the review period, should be used to offset the estimated overpayment. We have adjusted our recommendations accordingly.

Medical reviewers identified 2 claims as underpayments, citing that there should have been a significant change in condition adjustment to the 60-day episode payment. Section 4.1.7.2.1 of the Home Health Training Manual, published by Palmetto, states that the provider is granted the option to bill the significant change in condition adjustments in situations where the health insurance PPS code weight increases, and the agency is at a financial disadvantage. However, if the weight of the code decreases then the agency does not have an option and must bill the significant change in condition adjustment on the claim.

Since the circumstances would be at the option of Lifeline and Lifeline records indicated that there was an increase in the code, it would be up to Lifeline to file claims with the increased code. This information is only provided as a disclosure.

APPENDICES

APPENDIX A

SAMPLING METHODOLOGY

OBJECTIVE:

The sample objective was to estimate overpayments for claims containing home health services that did not meet Medicare eligibility and reimbursement requirements. To achieve our objective, we selected an unrestricted random sample of home health claims from a universe paid to Lifeline during the period of October 26, 2001 through June 26, 2002.

POPULATION:

The universe consisted of 4,617 paid claims for home health services representing $10,876,844.91 in home health benefits paid by the FI to Lifeline in Kentucky and Florida for the period of October 26, 2001 through June 30, 2002.

SAMPLING UNIT:

The sampling unit was a paid home health final action claim for a Medicare beneficiary. A final action claim includes all services claimed by Lifeline for the 60-day episode period covered by the claims.

SAMPLING DESIGN:

An unrestricted random sample of paid claims in Kentucky and Florida.

SAMPLE SIZE:

A sample of 100 claims.

ESTIMATION METHODOLOGY:

Using the HHS, OIG, Office of Audit Services (OAS) RATS-STATS Variable Appraisal Program, we estimated the overpayments for unallowable claims from the sample to the universe.

APPENDIX B

STATISTICAL SAMPLE INFORMATION

POPULATION	SAMPLE	ERRORS
Items: 4,617 Claims	Items: 100 Claims	Items: 19 Claims
Dollars: $10,876,845	Dollars: $255,217	Dollars: $43,944

The sample projection was obtained using the RAT-STATS unrestricted variable appraisal program. We reported the lower limit of the 90 percent confidence interval. Details of our projection appear below:

Projection of Sample Results
90 Percent Confidence Interval

Point Estimate:	$2,028,905
Precision Amount:	$ 855,576
Lower Limit:	$1,173,330

The Lifeline Health Group, Inc.

James M. Frazer
President

jim.frazer@lifelineweb.com

600 Clifty Street
Somerset, Kentucky 42503

April 20, 2004

Mr. Charles J. Curtis
Regional Inspector General for Audit Services
Region IV
61 Forsyth Street, S.W. – Suite 3T41
Atlanta, GA 30303

Re: The Lifeline Health Group, Inc.
Report # A-04-03-01000

Dear Mr. Curtis:

Enclosed you will the preliminary response of The Lifeline Health Group, Inc., to the Draft Report styled "Review of Home Health Services provided by the Lifeline Health Group, Inc.", March 2004.

I spoke this morning with Mr. Donald Czyzewski concerning our recent request for information. He indicated that he would be in contact within the next few days. Although we may respond to the sampling methodology, we are submitting our comments to the Program Safeguard Contractor's findings.

Thank you for your cooperation in this matter.

Yours very truly,

James M. Frazer
Attorney at Law
President and General Counsel

Phone: (606) 679-4100
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Debra Minton
VP of Human Resources and Compliance

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THE LIFELINE HEALTH GROUP, INC.

RESPONSE TO DRAFT OIG REPORT

"REVIEW OF HOME HEALTH SERVICES PROVIDED BY THE LIFELINE HEALTH GROUP, INC."

March, 2004

Report Number A-04-03-01000

Submitted by:

James M. Frazer
Attorney at Law
President and General Counsel

Debra Minton
VP For Compliance

Submitted: April 21, 2004

THE LIFELINE HEALTH GROUP, INC.
RESPONSE TO DRAFT OIG REPORT
"REVIEW OF HOME HEALTH SERVICES PROVIDED
BY THE LIFELINE HEALTH GROUP, INC."
March, 2004
Report Number A-04-03-01000

The Lifeline Health Group, Inc., does hereby make its response to the Draft Report submitted to the company by letter dated March 12, 2004. To properly address the issues raised by the Draft Report, it is necessary to submit a large amount of information. Consequently, we would apologize in advance for the large amount of paperwork contained in this response.

The various entities of The Lifeline Health Group, Inc., entered into a Corporate Integrity Agreement with the Office of Inspector General in October, 2001. The agreement contained the usual and customary provisions, and The Lifeline Health Group, Inc., has complied with all the provisions of the agreement since the date of the execution. The CIA required Lifeline to obtain the services of an Independent Review Organization and to have the IRO review annually 30 records. This has been done for the last two years, and the report furnished to the OIG. At a meeting between one Barbara Frederickson, of the Office of Counsel to the Inspector General and representatives of Lifeline, it was mutually agreed that 30 records were perhaps a small number, and that 100 records should be selected for review by the OIG.. That process began in the fall of 2002, with representatives of the Audit Services division meeting on several occasions with Senior Management of Lifeline, along with the representatives obtaining copies of various records from the company. The Lifeline Health Group, Inc., welcomed the audit by the OIG and cooperated fully with the representatives during the process.

An exit interview was conducted by field representatives of the Audit Division, at which The President of the company, the corporate compliance officer, Senior Clinical Managers and Quality Assurance personnel attended. At that time, The Lifeline Health Group, Inc., was furnished with the preliminary results of the Program Safeguard Contractor, and has had the same in its possession since the Fall of 2003. At that time, Lifeline's Senior Clinical Managers and its Quality Assurance personnel began review of each of the episodes of care which were set out by the Program Safeguard Contractor as being claims that were improperly paid by the Medicare Program to Lifeline.

Additionally, The Lifeline Health Group, Inc., sought an additional independent review by an outside Consulting firm. The results of the findings relating to the specific patients alleged to have been episodes that were improperly paid will be summarized hereinafter. Both the independent review and the Lifeline personnel did not find the vast majority of the denied claims to be substantiated.

The Lifeline Health Group, Inc., also questions the validity of the sampling techniques. Requests have been made for working papers as to the methodology of the

selection process, but as of the date of the writing of this response, no response has been received. Lifeline requests that it be permitted to supplement this response following receipt of information from the Audit Division.

This part of the response will address the issues raised by the Program Safeguard Contractor.

I. **THE PROGRAM SAFEGUARD CONTRCTOR WAS NOT CORRECT IN ITS FINDINGS REGARDING THE CLAIMS.**

The specific cases will be discussed in the order of the type of claim, i.e. not homebound, not reasonable and necessary, etc., with the exception of the case of [redacted] which will be discussed first.

A [redacted]: The contractor found that the beneficiary did not meet the eligibility requirement for home health services, in that "the records submitted by the HHA do not support the required homebound status as recorded in the OASIS". In other words, that the patient was not homebound. In the ordinary course of internal review, Lifeline discovered that it has improperly billed for the services rendered to the beneficiary. The sums of money that were paid to the company were returned to the Medicare program on October 31, 2002. This was well before the sample was selected. Consequently, as Lifeline identified the problem and made proper refunds, this case should not be used to calculate any refund to Medicare..

B. **Patients Alleged Not to be Homebound**: The Contractor found that 9 beneficiaries were allegedly not homebound, or that their homebound status was not adequately documented. These patients are as follows: [redacted] (see above); [redacted] The specifics of each will be addressed hereinafter.

Attached to this response, as "Exhibit A" is Section 204.1 of the Home Health Manual (HIM – 11) which relates to homebound status. For your information, the portion of the manual is set forth in its entirety.

With the above in mind, each case will be addressed: (Detail of each case is attached to this response, including copies of referenced documentation taken from the individual patient chart)

1. [redacted] While Lifeline believes that, in fact, the patient was homebound during the time of the episode, it must concede that the documentation contained in the record is less than convincing. The company will be refunding the sums of money received from Medicare.

2. [redacted] Both the 485 and the OASIS document support the homebound status of the beneficiary. The overall condition of the patient supports homebound status in the absence of specific statements indicating that she is not homebound. The patient was referred to home health following surgery. Upon evaluation by the physical therapist, it was determined that the patient needed a wheeled walker in order to ambulate. The referring physician requested nursing and therapy services for the patient, as well as home health aide. In fact, physical therapy services did, in fact, improve the patient's gait. In short, this was an elderly patient that had recently undergone surgery and required the use of a wheeled walker. It would appear from the record that even getting around the house, much less leaving it, would certainly require a "considerable and taxing effort".

3. [redacted] The patient has been discharged from a Rehab facility on February 21, 2002, and had to be readmitted two days later with fluid overload. On February 26, 2002, she was newly diagnosed with lung cancer and began a new course of oral chemotherapy. She was admitted to home health on March 5, 2002. The patient, upon admission, had a deficit in ambulation, transferring and bathing. She also used a walker and had poor balance. Additionally, she also attended dialysis three days per week. The regulations clearly permit a beneficiary to meet the guidelines for homebound status if he or she leaves for medical treatment, specifically dialysis. Clearly, this patient met the definition of "homebound".

4. [redacted] This patient suffered from bilateral amputations of his legs, a below knee amputation of the right knee and an above knee amputation on the left side. He was admitted to provide rehabilitation therapy and to help him get ready for new prosthesis. The development of pressure ulcers made the therapy extremely difficult, and at one time, during the episode in question, could even transfer from chair to chair. He was confined to a wheelchair with these double amputations, and it is difficult to imagine how this patient could not be homebound under the definitions set forth in the HIM-11.

5. [redacted] This patient was discharged to home health having undergone a Girdlestone procedure, in which the femoral head is removed without replacement. The patient's leg was left shorter and less stable. At the time of admission to home health, she used a walker and a wheelchair. Throughout the episode of care, the patient was dependent upon a walker and wheelchair. The therapist's notes indicate that patient will most likely always require the use of assistive devices. During the episode of care her ability to ambulate increased from 25 feet to 75 feet. Hospital notes attached to the detailed case statement are totally consistent with the findings of the Lifeline personnel. This patient could obviously not leave the home without a considerable and taxing effort and with the help of assistive devices.

6. [redacted] This patient sustained a CVA and was referred to home health following a hospital stay and a stay in a skilled nursing facility. At initial evaluation, the patient was found to be dependent in grooming, dressing, ambulation and transferring, in addition to suffering from frequent bowel incontinence. He moved about the home on a rolling walker and a slow wide spread gait. Throughout the episode of care, the patient was provided with various exercises to improve strength, and ambulation. Over the course of treatment, the patient progressed to the point that he was able to walk in his home without a device and used a cane outside on level surfaces. The patient was clearly homebound at the time of admission to home health, and during the period of time that he remained a patient. Upon meeting goals, patient was discharged.

7. [redacted] was admitted to home health with services earlier than the episode in question with major depression. She suffered with degenerative back disease, which she sometimes described as intractable. The patient wore a back brace and ambulated with the use of a cane. Her freedom of movement was further impaired by macular degeneration, causing vision impairment. During the episode of care in question, [redacted] continued to suffer with her joint disorder. She also was seeing an orthopedist, and was scheduled for an MRI and a new back brace. She continued to need a cane for ambulation. The patient's condition was such that she had a normal inability to leave home, and leaving home would have required a considerable and taxing effort.

8. [redacted] was discharged from the hospital on March 16, and admitted to home health the next day. During her three week hospitalization period, she suffered from malnutrition caused by a bowel obstruction and had surgery to remove portions of her intestine. At the time of discharge, [redacted] had an abdominal wound measuring 23 centimeters which was held in place with 26 staples and two sutures, Patient required a bedside commode and a hospital bed as she did not have strength to walk to the toilet, and required percocet to relieve pain. Dressing changes were done on the wound to the abdomen, as well as providing a home health aide to assist the patient with sponge baths in a chair. When the patient's condition improved and the wound was fully granulating, the patient was discharged.

C. **Patients which the contractor alleges had no need for skilled services.**
Five patients were identified by the Contractor as having no need for skilled services. These were: [redacted]

1. [redacted] Patient was referred from physician complaining of lack and strength and fatigue. Nurse performed assessment, noting that patient claimed independence in bathing, but had a foul body odor. Nurse performed a diet assessment and gave nutritional advice about improving anemic condition. OT was asked to evaluate, but did not reveal a need for intervention. By the end of

the third visit, it became apparent that the patient was no longer homebound, and patient's episode of care was terminated upon that basis.

2. [redacted] was a terminal patient that suffered from advanced cancer of the mouth. The nurse was requested by the physician to monitor the nutrition and hydration status of the patient. The oral cancer grew to the point that tissue had to be removed at the ER. Following this procedure, patient was transferred to hospice. It is submitted that this claim should have been allowed on the basis of Section 205.1.B.1 of the HIM 11. (Full copy attached)
3. [redacted] The Contractor denied this claim on the basis that the documentation in the record does not show current or prior need for intermittent skilled nursing or therapy services. The patient had an amputation at the knee on the right side and used a wheel chair. PT performed an evaluation on December 14, 2001. Due to the physical condition of the patient at the time, the patient could not be assessed for ambulation. The physical therapist planned to continue with therapy at such time as the patient was able to participate in therapy. The PT consulted with the physician, and obtained an order placing physical therapy on hold until such time as the OT succeeded in making the patient ready to participate. Consequently, a physical therapy plan of care was established prior to the initiation of OT, and therefore meets the guidelines. (For more detailed analysis, and copies of documents, please refer to the attached file of [redacted]
4. [redacted] The patient's condition supported the need for skilled care by nursing. Skilled assessments and interventions were performed including teaching the family basic supportive nursing measures. Home Health Aide services were appropriate. The patient's condition continued to deteriorate, and he expired at home. (See complete file of [redacted] and reference is made to HHA Manual, Sec. 205.1.B1.3.
5. [redacted] The patient's condition supported the need for skilled care by nursing after a 7 day hospitalization for cardiac problems. Skilled assessments and interventions were performed. See Home Health Agency Manual Sec. 205.1.B.1. Patient requested discharge after 3 visits, making this a LUPA.

D. **Patient which the Contractor alleges the services were not reasonable and necessary.**

[redacted] Five visits were performed within a short period of time to assure that wound care was being properly performed was reasonable. The Home Health Manual Sec. 205.1.B.3 states that teaching/training activities (including teaching wound care) would be considered reasonable and necessary when it is consistent with the patient's functional loss, illness or injury. (See detailed analysis of patient's medical chart attached)

E. **Patients which the Contractor alleges that the services were not supported by documentation.**

1. [redacted] The Contractor alleges that there was no OASIS Assessment made for the episode of care. The chart contains a follow-up OASIS completed March 15, 2002, for the period in question, and is attached in the detailed analysis.
2. [redacted] The Contractor alleges that there was no OASIS Assessment made for the episode of care. The chart contains a follow-up OASIS completed April 10, 2002, for the period in question, and is attached in the detailed analysis.

F. **Patients which the Contractor alleges received services that were not auyhorized by a physician.**

1. [redacted] We concur with the findings of the Contractor. There was an order in the chart, which appeared to be signed by a physician, but was, in fact, signed only by the therapist.

2. [redacted] Attached is a detailed analysis, along with copies of orders which were in the chart. The visits were in fact ordered by a physician and were signed by the physician. Therefore, the disallowance should not stand.

G. **GENERAL COMMENTS CONCERNING THE SPECIFIC CASES**

Through this entire process, Lifeline has attempted to fully cooperate with the Office of Inspector General, Audit Division. From the initial request by Counsel to the OIG, Lifeline welcomed the review of additional claims, as any review will help the company to continue to fully comply with the various statutes, regulations and directives relating to the Medicare and Medicaid program. Senior management met with representative of the Audit Division, and attempted to be as cooperative as possible. Field offices willingly answered any questions that the auditors had concerning specific cases, and the Company tried to expedite the requests as much as possible. The cooperation of the audit division during this process is greatly appreciated by The Lifeline Health Group, Inc.

Lifeline recognizes that there is a certain amount of subjectivity that is inherent in the audit process. However, there is no specific requirement as to the manner of documenting items such as homebound status, as evidenced by the HIM-11. We have attempted to set forth in great detail the reasons that Lifeline disagrees with the findings of the Program Safeguard Contractor, and believe strongly that we are correct in our interpretation. Had we felt that it is an improperly billed claim, we would have refunded the amount of the claim, as we did in the case of [redacted] discussed earlier in this response.

The company has developed many procedural safeguards to help insure that improper claims are not submitted. These include, among other things, extensive orientation of new nurses and therapists, including the mandated compliance training and

training in the home health legal requirements. Ongoing education is conducted on various aspects, ranging from the basics of home health to complex patient care issues. All plans of care are reviewed by supervisory clinicians for accuracy prior to submission to physicians, case care conferences among disciplines are mandatory, and random reviews of charts for accuracy and compliance are conducted by our Quality Assurance Department. We even have a clinician in the computer department to review and submit OASIS documents. Prior to submission of bills for payment, we have an elaborate process which requires a complete review of the chart prior to submitting the final claim, and a certification by a nurse as to the appropriateness of the bill.

Corporate compliance is a part of the culture of Lifeline. The President of the company has personally participated in all annual compliance meetings, which involve 24 offices in Kentucky and Florida, along with the Corporate Compliance Officer, and it is demanded of all employees that our code of conduct is strictly followed. Our employees are all aware of the Corporate Integrity Agreement and generally its provisions. We encourage our employees to follow not only the letter of the law, but the spirit and intent also.

As stated earlier herein, we do believe very strongly that the claims that are the subject of this response were properly submitted claims, and that the claims met all the requirements of the Medicare laws and regulations. While documentation may not have been of the highest standards, it nonetheless, as evidenced by the attachments to this response, established the propriety of the claim. We therefore respectfully request that the Audit Division review our response and make the appropriate revisions to the draft report.

[redacted]

This report was prepared under the direction of Charles Curtis. Other principal Office of Audit Services staff who contributed include:

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