

**CORPORATE INTEGRITY AGREEMENT**  
**Ambleside, Inc.**

This Corporate Integrity Agreement ("CIA") is entered into between Ambleside, Inc. ("Ambleside") and the Office of Inspector General ("OIG") of the United States Department of Health and Human Services ("HHS"). Pursuant to this CIA, Ambleside agrees to undertake the compliance obligations outlined below. Contemporaneously with this CIA, Ambleside is entering into a Settlement Agreement with the United States, and this CIA is incorporated by reference into the Settlement Agreement.

**I. PREAMBLE**

Ambleside is a Medicaid participating provider in the Community Alternatives Program for Persons with Mental Retardation/Developmental Disabilities of the State of North Carolina — a program designed to give persons with mental retardation and/or developmental disabilities a cost-effective alternative to care in an intermediate care facility for the mentally retarded ("ICF/MR"). The program's goal is to allow clients to live in the community with as much independence as possible.

Ambleside agrees to implement a Corporate Integrity Program designed to prevent fraud, abuse, and false billing to Medicaid, Medicare and other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)), by Ambleside and by its subsidiaries, officers, directors, employees, independent contractors, and agents who are directly involved in or responsible for the delivery, marketing, or documentation of services reimbursable by Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)) ("Federal health care program requirements") and those who are involved in or directly or indirectly responsible for the preparation or submission of claims, reports, or other requests for reimbursement for such services ("Covered Persons"). The Corporate Integrity Program shall be maintained so as to ensure that Ambleside and each of its Covered Persons maintains the business integrity required of a participant in Federal health care programs, and that Ambleside is in compliance with all laws and regulations applicable to such programs and with the terms of the CIA set out below.

**Glossary of Terms.** This CIA contains the following terms. This glossary is provided for convenience only. The obligations under this CIA are in no way limited to the following services:

**Client Behavior Intervention ("CBI")** — This refers to a variety of services

provided to both adults and children who are at risk for intensified disability or an inability to live successfully in the community. CBI is provided by paraprofessional staff. CBI seeks to promote and assist in the development of skills, behaviors and responsibilities needed by the client to function successfully in the community with the greatest possible degree of self-determination and independence.

**Community Alternatives Program for Persons with Mental Retardation/Developmental Disabilities ("CAP-MR/DD")**— This program provides home and community care to clients who otherwise would be institutionalized in an ICF/MR. CAP-MR/DD services include community inclusion, described below. The training and services described in this Glossary are provided through the CAP-MR/DD.

**Community Inclusion ("CI")** is a habilitation service that provides direct instruction on the independent living and social skills needed for basic interactions with others in one's home and in the community. The service may involve instructing the client in skills and behaviors that are appropriate to a specific setting or activity, such as the following: eating a meal with others or working with others to complete assignments or chores; teaching the client to complete activities or transactions that are a part of living in a non-institutional setting, such as accessing public transportation, using a vending machine or crossing the street; and developing cognitive skills, especially in the areas of reasoning, identifying options and making choices or decisions. The service usually involves describing and modeling the activity, followed by the client completing the activity with the instructor's guidance or oversight, as needed. The service is provided in the location(s) at which the skill or activity will be utilized.

**Progress Notes** — In order to be valid, progress notes must be signed and dated by the individual providing the CI services. In addition, progress notes must document the date of the service, the amount of time involved in the service, and a description of the activities related to the goals/objectives of the service.

## **II. CORPORATE INTEGRITY POLICIES AND CODE OF STANDARDS**

The period of the compliance obligations assumed by Ambleside under this CIA shall be four (4) years from the effective date of this CIA (unless otherwise specified). The effective date of this CIA shall be the date on which the final signatory of this CIA

executes this CIA.

Sections V, VI, VII, and VIII shall expire no later than 120 days from the OIG's receipt of (1) Ambleside's final annual report or (2) any additional materials submitted by Ambleside pursuant to the OIG's request, whichever is later.

All reports and notifications required under this CIA shall be sent to:

Civil Recoveries Branch -- Compliance Unit  
Office of Counsel to the Inspector General  
Office of Inspector General  
U.S. Department of Health and Human Services  
Cohen Building Room 5527  
330 Independence Avenue, S.W.  
Washington, D.C. 20201  
(202) 619-2078 Telephone  
(202) 205-0604 Fax

All OIG correspondence and notifications sent to Ambleside shall be sent to:

Elizabeth Osborne  
Corporate Compliance Officer  
Ambleside, Inc.  
670-C, Radio Drive  
Lexington, NC 27292  
(800) 769-4159  
(336) 224-2924

Unless otherwise specified, all notifications and reports required by this CIA may be made by certified mail, overnight mail, hand delivery or other means, provided that there is proof that such notification was received. For purposes of this requirement, internal facsimile confirmation sheets do not constitute proof of receipt.

Ambleside agrees to implement the following measures:

**A. Compliance Officer and Compliance Committee**

For at least the term of this CIA, Ambleside shall continue to have a Compliance

Officer responsible for developing and implementing policies, procedures, and practices designed to ensure compliance with the requirements set forth in this CIA and with Federal health care program requirements. The Compliance Officer shall be a member of senior management of Ambleside, shall make periodic (at least quarterly) reports regarding compliance matters directly to the CEO and/or to the Board of Directors of Ambleside, and shall be authorized to report on such matters to the Board of Directors at any time. The Compliance Officer shall be responsible for monitoring the day-to-day compliance activities engaged in by Ambleside, as well as for any reporting obligations created under this CIA.

Any changes in the identity or position description of the Compliance Officer, or any actions or changes that would affect the Compliance Officer's ability to perform the duties necessary to meet the obligations in this CIA, must be reported to OIG, in writing, within 15 days of such a change.

Within 90 days after the effective date of this CIA, Ambleside's Board of Directors shall create a Compliance Committee that shall be responsible for the Corporate Integrity Program. The members of the Compliance Committee shall at least include the Compliance Officer (presently Elizabeth Osborne), the Chairman of the Board of Directors (presently Delmas E. Minshew), and representatives of relevant components of Ambleside (*i.e.*, billing, human resources, *etc.*). The Compliance Officer will have primary responsibility for compliance operations and reporting requirements. Changes to the membership of the Compliance Committee will be noted in the Annual Report.

## **B. Written Standards**

**1. *Code of Conduct.*** Within 90 days of the effective date of this CIA, Ambleside shall establish and distribute to all Covered Persons a Code of Conduct. Ambleside shall make the promotion of, and adherence to, the Code of Conduct an element in evaluating the performance of all Covered Persons. The Code of Conduct shall, at a minimum, set forth:

- a. Ambleside's commitment to full compliance with all Federal health care program requirements, including its commitment to prepare and submit accurate claims consistent with such requirements;
- b. Ambleside's requirement that all of its Covered Persons shall be expected to comply with all Federal health care program

requirements and with Ambleside's own Policies and Procedures as implemented pursuant to this CIA;

c. the requirement that all of Ambleside's Covered Persons shall be expected to report to the Compliance Officer or other individual designated by Ambleside suspected violations of any Federal health care program requirements or of Ambleside's own Policies and Procedures;

d. the possible consequences to both Ambleside and Covered Persons of failure to comply with all Federal health care program requirements and with Ambleside's own Policies and Procedures or of failure to report such non-compliance; and

e. the right of all individuals to use the Confidential Disclosure Program described in this CIA, and Ambleside's commitment to maintain confidentiality, as appropriate, and non-retaliation with respect to disclosures.

Within 90 days of the effective date of the CIA, each Covered Person shall certify, in writing, that he or she has received, read, understood, and will abide by Ambleside's Code of Conduct. New Covered Persons shall receive the Code of Conduct and shall complete the required certification within two weeks after becoming a Covered Person or within 90 days of the effective date of the CIA, whichever is later.

Ambleside shall annually review the Code of Conduct to determine if revisions are appropriate and shall make any necessary revisions based on such a review. Any such revised Code of Conduct shall be distributed within 30 days of finalizing such changes. Covered Persons shall certify that they have received, read, understood and will abide by the revised Code of Conduct within 30 days of the distribution of such revisions.

**2. Policies and Procedures.** Within 90 days of the effective date of this CIA, Ambleside shall implement written Policies and Procedures regarding the operation of Ambleside's compliance program and its compliance with Federal health care program requirements, especially those statutes, regulations, policies, procedures and guidelines related to the delivery of home and community care services, including the requirement that all services be accurately documented by the individual providing the service and accurately represented in any claims for payment. At a minimum, the Policies and

Procedures shall address:

- a. the subjects relating to the Code of Conduct identified above;
- b. the requirement that the Compliance Officer perform on-site inspections and periodic reviews (at least quarterly) of documents, including, but not limited to, Covered Persons' time sheets, progress notes (including but not limited to progress notes for CI and CBI), medical records, billing sheets, and census reports from each residential facility to verify compliance with Medicaid, Medicare and other Federal laws and regulations, as well as Ambleside's own policies and procedures;
- c. the requirement that the number of billed CI and CBI hours accurately reflect the number of hours recorded in the CI and CBI progress notes;
- d. the requirement that all CI and CBI progress notes be signed and dated by the Covered Person who provided the services documented in the progress note;
- e. the requirement that the clients' medical records and progress notes accurately reflect the client's location;
- f. the requirement that the clients be present at locations that are appropriate to the services being provided;
- g. the requirement that all CI and CBI progress notes include a signed certification by the Covered Person who provided the service that the stated hours and services are true and accurate to the Covered Person's knowledge;
- h. the requirement that all CI and CBI progress notes be signed and certified as described above *before* seeking payment for those services, and in any event, no less than 24 hours from the date the services described in the progress notes were rendered;
- i. the requirement that all Covered Persons' time sheets include a

signature and certification from the Covered Person that the stated dates and hours worked are true and accurate to the Covered Person's knowledge;

j. the requirement that all Covered Persons' time sheets be signed and certified as described above, within two weeks of the dates worked;

k. the requirement that the Covered Person signing the time sheets and CI and CBI progress notes be the same individual who actually worked the hours and provided the services described therein;

l. the requirement that *individual* CI and CBI services be billed only for CI and CBI services that are provided to *one* client at a time;

m. the requirement that payment be returned to Medicaid or any other relevant payor for services that do not satisfy the above-listed policies or that otherwise violate the policies, regulations and laws applicable to the relevant payor.

The Policies and Procedures shall be available to OIG, upon request. Within 90 days of the effective date of the CIA, the relevant portions of the Policies and Procedures shall be distributed to all individuals whose job functions are related to those Policies and Procedures. Appropriate and knowledgeable staff shall be available to explain the Policies and Procedures.

At least annually (and more frequently if appropriate), Ambleside shall assess and update as necessary the Policies and Procedures. Within 30 days of the effective date of any revisions, the relevant portions of any such revised Policies and Procedures shall be distributed to all individuals whose job functions are related to those Policies and Procedures.

### **C. Training and Education**

**1. *General Training.*** Within 90 days of the effective date of this CIA, Ambleside shall provide at least two hours of general training to each Covered Person. This training, at a minimum, shall explain Ambleside's:

a. CIA requirements; and

- b. Compliance Program (including the Code of Conduct and the Policies and Procedures as they pertain to general compliance issues).

All training materials shall be made available to OIG, upon request.

New Covered Persons shall receive the general training described above within 30 days of becoming a Covered Person or within 90 days after the effective date of this CIA, whichever is later. After receiving the initial training described above, each Covered Person shall receive at least one hour of general training annually.

**2. Specific Training.** Within 90 days of the effective date of this CIA, each Covered Person who is involved in the delivery of patient care items or services and/or in the preparation or submission of claims for reimbursement from any Federal health care program (hereinafter referred to as "Relevant Covered Persons") shall receive at least two hours of specific training in addition to the general training required above. This specific training shall include a discussion of:

- a. the submission of accurate bills for services rendered to Federal health care program patients;
- b. policies, procedures and other requirements applicable to the documentation of medical records, progress notes, and other relevant documents;
- c. the personal obligation of each individual involved in the billing process to ensure that such billings are accurate;
- d. applicable reimbursement statutes, regulations, and program requirements and directives;
- e. the legal sanctions for improper billings; and
- f. examples of proper and improper billing practices.

All training materials shall be made available to OIG, upon request. Persons providing the training must be knowledgeable about the subject area, including, but not limited to, the requirements for proper billing under the CAP-MR/DD.



Relevant Covered Persons shall receive this training within 30 days of the beginning of their employment or becoming Relevant Covered Persons or within 90 days of the effective date of this CIA, whichever is later. An Ambleside employee who has completed the specific training shall review a new Relevant Covered Person's work, to the extent that the work relates to the delivery of patient care items or services and/or in the preparation or submission of claims for reimbursement from any Federal health care program, until such time as the new Relevant Covered Person completes applicable training.

After receiving the initial training described in this section, every Relevant Covered Person shall receive at least two hours of specific training annually.

**3. Certification.** Each individual who is required to attend training shall certify, in writing, that he or she has received the required training. The certification shall specify the type of training received and the date received. The Compliance Officer (or his or her designee) shall retain the certifications, along with all course materials. These shall be made available to OIG, upon request.

#### **D. Review Procedures**

##### **1. *General Description.***

a. Retention of Independent Review Organization. Within 90 days of the effective date of this CIA, Ambleside shall retain an entity (or entities), such as an accounting, auditing or consulting firm (hereinafter "Independent Review Organization" or "IRO"), to perform review engagements to assist Ambleside in evaluating its billing and coding practices and its compliance obligations pursuant to this CIA and the Settlement Agreement. Each Independent Review Organization retained by Ambleside shall have expertise in the billing, coding, reporting and other requirements of the particular section of the health care industry pertaining to this CIA and in the general requirements of the Federal health care program(s) from which Ambleside seeks reimbursement. Each IRO shall assess, along with Ambleside, whether it can perform the IRO engagements in a professionally independent fashion taking into account any other business relationships or other engagements that may exist.

b. Types of Engagements. The IRO(s) shall conduct two separate engagements. One engagement shall address Ambleside's billing and coding to the Federal health care programs ("Billing Engagement"). The second engagement shall address Ambleside's compliance with the obligations assumed under this CIA and the Settlement Agreement ("Compliance Engagement"). The IRO(s) shall prepare a report for each engagement, namely, a Billing Engagement Report and a Compliance Engagement Report.

c. Frequency of Billing and Compliance Engagements. The Billing Engagement shall be performed annually and shall cover each of the one-year periods beginning with the effective date of this CIA. The IRO(s) shall perform all components of each annual Billing Engagement. The Compliance Engagement shall be performed by the IRO for the first one-year period beginning with the effective date of this CIA.

d. Retention of Records. The IRO and Ambleside shall retain and make available to the OIG upon request all work papers, supporting documentation, correspondence, and draft reports related to the engagements.

## ***2. Billing Engagement.***

The Billing Engagement shall be composed of two separate reviews, a "Claims Review" and a "Systems Review." The Claims Review and corresponding Claims Review Report are discussed in detail in Appendix A to this CIA, which is incorporated by reference.

a. Claims Review. The IRO shall perform a Claims Review to identify any overpayments through an appraisal of Paid Claims submitted by Ambleside to the Medicare and Medicaid programs. The Claims Review shall be performed in accordance with the procedures set forth in Appendix A to this CIA.

b. Claims Review Report. The IRO shall prepare a report based upon each Claims Review performed ("Claims Review Report"). The Claims Review Report shall be created in accordance with the procedures set forth in Appendix A to this CIA.

c. Systems Review. The IRO shall review Ambleside's billing and coding systems and/or operations (the "Systems Review"). The Systems Review shall consist of a thorough review of the following:

i. Ambleside's billing systems and/or operations relating to claims submitted to all Federal health care programs (including, but not limited to, the operation of the billing system, safeguards to ensure proper claim submission and billing, and procedures to correct inaccurate billing) and

ii. Ambleside's coding systems and/or operations relating to claims submitted to all Federal health care programs (including, but not limited to, the process by which claims are coded, safeguards to ensure proper coding, and procedures to correct inaccurate coding).

d. Systems Review Report. The IRO shall prepare a report based upon each Systems Review performed ("Systems Review Report"). The Systems Review Report shall include the IRO's findings and supporting rationale regarding:

i. the strengths and weaknesses in Ambleside's billing systems and/or operations;

ii. the strengths and weaknesses in Ambleside's coding systems and/or operations; and

iii. any recommendations the IRO may have to improve any of these systems, operations, and processes.

### ***3. Compliance Engagement.***

a. Compliance Review. The IRO shall conduct a review of Ambleside's compliance activities ("Compliance Review"). The Compliance Review shall consist of a review of Ambleside's compliance with the obligations set forth in each section of this CIA, and a review of Ambleside's compliance with certain provisions of the Settlement Agreement.

i. CIA Obligations Review. The IRO shall evaluate Ambleside's compliance with the obligations set forth in each section of this CIA.

ii. Unallowable Costs Review. The IRO shall determine whether Ambleside has complied with its obligation not to charge to, or otherwise seek payment from, Federal or State payors for unallowable costs (as defined in the Settlement Agreement) and its obligation to identify to applicable Federal or State payors any unallowable costs included in payments previously sought from the United States, or any State Medicaid program. This unallowable cost analysis shall include, but not be limited to, payments sought in any cost reports, cost statements, information reports, or payment requests already submitted by Ambleside or any of its subsidiaries, and to request, and agree, that such cost reports, cost statements, information reports or payment requests, even if already settled, be adjusted to account for the effect of the inclusion of the unallowable costs. In making this determination, the IRO may need to review cost statements from the year of the Settlement Agreement, as well as from previous years.

b. Compliance Review Report. The IRO shall prepare a report based upon the Compliance Review performed (the "Compliance Review Report"). The Compliance Review Report shall include:

i. the IRO's findings, supporting rationale, and a summary of such findings and rationale regarding Ambleside's compliance with the terms of sections I through VIII of the CIA, as applicable; and

ii. the IRO's findings and supporting rationale regarding whether Ambleside has complied with its obligation not to charge to, or otherwise seek payment from, Federal or State payors for unallowable costs (as defined in the Settlement Agreement) and its obligation to identify to applicable Federal or State payors any unallowable costs included in payments previously sought from such payor.

**4. *Validation Review.*** In the event the OIG has reason to believe that: (a) Ambleside's Billing or Compliance Engagement fails to conform to the requirements of this CIA or (b) the findings or Claims Review results are inaccurate, the OIG may, at its sole discretion, conduct its own review to determine whether the Billing and Compliance Engagements comply with the requirements of the CIA and/or the findings or Claims Review results are inaccurate. Ambleside agrees to pay for the reasonable cost of any such review performed by the OIG or any of its designated agents so long as it is initiated before one year after the final submission (as described in section II) is received by the OIG.

Prior to initiating a Validation Review, the OIG shall notify Ambleside of its intent to do so and provide an explanation for believing why such a review is necessary. In order to resolve any concerns raised by the OIG, Ambleside may request a meeting with the OIG to discuss the results of any Engagement submissions or any Claims Review findings; present any additional or relevant information to clarify the results of the Engagements or to correct the inaccuracy of the Claims Review; and/or propose alternatives to the proposed Validation Review. Ambleside agrees to provide any additional information as may be requested by the OIG under this section in an expedited manner. The OIG will attempt in good faith to resolve any Billing or Compliance Engagement and/or Claims Review issues with Ambleside prior to conducting a Validation Review. However, the final determination as to whether or not to proceed with a Validation Review shall be made at the sole discretion of the OIG.

**5. *Independence Certification.*** Within 120 days from the effective date of this CIA, the IRO shall provide to Ambleside a certification or sworn affidavit that it has evaluated its professional independence with regard to the Billing and Compliance Engagements and that it has concluded that it is, in fact, independent. Such certification shall be included in Ambleside's Implementation Report submission.

#### **E. Confidential Disclosure Program**

Within ninety (90) days of execution of this CIA, Ambleside shall establish a Confidential Disclosure Program enabling Covered Persons to communicate about compliance issues to the Compliance Officer. The Confidential Disclosure Program shall include methods, such as a toll-free compliance "hotline," for Covered Persons to disclose any practices or procedures with respect to Medicare, Medicaid, or any other Federal health care program, alleged by the individual to be inappropriate, to the Compliance Officer or some other person who is not in the reporting individual's chain of command.

The Confidential Disclosure Program shall emphasize a non-retribution, non-retaliation policy, and shall include a reporting mechanism for anonymous, confidential communication. Ambleside shall appropriately publicize the existence of the disclosure methods (e.g., via periodic e-mails to employees or by posting the information in prominent common areas). Ambleside shall use intake procedures designed to elicit all relevant information from individuals reporting alleged misconduct. For any disclosure that is sufficiently specific that it reasonably (1) permits a determination of the appropriateness of the alleged improper practice, and (2) provides opportunity for the taking of corrective action, Ambleside shall conduct an internal review of the allegations set forth in such disclosure and ensure that proper follow-up is conducted. Ambleside shall, in good faith, make a preliminary inquiry into the allegations set forth in every disclosure to ensure that it has obtained all of the information necessary to determine whether it should conduct an internal review as provided above. The Compliance Officer shall maintain a confidential disclosure log, which shall include a record of each allegation received, status of the internal review of the allegation, and any corrective action taken in response to the internal review. The Compliance Officer shall maintain all documentation related to information in the log and the log shall be made available to OIG, upon request.

#### **F. Ineligible Persons**

**1. Definition.** For purposes of this CIA, an "Ineligible Person" shall be any individual or entity who: (a) is currently excluded, debarred or otherwise ineligible to participate in the Federal health care programs or in Federal procurement or non-procurement programs; or (b) has been convicted of a criminal offense related to the provision of health care items or services, but has not yet been excluded, debarred or otherwise declared ineligible.

**2. Screening Requirements.** Ambleside shall not hire as employees or engage as contractors any Ineligible Person. To prevent hiring or contracting with any Ineligible Person, Ambleside shall screen all prospective employees and prospective contractors prior to engaging their services by: (a) requiring applicants to disclose whether they are Ineligible Persons; and (b) reviewing the General Services Administration's List of Parties Excluded from Federal Programs (available through the Internet at <http://epls.arnet.gov>) and the HHS/OIG List of Excluded Individuals/Entities (available through the Internet at <http://www.hhs.gov/oig>) (these lists will hereinafter be referred to as the "Exclusion Lists").

**3. *Review and Removal Requirement.*** Within 90 days of the effective date of this CIA, Ambleside shall review its list of current employees and contractors against the Exclusion Lists. Thereafter, Ambleside shall review the list semi-annually. In addition, Ambleside shall require employees and contractors to disclose immediately any debarment, exclusion or other event that makes the employee an Ineligible Person.

If Ambleside has notice that an employee or contractor has become an Ineligible Person, Ambleside shall remove such person from responsibility for, or involvement with, Ambleside's business operations related to the Federal health care programs and shall remove such person from any position for which the person's salary or the items or services rendered, ordered, or prescribed by the person are paid in whole or part, directly or indirectly, by Federal health care programs or otherwise with Federal funds at least until such time as the person is reinstated into participation in the Federal health care programs.

**4. *Pending Charges and Proposed Exclusions.*** If Ambleside has notice that an employee or contractor is charged with a criminal offense related to any Federal health care program, or is proposed for exclusion during his or her employment or contract, Ambleside shall take all appropriate actions to ensure that the responsibilities of that employee or contractor have not and shall not adversely affect the quality of care rendered to any beneficiary, patient or resident, or the accuracy of any claims submitted to any Federal health care program.

#### **G. Notification of Government Investigation or Legal Proceedings**

Within 30 days of discovery, Ambleside shall notify OIG, in writing, of any ongoing investigation or legal proceeding conducted or brought by a governmental entity or its agents involving an allegation that Ambleside has committed a crime or has engaged in fraudulent activities. This notification shall include a description of the allegation, the identity of the investigating or prosecuting agency, and the status of such investigation or legal proceeding. Ambleside shall also provide written notice to OIG within 30 days of the resolution of the matter, and shall provide OIG with a description of the findings and/or results of the proceedings, if any.

#### **H. Reporting**

##### ***1. Overpayments***

*a. Definition of Overpayments.* For purposes of this CIA, an

“overpayment” shall mean the amount of money Ambleside has received in excess of the amount due and payable under any Federal health care program requirements. Ambleside may not subtract any underpayments for purposes of determining the amount of relevant “overpayments.”

*b. Reporting of Overpayments.* If, at any time, Ambleside identifies or learns of any overpayments, Ambleside shall notify the payor (e.g., Medicaid agency) and repay any identified overpayments within 30 days of identification and take remedial steps within 60 days of discovery (or such additional time as may be agreed to by the payor) to correct the problem, including preventing the underlying problem and the overpayments from recurring. If not yet quantified, within 30 days of identification, Ambleside shall notify the payor of its efforts to quantify the overpayment amount along with a schedule of when such work is expected to be completed. Notification and repayment to the payor should be done in accordance with the payor’s policies.

## **2. Material Deficiencies**

*a. Definition of Material Deficiency.* For purposes of this CIA, a “Material Deficiency” means anything that involves:

- (i) a substantial overpayment; or
- (ii) a matter that a reasonable person would consider a potential violation of criminal, civil, or administrative laws applicable to any Federal health care program for which penalties or exclusion may be authorized.

A Material Deficiency may be the result of an isolated event or a series of occurrences.

*b. Reporting of Material Deficiencies.* If Ambleside determines that there is a Material Deficiency, Ambleside shall notify OIG, in writing, within 30 days of making the determination that the Material Deficiency exists. The report to the OIG shall include the following information:



(i) If the Material Deficiency results in an overpayment, the report to the OIG shall be made at the same time as the notification to the payor required in section III.H.1, and shall include all of the information on the Overpayment Refund Form, as well as:

(A) the payor's name, address, and contact person to whom the overpayment was sent; and

(B) the date of the check and identification number (or electronic transaction number) on which the overpayment was repaid/refunded;

(ii) a complete description of the Material Deficiency, including the relevant facts, persons involved, and legal and Federal health care program authorities implicated;

(iii) a description of Ambleside's actions taken to correct the Material Deficiency; and

(iv) any further steps Ambleside plans to take to address the Material Deficiency and prevent it from recurring.

### **III. NEW BUSINESS UNITS OR LOCATIONS**

In the event that, after the effective date of this CIA, Ambleside changes locations or purchases or establishes new business units related to the furnishing of items or services that may be reimbursed by Federal health care programs, Ambleside shall notify OIG of this fact as soon as possible, but no later than within 30 days of the date of change of location, purchase or establishment. This notification shall include the location of the new operation(s), phone number, fax number, Medicare provider number(s) (if any), and the corresponding contractor's name and address that has issued each Medicare provider number. All Covered Persons at such locations shall be subject to the applicable requirements in this CIA (e.g., completing certifications and undergoing training).

### **IV. IMPLEMENTATION AND ANNUAL REPORTS**

**A. Implementation Report.** Within 120 days after the effective date of this CIA,

Ambleside shall submit a written report to OIG summarizing the status of its implementation of the requirements of this CIA. This Implementation Report shall include:

1. the name, address, phone number and position description of the Compliance Officer required by this CIA;
2. the names and positions of the members of the Compliance Committee required by this CIA;
3. a copy of Ambleside's Code of Conduct required by this CIA;
4. the summary of the Policies and Procedures required by this CIA;
5. a description of the training required by this CIA, including a description of the targeted audiences, length of sessions, which sessions were mandatory and for whom, percentage of attendance, and a schedule of when the training sessions were held;
6. a certification by the Compliance Officer that:
  - a. the Policies and Procedures required by this CIA have been developed, are being implemented, and have been distributed to all appropriate Covered Persons;
  - b. all Covered Persons have completed the Code of Conduct certification required by this CIA; and
  - c. all Covered Persons have completed the applicable training and executed the certification(s) required by this CIA.

The documentation supporting this certification shall be available to OIG, upon request.

7. a description of the Confidential Disclosure Program required by this CIA;
8. the identity of the IRO(s), the proposed start and completion dates of the first annual review, and a summary/description of all engagements between

Ambleside and the IRO, including, but not limited to, any outside financial audits, compliance program engagements, or reimbursement consulting;

9. a summary of personnel actions taken pursuant to section II.F.;

10. a list of all of Ambleside's locations (including locations and mailing addresses), the corresponding name under which each location is doing business, the corresponding phone numbers and fax numbers, each location's Medicaid provider identification number(s), and the contractor's name and address that issued each provider identification number;

11. to the extent not already furnished to OIG, or if modified, a description of Ambleside's corporate structure, including identification of any parent and sister companies, subsidiaries and their respective lines of business; and

12. the certification required by section IV.C.

**B. Annual Reports.** Ambleside shall submit to OIG Annual Reports with respect to the status of and findings regarding of Ambleside's compliance activities for each of the four one-year periods beginning on the effective date of the CIA. (The one-year period covered by each Annual Report shall be referred to as "the Reporting Period").

Each Annual Report shall include:

1. any change in the identity or position description of the Compliance Officer and/or members of the Compliance Committee;

2. a certification by the Compliance Officer that:

a. All Covered Persons have completed any Code of Conduct certifications required by this CIA;

b. all Covered Persons have completed the applicable training and executed the certification(s) required by this CIA;

c. Ambleside has complied with its obligations under the Settlement Agreement: (i) not to resubmit to any Federal health care program

payors any previously denied claims related to the Covered Conduct addressed in the Settlement Agreement, and not to appeal any such denials of claims; and (ii) not to charge to or otherwise seek payment from Federal or state payors for unallowable costs (as defined in the Settlement Agreement); and (iii) to identify and adjust any past charges or claims for unallowable costs;

The documentation supporting this certification shall be available to OIG, upon request.

3. a summary of any significant changes or amendments to the Policies and Procedures required by this CIA and the reasons for such changes (e.g., change in Medicaid policy);

4. a description of the training required by this CIA conducted during the Reporting Period, including a description of the targeted audiences, length of sessions, which sessions were mandatory and for whom, percentage of attendance, and a schedule of when the training sessions were held;

5. a complete copy of all reports prepared pursuant to the IRO's billing and compliance engagements, including a copy of the methodology used, along with a copy of the IRO's engagement letter, and a revised summary/description of all engagements between Ambleside and the IRO, including, but not limited to, any outside financial audits, compliance program engagements, or reimbursement consulting, if different from what was submitted as part of the Implementation Report;

6. Ambleside's response and corrective action plan(s) related to any issues raised by the IRO(s);

7. a summary of Material Deficiencies (as defined in II.H) identified during the Reporting Period and the status of any corrective and preventative action relating to all such Material Deficiencies;

8. a report of the aggregate overpayments that have been returned to the Federal health care programs. Overpayment amounts should be broken down into the following categories: Medicare, Medicaid, and other Federal health care programs;

9. a summary of the disclosures in the confidential disclosure log required by this CIA that: (a) relate to Federal health care programs; or (b) allege abuse or neglect of patients;

10. a description of any personnel actions (other than hiring) taken by Ambleside as a result of the obligations in section II.F, and the name, title, and responsibilities of any person that falls within the ambit of section II.F.4, and the actions taken in response to the obligations set forth in that section;

11. a summary describing any ongoing investigation or legal proceeding required to have been reported pursuant to section II.G. The summary shall include a description of the allegation, the identity of the investigating or prosecuting agency, and the status of such investigation or legal proceeding;

12. a description of all changes to the most recently provided list (as updated) of Ambleside's locations (including locations and mailing addresses) as required by section IV.A.10, the corresponding name under which each location is doing business, the corresponding phone numbers and fax numbers, and each location's Federal health care program provider identification number(s); and

13. the certification required by section IV.C.

The first Annual Report shall be received by the OIG no later than 60 days after the end of the first Reporting Period. Subsequent Annual Reports shall be received by OIG no later than the anniversary date of the due date of the first Annual Report.

**C. Certifications.** The Implementation Report and Annual Reports shall include a certification by the Compliance Officer that: (1) except as otherwise described in the applicable report, Ambleside is in compliance with all of the requirements of this CIA, to the best of his or her knowledge; and (2) the Compliance Officer has reviewed the Report and has made reasonable inquiry regarding its content and believes that the information is accurate and truthful.

**D. Designation of Information.** Ambleside shall clearly identify any portions of its submissions that it believes are trade secrets, or information that is commercial or financial and privileged or confidential, and therefore exempt from disclosure under the

Freedom of Information Act ("FOIA"), 5 U.S.C. § 552. Ambleside shall refrain from identifying any information as exempt from disclosure if that information does not meet the criteria for exemption from disclosure under FOIA.

#### **V. OIG INSPECTION, AUDIT AND REVIEW RIGHTS**

In addition to any other rights OIG may have by statute, regulation, or contract, OIG or its duly authorized representative(s) may examine or request copies of Ambleside's books, records, and other documents and supporting materials and/or conduct on-site reviews of any of Ambleside's locations for the purpose of verifying and evaluating: (a) Ambleside's compliance with the terms of this CIA; and (b) Ambleside's compliance with the requirements of the Federal health care programs in which it participates. The documentation described above shall be made available by Ambleside to OIG or its duly authorized representative(s) at all reasonable times for inspection, audit or reproduction. Furthermore, for purposes of this provision, OIG or its duly authorized representative(s) may interview any of Ambleside's employees, contractors, or agents who consent to be interviewed at the individual's place of business during normal business hours or at such other place and time as may be mutually agreed upon between the individual and OIG. Ambleside agrees to assist OIG or its duly authorized representative(s) in contacting and arranging interviews with such individuals upon OIG's request. Ambleside's employees may elect to be interviewed with or without a representative of Ambleside present.

#### **VI. DOCUMENT AND RECORD RETENTION**

Ambleside shall maintain for inspection documents and records relating to Medicaid, Medicare or other Federal reimbursement, or to compliance with this CIA, for a period of five (5) years following the execution of this CIA, or for whatever other period of time required by law or policy, whichever is longer.

#### **VII. DISCLOSURES**

Consistent with HHS's FOIA procedures, set forth in 45 C.F.R. Part 5, the OIG shall make a reasonable effort to notify Ambleside prior to any release by OIG of information submitted by Ambleside pursuant to its obligations under this CIA and identified upon submission by Ambleside as trade secrets, or information that is commercial or financial and privileged or confidential, under the FOIA rules. With respect to such releases, Ambleside shall have the rights set forth at 45 C.F.R. § 5.65(d). Ambleside shall refrain from identifying any information as exempt from release if that

information does not meet the criteria for exemption from disclosure under FOIA.

### **VIII. Breach and Default Provisions**

Ambleside is expected to fully and timely comply with all of its CIA obligations.

**A. Stipulated Penalties for Failure to Comply with Certain Obligations.** As a contractual remedy, Ambleside and OIG hereby agree that failure to comply with certain obligations set forth in this CIA may lead to the imposition of the following monetary penalties (hereinafter referred to as “Stipulated Penalties”) in accordance with the following provisions.

1. A Stipulated Penalty of \$1,500 (which shall begin to accrue on the day after the date the obligation became due) for each day Ambleside fails to have in place any of the following:

- a. a Compliance Officer as described in this CIA;
- b. a Compliance Committee as described in this CIA;
- c. a written Code of Conduct as described in this CIA;
- d. written Policies and Procedures as described in this CIA;
- e. a requirement that Covered Persons be trained as described in this CIA; and
- f. a Confidential Disclosure Program as described in this CIA.

2. A Stipulated Penalty of \$1,500 (which shall begin to accrue on the day after the date the obligation became due) for each day Ambleside fails to retain an IRO, as required by this CIA.

3. A Stipulated Penalty of \$1,500 (which shall begin to accrue on the day after the date the obligation became due) for each day Ambleside fails to meet any of the deadlines for the submission of the Implementation Report or the Annual Reports to OIG.

4. A Stipulated Penalty of \$1,500 (which shall begin to accrue on the date

the failure to comply began) for each day Ambleside employs or contracts with an Ineligible Person and that person: (i) has responsibility for, or involvement with, Ambleside's business operations related to the Federal health care programs; or (ii) is in a position for which the person's salary or the items or services rendered, ordered, or prescribed by the person are paid in whole or part, directly or indirectly, by Federal health care programs or otherwise with Federal funds (the Stipulated Penalty described in this paragraph shall not be demanded for any time period during which Ambleside can demonstrate that it did not discover the person's exclusion or other ineligibility after making a reasonable inquiry (as described in section II.F) as to the status of the person).

5. A Stipulated Penalty of \$1,500 for each day Ambleside fails to grant access to the information or documentation as required in section V. of this CIA. (This Stipulated Penalty shall begin to accrue on the date Ambleside fails to grant access.)

6. A Stipulated Penalty of \$1,000 for each day Ambleside fails to comply fully and adequately with any obligation of this CIA. In its notice to Ambleside, OIG shall state the specific grounds for its determination that Ambleside has failed to comply fully and adequately with the CIA obligation(s) at issue and steps Ambleside must take to comply with the CIA. (This Stipulated Penalty shall begin to accrue 10 days after the date that OIG provides notice to Ambleside of the failure to comply.) A Stipulated Penalty as described in this paragraph shall not be demanded for any violation for which the OIG has sought a Stipulated Penalty under paragraphs 1-5 of this section.

**B. Timely Written Requests for Extensions.** Ambleside may, in advance of the due date, submit a timely written request for an extension of time to perform any act or file any notification or report required by this CIA. Notwithstanding any other provision in this section, if OIG grants the timely written request with respect to an act, notification, or report, Stipulated Penalties for failure to perform the act or file the notification or report shall not begin to accrue until one day after Ambleside fails to meet the revised deadline set by OIG. Notwithstanding any other provision in this section, if OIG denies such a timely written request, Stipulated Penalties for failure to perform the act or file the notification or report shall not begin to accrue until three business days after Ambleside receives OIG's written denial of such request or the original due date, whichever is later. A "timely written request" is defined as a request in writing received by OIG at least five business days prior to the date by which any act is due to be performed or any notification or report is due to be filed.



### **C. Payment of Stipulated Penalties**

**1. Demand Letter.** Upon a finding that Ambleside has failed to comply with any of the obligations described in section VIII.A and after determining that Stipulated Penalties are appropriate, OIG shall notify Ambleside of: (a) Ambleside's failure to comply; and (b) the OIG's exercise of its contractual right to demand payment of the Stipulated Penalties (this notification is hereinafter referred to as the "Demand Letter").

**2. Response to Demand Letter.** Within 10 days of the receipt of the Demand Letter, Ambleside shall either: (a) cure the breach to OIG's satisfaction and pay the applicable Stipulated Penalties; or (b) request a hearing before an HHS administrative law judge ("ALJ") to dispute OIG's determination of noncompliance, pursuant to the agreed upon provisions set forth below in section VIII.E. In the event Ambleside elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until Ambleside cures, to OIG's satisfaction, the alleged breach in dispute. Failure to respond to the Demand Letter in one of these two manners within the allowed time period shall be considered a material breach of this CIA and shall be grounds for exclusion under section VIII.D.

**3. Form of Payment.** Payment of the Stipulated Penalties shall be made by certified or cashier's check, payable to: "Secretary of the Department of Health and Human Services," and submitted to OIG at the address set forth in section II.

**4. Independence from Material Breach Determination.** Except as set forth in section VIII.D.1.c, these provisions for payment of Stipulated Penalties shall not affect or otherwise set a standard for OIG's decision that Ambleside has materially breached this CIA, which decision shall be made at OIG's discretion and shall be governed by the provisions in section VIII.D, below.

### **D. Exclusion for Material Breach of this CIA**

**1. Definition of Material Breach.** A material breach of this CIA means:

a. a failure by Ambleside to report a Material Deficiency, take corrective action and make the appropriate refunds, as required in section II.H;

b. a repeated or flagrant violation of the obligations under this CIA,

including, but not limited to, the obligations addressed in section VIII.A;

c. a failure to respond to a Demand Letter concerning the payment of Stipulated Penalties in accordance with section VIII.C; or

d. a failure to retain and use an Independent Review Organization in accordance with section II.D.

**2. Notice of Material Breach and Intent to Exclude.** The parties agree that a material breach of this CIA by Ambleside constitutes an independent basis for Ambleside's exclusion from participation in the Federal health care programs. Upon a determination by OIG that Ambleside has materially breached this CIA and that exclusion should be imposed, OIG shall notify Ambleside of: (a) Ambleside's material breach; and (b) OIG's intent to exercise its contractual right to impose exclusion (this notification is hereinafter referred to as the "Notice of Material Breach and Intent to Exclude").

**3. Opportunity to Cure.** Ambleside shall have 30 days from the date of receipt of the Notice of Material Breach and Intent to Exclude to demonstrate to OIG's satisfaction that:

a. Ambleside is in compliance with the obligations of the CIA cited by the OIG as being the basis for the material breach;

b. the alleged material breach has been cured; or

c. the alleged material breach cannot be cured within the 30-day period, but that: (i) Ambleside has begun to take action to cure the material breach; (ii) Ambleside is pursuing such action with due diligence; and (iii) Ambleside has provided to OIG a reasonable timetable for curing the material breach.

**4. Exclusion Letter.** If at the conclusion of the 30-day period, Ambleside fails to satisfy the requirements of section VIII.D.3, OIG may exclude Ambleside from participation in the Federal health care programs. OIG will notify Ambleside of its determination to exclude Ambleside (this letter shall be referred to hereinafter as the "Exclusion Letter"). Subject to the Dispute Resolution provisions in section VIII.E, below, the exclusion shall go into effect 30 days after the date of the Exclusion Letter.

The exclusion shall have national effect and shall also apply to all other Federal procurement and non-procurement programs. Reinstatement to program participation is not automatic. If at the end of the period of exclusion, Ambleside wishes to apply for reinstatement, Ambleside must submit a written request for reinstatement in accordance with the provisions at 42 C.F.R. §§ 1001.3001-.3004.

## **E. Dispute Resolution**

**1. Review Rights.** Upon OIG's delivery to Ambleside of its Demand Letter or of its Exclusion Letter, and as an agreed-upon contractual remedy for the resolution of disputes arising under this CIA, Ambleside shall be afforded certain review rights comparable to the ones that are provided in 42 U.S.C. § 1320a-7(f) and 42 C.F.R. Part 1005 as if they applied to the Stipulated Penalties or exclusion sought pursuant to this CIA. Specifically, OIG's determination to demand payment of Stipulated Penalties or to seek exclusion shall be subject to review by an HHS ALJ and, in the event of an appeal, the HHS Departmental Appeals Board ("DAB"), in a manner consistent with the provisions in 42 C.F.R. §§ 1005.2-1005.21. Notwithstanding the language in 42 C.F.R. § 1005.2(c), the request for a hearing involving Stipulated Penalties shall be made within 10 days of the receipt of the Demand Letter and the request for a hearing involving exclusion shall be made within 25 days of receipt of the Exclusion Letter.

**2. Stipulated Penalties Review.** Notwithstanding any provision of Title 42 of the United States Code or Chapter 42 of the Code of Federal Regulations, the only issues in a proceeding for Stipulated Penalties under this CIA shall be: (a) whether Ambleside was in full and timely compliance with the obligations of this CIA for which the OIG demands payment; and (b) the period of noncompliance. Ambleside shall have the burden of proving its full and timely compliance and the steps taken to cure the noncompliance, if any. If the ALJ agrees with OIG with regard to a finding of a breach of this CIA and orders Ambleside to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable 20 days after the ALJ issues such a decision unless Ambleside requests review of the ALJ decision by the DAB. If the ALJ decision is properly appealed to the DAB and the DAB upholds the determination of OIG, the Stipulated Penalties shall become due and payable 20 days after the DAB issues its decision.

**3. Exclusion Review.** Notwithstanding any provision of Title 42 of the United States Code or Chapter 42 of the Code of Federal Regulations, the only issues in a proceeding for exclusion based on a material breach of this CIA shall be:

- a. whether Ambleside was in material breach of this CIA;
- b. whether such breach was continuing on the date of the Exclusion Letter; and
- c. whether the alleged material breach could not have been cured within the 30 day period, but that:
  - (i) Ambleside had begun to take action to cure the material breach within that period;
  - (ii) Ambleside has pursued and is pursuing such action with due diligence; and
  - (iii) Ambleside provided to OIG within that period a reasonable timetable for curing the material breach and Ambleside has followed the timetable.

For purposes of the exclusion herein, exclusion shall take effect only after an ALJ decision favorable to OIG, or, if the ALJ rules for Ambleside, only after a DAB decision in favor of OIG. Ambleside's election of its contractual right to appeal to the DAB shall not abrogate the OIG's authority to exclude Ambleside upon the issuance of an ALJ's decision in favor of the OIG. If the ALJ sustains the determination of the OIG and determines that exclusion is authorized, such exclusion shall take effect 20 days after the ALJ issues such a decision, notwithstanding that Ambleside may request review of the ALJ decision by the DAB. If the DAB finds in favor of OIG after an ALJ decision adverse to OIG, the exclusion shall take effect 20 days after the DAB decision. Ambleside agrees to waive its right to any notice of such an exclusion if a decision upholding the exclusion is rendered by the ALJ or DAB.

**4. *Finality of Decision.*** The review by an ALJ or DAB provided for above shall not be considered to be an appeal right arising under any statutes or regulations. Consequently, the parties to this CIA agree that the DAB's decision (or the ALJ's decision if not appealed) shall be considered final for all purposes under this CIA.

## **IX. EFFECTIVE AND BINDING AGREEMENT**

Consistent with the provisions in the Settlement Agreement pursuant to which this CIA is entered, and into which this CIA is incorporated, Ambleside and OIG agree as

follows:

A. This CIA shall be binding on the successors, assigns, and transferees of Ambleside;

B. This CIA shall become final and binding on the date the final signature is obtained on the CIA;

C. Any modifications to this CIA shall be made with the prior written consent of the parties to this CIA;


D. OIG may agree to a suspension of Ambleside's obligations under the CIA in the event of Ambleside's cessation of participation in Federal health care programs. If Ambleside withdraws from participation in Federal health care programs and is relieved from its CIA obligations by the OIG, Ambleside agrees to notify OIG 30 days in advance of Ambleside's intent to reapply as a participating provider or supplier with the Federal health care programs. Upon receipt of such notification, OIG will evaluate whether the CIA should be reactivated or modified; and

E. The undersigned Ambleside signatories represent and warrant that they are authorized to execute this CIA. The undersigned OIG signatory represents that he is signing this CIA in his official capacity and that he is authorized to execute this CIA.

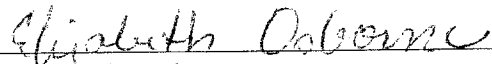
IN WITNESS WHEREOF, the parties hereto affix their signatures

FOR AMBLESIDE, INC.:

7-17-01  
Date


  
Delmas E. Minshew, President

7/17/01  
Date

  
Elizabeth Osborne  
Corporate Compliance Officer for Ambleside, Inc.

FOR THE U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

7/20/01  
Date

  
Lewis Morris  
Assistant Inspector General for Legal Affairs  
Office of Counsel to the Inspector General  
Office of Inspector General  
Department of Health and Human Services

## APPENDIX A

### A. Claims Review.

*1. Definitions.* For the purposes of the Claims Review, the following definitions shall be used:

- a. Claims Review Sample: A statistically valid, randomly selected, sample of items selected for appraisal in the Claims Review.
- b. Item: Any discrete unit that can be sampled (e.g., code, line item, beneficiary, patient encounter, etc.).
- c. Overpayment: Consistent with the definition of Overpayment as articulated in section III.H.1.a of the CIA, the amount of money Ambleside has received in excess of the amount due and payable under any Federal health care program requirements. For the purposes of the Claims Review and all reporting to the OIG under this CIA, Ambleside shall not subtract or “net out” underpayments when determining the amount of relevant Overpayments.
- d. Paid Claim: A code or line item submitted by Ambleside and for which Ambleside has received reimbursement from the Medicaid or Medicare programs.
- e. Population: All Items for which Ambleside has submitted a code or line item and for which Ambleside has received reimbursement from the Medicaid and Medicare programs (i.e., a Paid Claim) during the 12-month period covered by the Claims Review. To be included in the Population, an Item must have resulted in at least one Paid Claim.
- f. Probe Sample: A sample of Items selected through simple random sampling from the Population for the purpose of estimating the mean and standard deviation of Overpayments in the Population. The estimated mean and standard deviation of Overpayments in the Population are to be used to calculate the minimum number of Items that shall be included in the Claims Review Sample in order to achieve the required confidence and precision levels.

g. RAT-STATS: OIG's Office of Audit Services Statistical Sampling Software. RAT-STATS is publicly available to download through the Internet at "[www.hhs.gov/oig/oas/ratstat.html](http://www.hhs.gov/oig/oas/ratstat.html)".

2. *Description of Claims Review*. The Claims Review shall consist of an appraisal of a statistically valid sample of Items (the Claims Review Sample) that can be projected to the total Population.

a. Confidence and Precision Requirements. The Claims Review Sample should contain a sufficient number of Items (according to the RAT-STATS calculation) so that if the Overpayments identified in the Claims Review Sample were projected to the Population, the projection would provide a 90% confidence level and a maximum relative precision (i.e., semi-width of the confidence interval) of plus or minus 25% of the point estimate. In other words, if the Claims Review Overpayment results were projected to the Population at a 90% confidence level, the confidence interval (expressed in dollars) should be sufficiently narrow that the upper bound of the confidence interval would not exceed 125% of the midpoint of the confidence interval (the point estimate), and the lower bound of the confidence interval would not be less than 75% of the midpoint of the confidence interval.

b. Use of a Probe Sample to Determine Claims Review Sample Size. To determine how many Items must be included in the Claims Review Sample to meet the 90% confidence level and 25% precision requirements, the mean and the standard deviation of Overpayments in the Population must be estimated. Estimates for each unique Population shall be developed through the use of a single Probe Sample. The Probe Sample shall be used to determine the minimum Claims Review Sample size through one of the two following options:

i. *Probe Sample with a Minimum Size of Thirty Items*. The Probe Sample shall include at least 30 Items, and shall be selected through the use of RAT-STATS' "Random Numbers" function. Once all Paid Claims associated with the Items included in the Probe Sample have been reviewed, the estimated mean and standard deviation of Overpayments in the Population shall be determined. This determination is based on the Overpayment amount received by Ambleside for each Item in the sample. The "Difference Values



Only” function located under the “Variable Appraisals” component of RAT-STATS shall be used to calculate the estimated mean and standard deviation of Overpayments in the Population. For purposes of estimating the mean and standard deviation of Overpayments in the Population, and entering this information into the “Variable Appraisals”, “Difference Values Only” function of RAT-STATS, any underpayment identified for a Paid Claim in the Probe Sample shall be treated as a zero overpayment. If no Overpayments are found in this Probe Sample, then a second Probe Sample, of at least 30 Items, must be selected and reviewed. The estimated mean and standard deviation of Overpayments in the Population (based on the amount of Overpayments received by Ambleside for each sample Item) shall be determined from this Probe Sample, using RAT-STATS’ “Difference Values Only” function located under the “Variable Appraisals” component. If no Overpayments are found in this second Probe Sample, then the Claims Review can be terminated with the results of the second Probe Sample, and the results of the two Probe Samples shall be reported in lieu of the Claims Review when preparing and submitting the Claims Review Report (see section B, below); or

ii. *Probe Sample with a Minimum Size of Fifty Items.* The Probe Sample shall include at least 50 Items, and shall be selected through the use of RAT-STATS’ “Random Numbers” function. Once all Paid Claims associated with the Items included in the Probe Sample have been reviewed, the estimated mean and standard deviation of Overpayments in the Population shall be determined. This determination is based on the Overpayment amount received by Ambleside for each Item in the sample. The “Difference Values Only” function located under the “Variable Appraisals” component of RAT-STATS shall be used to calculate the estimated mean and standard deviation of Overpayments in the Population. For purposes of estimating the mean and standard deviation of Overpayments in the Population, and entering this information into the “Variable Appraisals”, “Difference Values Only” function of RAT-STATS, any underpayment identified for a Paid Claim in the Probe Sample shall be treated as a zero overpayment. If no Overpayments are found in this 50 Item Probe Sample, then the Claims Review can be terminated with the review of the Probe Sample and the results of

the Probe Sample shall be reported in lieu of the results of the Claims Review when preparing and submitting the Claims Review Report (see section B, below).

c. Calculation of Claims Review Sample Size and Selection of the Claims Review Sample. The estimates of the mean and the standard deviation of Overpayments in the Population obtained through the review of the Probe Sample shall be used to estimate the minimum size of the Claims Review Sample. In order to estimate the number of Items that must be included in the Claims Review Sample to meet the 90% confidence level and 25% precision requirements, RAT-STATS' "Sample Size Estimators" (located under the "Utility Programs" file) shall be used. Whereas the Claims Review Sample size is estimated from the results of the probe sample, there is a possibility that examining the number of Items identified by RAT-STATS may not achieve the 90% confidence and 25% precision levels. If the reviewer can demonstrate that the review was properly conducted, but the 90% confidence level and 25% precision interval could not be achieved, the reviewer will not be required to examine additional items.

The Claims Review Sample shall be selected by using RAT-STATS' "Random Numbers" function, and shall be selected from the entire Population, with the Population including those Items reviewed as part of the Probe Sample, so that all Items in the Population have an equal chance of inclusion in the Claims Review Sample.

d. Item Appraisal. For each Item appraised (either as part of the Claims Review Sample or of the Probe Sample), only Paid Claims shall be evaluated. Every Paid Claim in the Claims Review Sample shall be evaluated by the IRO to determine whether the claim submitted was correctly coded, submitted, and reimbursed. Each appraisal must be sufficient to provide all information required under the Claims Review Report.

e. Paid Claims without Supporting Documentation. For the purpose of appraising Items included in the Claims Review and/or the Probe Sample, any Paid Claim for which Ambleside cannot produce documentation sufficient to support the Paid Claim shall be considered an error and the total reimbursement received by Ambleside for such Paid Claim shall be deemed an Overpayment. Replacement sampling for Paid Claims with

missing documentation is not permitted.

f. Use of First Samples Drawn. For the purposes of all samples (Probe Sample(s) and Claims Review Sample(s)) discussed in this Appendix, the Paid Claims associated with the Items selected in the first sample (or first sample for each strata, if applicable) shall be used. In other words, it is not permissible to generate a number of random samples and then select one for use as the Probe Sample or Claims Review Sample.

**B. Claims Review Report**. The following information shall be included in each Claims Review Report:

1. *Claims Review Methodology*

a. Claims Review Objective: A clear statement of the objective intended to be achieved by the Claims Review.

b. Sampling Unit: A description of the Item as that term is utilized for the Claims Review. As noted in section A.1.b above, for purposes of this Billing Engagement, the term "Item" may refer to any discrete unit that can be sampled (e.g., claim, line item, beneficiary, patient encounter, etc.).

c. Claims Review Population: A description of the Population subject to the Claims Review.

d. Sampling Frame: A description of the sampling frame, which is the totality of Items from which the Probe and Claims Review Sample have been selected and an explanation of the methodology used to identify the sampling frame. In most circumstances, the sampling frame will be identical to the Population.

e. Sources of Data: A description of the documentation relied upon by the IRO when performing the Claims Review (e.g., medical records, physician orders, certificates of medical necessity, requisition forms, HCFA program memoranda, Medicare or Medicaid manuals or bulletins, other policies, regulations, or directives).

f. Review Protocol: A narrative description of how the Claims Review was conducted and what was evaluated.

## *2. Statistical Sampling Documentation*

- a. The number of Items appraised in the Probe Sample(s) and in the Claims Review Sample.
- b. A copy of the RAT-STATS printout of the random numbers generated by the "Random Numbers" function.
- c. A copy of the RAT-STATS printout of the "Sample Size Estimators" results used to calculate the minimum number of Items for inclusion in the Claims Review Sample.
- d. A copy of the RAT-STATS printout of the "Variable Appraisals", "Difference Values Only" function results for the Probe Sample, including a copy of the data file.
- e. The Sampling Frame used in the Probe Sample(s) and the Claims Review Sample will be available to the OIG upon request.

## *3. Claims Review Results*

- a. Total number and percentage of instances in which the IRO determined that the Paid Claims submitted by Ambleside ("Claim Submitted") differed from what should have been the correct claim ("Correct Claim"), regardless of the effect on the payment.
- b. Total number and percentage of instances in which the Claim Submitted differed from the Correct Claim and in which such difference resulted in an Overpayment to Ambleside.
- c. The total dollar amount of all Paid Claims in the Claims Review Sample and the total dollar amount of Overpayments associated with the Paid Claims identified by the Claims Review. (This is the total dollar amount of the Overpayments identified in section B.3.b above.) The IRO may, in its report to Ambleside, identify underpayments, but any underpayments identified during the Claims Review shall not be offset or "netted out" of the total dollar amount of Paid Claims or of the Overpayments when reporting these amounts in the Claims Review Report to the OIG.
- d. The level of precision achieved by the Claims Review at a 90% confidence

level.

e. A spreadsheet of the Claims Review results that includes the following information for each Paid Claim appraised: Federal health care program billed, beneficiary health insurance claim number, date of service, procedure code submitted, procedure code reimbursed, allowed amount reimbursed by payor, correct procedure code (as determined by the IRO), correct allowed amount (as determined by the IRO), dollar difference between allowed amount reimbursed by payor and the correct allowed amount. (See Attachment 1 to this Appendix.)

4. **Credentials.** The names and credentials of the individuals who: (1) designed the statistical sampling procedures and the review methodology utilized for the Claims Review; and (2) performed the Claims Review.

**AMENDMENT TO THE CORPORATE INTEGRITY AGREEMENT  
BETWEEN THE  
OFFICE OF INSPECTOR GENERAL OF THE  
DEPARTMENT OF HEALTH AND HUMAN SERVICES  
AND  
AMBLESIDE, INC.**

The Office of Inspector General ("OIG") of the Department of Health and Human Services and Ambleside, Inc. ("Ambleside") entered into a Corporate Integrity Agreement ("CIA") on July 20, 2001.

1. Pursuant to section IX. of the CIA, modifications to the CIA may be made with the prior written consent of both the OIG and Ambleside. Therefore, the OIG and Ambleside hereby agree that Ambleside's CIA will be amended as follows:

Section III.D., Review Procedures of the CIA is hereby superceded by the attached new section III.D., Review Procedures.

Appendix A of Ambleside's CIA is hereby superceded by the attached new Appendix A.

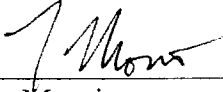
2. The OIG and Ambleside agree that all other sections of Ambleside's CIA will remain unchanged and in effect, unless specifically amended upon the prior written consent of the OIG and Ambleside.
3. The undersigned Ambleside signatories represent and warrant that they are authorized to execute this Amendment. The undersigned OIG signatory represents that he is signing the Amendment in his official capacity and that he is authorized to execute this Amendment.
4. This effective date of this Amendment will be the date on which the final signatory of this Amendment signs this Amendment.

**ON BEHALF OF AMBLESIDE, INC.**

*Karen Bowdle, Assistant Director of Operations*  
[Name]  
[Title]

3-1-02  
DATE

**ON BEHALF OF THE OFFICE OF INSPECTOR GENERAL OF THE  
DEPARTMENT OF HEALTH AND HUMAN SERVICES**



\_\_\_\_\_  
Lewis Morris  
Assistant Inspector General for Legal Affairs  
Office of Inspector General  
U.S. Department of Health and Human Services

3/6/02  
DATE

D. Review Procedures.

1. *General Description.*

a. Retention of Independent Review Organization. Within 90 days of the effective date of this CIA, Ambleside shall retain an entity (or entities), such as an accounting, auditing or consulting firm (hereinafter “Independent Review Organization” or “IRO”), to perform reviews to assist Ambleside in assessing and evaluating its billing and coding practices and systems, and its compliance obligations pursuant to this CIA and the Settlement Agreement. Each IRO retained by Ambleside shall have expertise in the billing, coding, reporting and other requirements of the particular section of the health care industry pertaining to this CIA and in the general requirements of the Federal health care program(s) from which Ambleside seeks reimbursement. Each IRO shall assess, along with Ambleside, whether it can perform the IRO review in a professionally independent fashion taking into account any other business relationships or other engagements that may exist. The IRO(s) review shall address and analyze Ambleside’s billing and coding to the Federal health care programs (“Claims Review”), shall analyze whether Ambleside sought payment for certain unallowable costs (“Unallowable Cost Review”), and shall analyze Ambleside’s compliance with the obligations assumed under this CIA and Settlement Agreement (“Compliance Review”).

b. Frequency of Claims Review. The Claims Review shall be performed annually and shall cover each of the one-year periods of the CIA beginning with the effective date of this CIA. The IRO(s) shall perform all components of each annual Claims Review.

c. Frequency of Unallowable Cost Review. The Unallowable Cost Review shall be performed by the IRO for the first one-year reporting period beginning with the effective date of the CIA.

d. Frequency of Compliance Review. The Compliance Review shall be performed by the IRO for the first one-year period beginning with the effective date of this CIA.

e. Retention of Records. The IRO and Ambleside shall retain and make available to the OIG, upon request, all work papers, supporting documentation, correspondence, and draft reports (those exchanged between the IRO and Ambleside related to the reviews).



2. *Claims Review.*

The Claims Review shall include a Discovery Sample and, if necessary, a Full Sample. The applicable definitions, procedures, and reporting requirements are outlined in Appendix A to this CIA, which is incorporated by reference.

a. Discovery Sample. The IRO shall randomly select and review a sample of 50 Medicare and Medicaid Paid Claims submitted by or on behalf of Ambleside. The Paid Claims shall be reviewed based on the supporting documentation available at Ambleside or under Ambleside's control and applicable billing and coding regulations and guidance to determine whether the claim submitted was correctly coded, submitted and reimbursed.

i. Results of Discovery Sample. If the Error Rate (as defined in Appendix A) is less than 5%, no additional sampling is required, nor is the Systems Review required. (Note: The threshold listed above does not imply that this is an acceptable error rate. Accordingly, Ambleside should, as appropriate, further analyze any errors identified in the Discovery Sample. Ambleside recognizes that the OIG or other HHS component, in its discretion and as authorized by statute, regulation, or other appropriate authority may also analyze or review Paid Claims included, or errors identified, in the Discovery Sample.)

ii. If the Discovery Sample indicates that the Error Rate is 5% or greater, the IRO shall perform a Full Sample and a Systems Review, as described below.

b. Full Sample. If necessary, as determined by procedures set forth in Section II.D.2.a., the IRO shall perform an additional sample of Paid Claims using commonly accepted sampling methods and in accordance with Appendix A. The Full Sample should be designed to (1) estimate the actual Overpayment in the population with a 90% confidence level and with a maximum relative precision of 25% of the point estimate and (2) conform with the Centers for Medicare and Medicaid Services' statistical sampling for overpayment estimation guidelines. The Paid Claims shall be reviewed based on supporting documentation available at Ambleside or under Ambleside's control and applicable billing and coding regulations and guidance to determine whether the claim submitted was correctly coded,

submitted, and reimbursed. For purposes of calculating the size of the Full Sample, the Discovery Sample may serve as the probe sample, if statistically appropriate. Additionally, Ambleside may use the Items sampled as part of the Discovery Sample, and the corresponding findings for those 50 Items, as part of its Full Sample. The OIG, in its full discretion, may refer the findings of the Full Sample (and any related workpapers) received from Ambleside to the appropriate Federal health care program payor, including the Medicare contractor (e.g., carrier, fiscal intermediary, or DMERC), for appropriate follow-up by that payor.

c. Systems Review. If Ambleside's Discovery Sample identifies an Error Rate of 5% or greater, Ambleside's IRO shall also conduct a Systems Review. Specifically, for each claim in the Discovery Sample and Full Sample that resulted in an Overpayment, the IRO should perform a "walk through" of the system(s) and process(es), that generated the claim to identify any problems or weaknesses that may have resulted in the identified Overpayments. The IRO shall provide to Ambleside observations and recommendations on suggested improvements to the system(s) and the process(es) that generated the claim.

d. Repayment of Identified Overpayments. In accordance with section III.H.1 of the CIA, Ambleside agrees to repay within 30 days any Overpayment(s) identified in the Discovery Sample or the Full Sample (if applicable), regardless of the Error Rate, to the appropriate payor and in accordance with payor refund policies. Ambleside agrees to make available to the OIG any and all documentation that reflects the refund of the Overpayment(s) to the payor and the associated documentation.

3. *Claims Review Report*. The IRO shall prepare a report based upon the Claims Review performed (the "Claims Review Report"). Information to be included in the Claims Review Report is detailed in Appendix A.
4. *Unallowable Cost Review*. If applicable, the IRO shall conduct a review of Ambleside's compliance with the unallowable cost provisions of the Settlement Agreement.
  - a. The IRO shall determine whether Ambleside has complied with its obligations not to charge to, or otherwise seek payment from, Federal or State payors for unallowable costs (as defined in the Settlement Agreement) and its obligation to identify to applicable Federal or State payors any unallowable costs included in payments previously sought from the United

States, or any State Medicaid program. This unallowable cost analysis shall include, but not be limited to, payments sought in any cost reports, cost statements, information reports, or payment requests already submitted by Ambleside or any of its subsidiaries, and to request, and agree, that such cost reports, cost statements, information reports or payment requests, even if already settled, be adjusted to account for the effect of the inclusion of the unallowable costs. In making this determination, the IRO may need to review cost reports and/or financial statements from the year in which the Settlement Agreement was executed, as well as from previous years.

5. *Unallowable Cost Review Report.* If, applicable, the IRO shall prepare a report based upon the Unallowable Cost Review performed. The Unallowable Cost Review Report shall include:
  - a. the IRO's findings and supporting rationale regarding the Unallowable Costs Review and whether Ambleside has complied with its obligation not to charge to, or otherwise seek payment from, Federal or State payors for unallowable costs (as defined in the Settlement Agreement) and its obligation to identify to applicable Federal or State payors any unallowable costs included in payments previously sought from such payor.
6. *Compliance Review.* The IRO shall conduct a review of Ambleside's compliance activities. The Compliance Review shall consist of a review of Ambleside's compliance with the obligations set forth in each section of this CIA.
7. *Compliance Review Report.* The IRO shall prepare a report based upon the Compliance Review performed. The Compliance Review Report shall include:
  - a. the IRO's findings, supporting rationale, and a summary of such findings and rationale regarding Ambleside's compliance with the terms of each section of the CIA, as applicable; and
  - b. if applicable, the IRO's findings and supporting rationale regarding whether Ambleside has complied with its obligation not to charge to, or otherwise seek payment from, Federal or State payors for unallowable costs (as defined in the Settlement Agreement) and its obligation to identify to applicable or State payors any unallowable costs included in payments previously sought from such payors.

8. *Validation Review.* In the event the OIG has reason to believe that: (a) Ambleside's Claims Review, Unallowable Cost Review or Compliance Review fails to conform to the requirements of this CIA; or (b) the IRO's findings or Claims Review results are inaccurate, the OIG may, at its sole discretion, conduct its own review to determine whether the Claims Review, Unallowable Cost Review or Compliance Review complied with the requirements of the CIA and/or the findings or Claims Review results are inaccurate ("Validation Review"). Ambleside agrees to pay for the reasonable cost of any such review performed by the OIG or any of its designated agents so long as it is initiated before one year after Ambleside's final submission is received by the OIG.

Prior to initiating a Validation Review, the OIG shall notify Ambleside of its intent to do so and provide a written explanation of why the OIG believes such a review is necessary. To resolve any concerns raised by the OIG, Ambleside may request a meeting with the OIG to discuss the results of any Claims Review, Unallowable Cost Review, or Compliance Review submissions or findings; present any additional or relevant information to clarify the results of the Claims Review, Unallowable Cost Review, or Compliance Review or to correct the inaccuracy of the Claims Review; and/or propose alternatives to the proposed Validation Review. Ambleside agrees to provide any additional information as may be requested by the OIG under this section in an expedited manner. The OIG will attempt in good faith to resolve any Claims Review, Unallowable Cost Review or Compliance Review issues with Ambleside prior to conducting a Validation Review. However, the final determination as to whether or not to proceed with a Validation Review shall be made at the sole discretion of the OIG.

9. *Independence Certification.* The IRO shall include in its report(s) to Ambleside a certification or sworn affidavit that it has evaluated its professional independence with regard to the Claims Review, Unallowable Cost Review, and Compliance Review and that it has concluded that it was, in fact, independent.

## APPENDIX A

### A. Claims Review.

1. **Definitions.** For the purposes of the Claims Review, the following definitions shall be used:
  - a. Overpayment: The amount of money Ambleside has received in excess of the amount due and payable under any Federal health care program requirements.
  - b. Item: Any discrete unit that can be sampled (e.g., code, line item, beneficiary, patient encounter, etc.).
  - c. Paid Claim: A code or line item submitted by Ambleside and for which Ambleside has received reimbursement from the Medicare and Medicaid programs.
  - d. Population: All Items for which Ambleside has submitted a code or line item and for which Ambleside has received reimbursement from the Medicare and Medicaid programs (i.e., a Paid Claim) during the 12-month period covered by the Claims Review. To be included in the Population, an Item must have resulted in at least one Paid Claim.
  - e. Error Rate: The Error Rate shall be the percentage of net overpayments identified in the sample. The Error Rate is calculated by dividing the net Overpayment identified in the sample by the total dollar amount associated with the Items in the sample.
2. **Other Requirements.**
  - a. Paid Claims without Supporting Documentation. For the purpose of appraising Items included in the Claims Review, any Paid Claim for which Ambleside cannot produce documentation sufficient to support the Paid Claim shall be considered an error and the total reimbursement received by Ambleside for such Paid Claim shall be deemed an Overpayment. Replacement sampling for Paid Claims with missing documentation is not permitted.
  - b. Use of First Samples Drawn. For the purposes of all samples (Discovery Sample(s) and Full Sample(s)) discussed in this Appendix, the Paid Claims

associated with the Items selected in each first sample (or first sample for each strata, if applicable) shall be used. In other words, it is not permissible to generate more than one list of random samples and then select one for use with the Discovery Sample or Full Sample.

**B. Claims Review Report.** The following information shall be included in the Claims Review Report for each Discovery Sample and Full Sample (if applicable).

**1. Claims Review Methodology.**

a. Sampling Unit. A description of the Item as that term is utilized for the Claims Review. For purposes of this Claims Review, the term “Item” may refer to any discrete unit that can be sampled (e.g., claim, line item, beneficiary, patient encounter, etc.).

b. Claims Review Population. A description of the Population subject to the Claims Review.

c. Claims Review Objective. A clear statement of the objective intended to be achieved by the Claims Review.

d. Sampling Frame: A description of the sampling frame, which is the totality of Items from which the Discovery Sample and, if any, Full Sample has been selected and an explanation of the methodology used to identify the sampling frame. In most circumstances, the sampling frame will be identical to the Population.

e. Source of Data: A description of the documentation relied upon by the IRO when performing the Claims Review (e.g., medical records, physician orders, certificates of medical necessity, requisition forms, local medical review policies, CMS program memoranda, Medicare carrier or intermediary manual or bulletins, other policies, regulations, or directives).

f. Review Protocol: A narrative description of how the Claims Review was conducted and what was evaluated.

2. **Claims Review Findings.**

- a. a description of Ambleside's billing and coding system(s), including the identification, by position description, of the personnel involved in coding and billing;
- b. the IRO's findings, supporting rationale, and a summary of such findings and rationale regarding the Claims Review, including the results of the Discovery Sample, and the results of the Full Sample (if any) with the gross Overpayment amount, the net Overpayment amount, and the corresponding Error Rate(s) related to the net Overpayment. Note: for the purpose of this reporting, any potential cost settlements or other supplemental payments should not be included in the net Overpayment calculation. Rather, only underpayments identified as part of the Discovery Sample or Full Sample (as applicable) shall be included as part of the net Overpayment calculation; and
- c. the IRO's findings and recommendations concerning the Systems Review (if any).

3. **Statistical Sampling Documentation.**

- a. The number of Items appraised in the Discovery Sample and, if applicable, in the Full Sample.
- b. A copy of the printout of the random numbers generated by the "Random Numbers" function of the statistical sampling software used by the IRO.
- c. A copy of the statistical software printout(s) estimating how many Items are to be included in the Full Sample.
- d. A description or identification of the statistical sampling software package used to conduct the sampling.

4. **Claims Review Results.**

- a. Total number and percentage of instances in which the IRO determined that the Paid Claims submitted by Ambleside ("Claims Submitted") differed from what should have been the correct claim ("Correct Claim"), regardless

of the effect on the payment.

b. Total number and percentage of instances in which the Claim Submitted differed from the Correct Claim and in which such difference resulted in an Overpayment to Ambleside.

c. Total dollar amount of paid Items included in the sample and the net Overpayment associated with the sample.

d. Error Rate in the sample.

e. A spreadsheet of the Claims Review results that includes the following information for each Paid Claim appraised: Federal health care program billed, beneficiary health insurance claim number, date of service, procedure code submitted, procedure code reimbursed, allowed amount reimbursed by payor, correct procedure code (as determined by the IRO), correct allowed amount (as determined by the IRO), dollar difference between allowed amount reimbursed by payor and the correct allowed amount. (See Attachment 1 to this Appendix.)

5. **Systems Review.** Observations and recommendations on possible improvements to the system(s) and process(es) that generated the Overpayment(s) in the sample Population.
6. **Credentials.** The names and credentials of the individuals who: (1) designed the statistical sampling procedures and the review methodology utilized for the Claims Review; and (2) performed the Claims Review.