CORPORATE INTEGRITY AGREEMENT
BETWEEN THE
OFFICE OF INSPECTOR GENERAL
OF THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND
PENNMED

I. PREAMBLE

PennMed Consultants, Inc., Briarcliff Nursing Center Associates, Easton Nursing Center Associates, Greenridge Nursing Center Associates, Lancaster Nursing Center Associates, Milville Nursing Center Associates, Orangeville Nursing Center Associates, Overlook Nursing Center Associates, White Cliff Nursing Center Associates, and Francis Hayman, Jr. (hereinafter referred to collectively as "PennMed") enter into this Corporate Integrity Agreement ("CIA") with the Office of Inspector General ("OIG") of the United States Department of Health and Human Services ("HHS") to ensure compliance by the nursing facilities that they manage or own presently or in the future, their affiliates, subsidiaries, directors, employees, physicians, other health care professionals, contractors, and agents with the requirements of the Medicare, Medicaid and all other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)) (hereinafter collectively referred to as the "Federal health care programs"). PennMed's compliance with the terms and conditions in this CIA shall constitute an element of PennMed's present responsibility with regard to participation in the Federal health care programs. Contemporaneously with this CIA, PennMed is entering into a Settlement Agreement with the United States, and this CIA is incorporated by reference into the Settlement Agreement.

II. TERM OF THE CIA

The period of the compliance obligations assumed by PennMed under this CIA shall be five (5) years from the effective date of this CIA (unless otherwise specified). The effective date of this CIA will be the date on which the final signatory of this CIA executes this CIA (the "effective date").

III. CORPORATE INTEGRITY OBLIGATIONS

PennMed shall establish a compliance program that includes the following elements.

A. Compliance Officer and Committee. Within ninety (90) days after the effective date of this CIA, PennMed shall appoint an individual to serve as Compliance Officer, who shall be responsible for developing and implementing policies, procedures, and practices designed to ensure compliance with the requirements set forth in this CIA and with the requirements of the Federal health care programs. The Compliance Officer shall be a member of senior management

of PennMed, shall make regular (at least quarterly) reports regarding compliance matters directly to the CEO and/or to the Board of Directors of PennMed, and shall be authorized to report to the Board of Directors at any time. The Compliance Officer shall be responsible for monitoring the day-to-day activities engaged in by PennMed to further its compliance objectives as well as any reporting obligations created under this CIA. In the event a new Compliance Officer is appointed during the term of this CIA, PennMed shall notify the OIG, in writing, within fifteen (15) days of such a change.

PennMed shall also appoint a Compliance Committee within ninety (90) days after the effective date of this CIA. The Compliance Committee shall, at a minimum, include the Compliance Officer and any other appropriate officers as necessary to meet the requirements of this CIA within PennMed's corporate structure (*e.g.*, senior executives of each major department, such as billing, clinical, human resources, audit, and operations). The Compliance Officer shall chair the Compliance Committee and the Committee shall support the Compliance Officer in fulfilling his/her responsibilities.

B. Written Standards.

1. *Code of Conduct.* Within ninety (90) days of the effective date of this CIA, PennMed shall establish a Code of Conduct. The Code of Conduct shall be distributed to all of PennMed's officers, directors, employees, and agents (hereinafter referred to collectively as the "covered persons") within ninety (90) days of the effective date of this CIA. PennMed shall make the promotion of, and adherence to, the Code of Conduct an element in evaluating the performance of covered persons. The Code of Conduct shall, at a minimum, set forth:

a. PennMed's commitment to full compliance with all statutes, regulations, and guidelines applicable to Federal health care programs, including its commitment to prepare and submit accurate billings and reports consistent with Federal health care program regulations and procedures or instructions otherwise communicated by the Health Care Financing Administration ("HCFA"), and/or its agents;

b. PennMed's requirement that all covered persons shall be expected to comply with all statutes, regulations, and guidelines applicable to Federal health care programs and with PennMed's own policies and procedures (including the requirements of this CIA);

c. The requirement that all covered persons shall be expected to report suspected violations of any statute, regulation, or guideline applicable to Federal health care programs or suspected violations of PennMed's own policies and procedures;

d. The possible consequences to both PennMed and to any covered person of failure to comply with all statutes, regulations, and guidelines applicable to Federal health care programs and with PennMed's own policies and procedures or of failure to report such non-compliance; and

e. The right of all covered persons to use the confidential disclosure program, as well as PennMed's commitment to confidentiality and non-retaliation with respect to disclosures.

Within ninety (90) days of the effective date of the CIA, each covered person shall certify, in writing, that he or she has received, read, understands, and will abide by PennMed's Code of Conduct. New covered persons shall receive the Code of Conduct and shall complete the required certification within two (2) weeks after becoming a covered person or within ninety (90) days of the effective date of the CIA, whichever is later.

PennMed will annually review the Code of Conduct and will make any necessary revisions. These revisions shall be distributed within thirty (30) days of initiating such a change. Covered persons shall certify on an annual basis that they have received, read, understand and will abide by the Code of Conduct.

2. *Policies and Procedures.* Within ninety (90) days of the effective date of this CIA, PennMed shall develop and initiate implementation of written Policies and Procedures regarding the operation of its compliance program and regarding its compliance with all federal and state health care statutes, regulations, and guidelines. At a minimum, the Policies and Procedures shall specifically address:

a. Measures designed to ensure that PennMed fully complies with the particular provisions of Titles XVIII and XIX of the Social Security Act, 42 U.S.C. §§ 1395-1395ggg (1999) and 1396-1396v (1997), the Americans with Disabilities Act, 42 U.S.C. §§ 12101-12213, and all regulations and guidelines promulgated pursuant to these statutes, including, but not limited to, 42 C.F.R. Parts 424 and 483.

b. Measures designed to ensure that PennMed complies with all requirements applicable to Medicare's Prospective Payment System (PPS) for skilled nursing facilities, including but not limited to: ensuring the accuracy of the clinical data required under the Minimum Data Set ("MDS") as specified by the Resident Assessment Instrument User's Manual; ensuring that facilities are appropriately and accurately using the current Resource Utilization Groups ("RUG") classification system; ensuring the accuracy of billing and cost report preparation policies and procedures.

c. Measures designed to ensure the coordinated interdisciplinary approach to providing care to patients, including but not limited to, resident assessment and care planning; nutrition; diabetes care; wound care; infection control; abuse and neglect policies and reporting procedures; appropriate drug therapies; appropriate mental health services; provision of basic care needs; incontinence care; resident rights and restraint use; activities of daily living (ADL) care; therapy services; quality of life, including accommodation of needs and activities; and assessment of patient competence to make treatment decisions.

d. Disciplinary guidelines and methods for employees to make disclosures or otherwise report on compliance issues to PennMed management through the Confidential Disclosure Program required by section III.E.

e. Measures designed to ensure that compliance issues identified internally (*e.g.*, through reports to supervisors, internal audits) or externally (*e.g.*, audits performed by PennMed's audit or accounting firm(s) or any other externally performed reviews) are promptly and appropriately investigated and, if the investigation substantiates compliance issues, PennMed implements appropriate corrective action plans and monitors compliance with such plans.

f. Measures designed to ensure that cost reports correctly reflect relationships with related parties and that any exceptions to the related party rules are obtained annually from the intermediary.

PennMed shall assess and update the Policies and Procedures at least annually and more frequently, as necessary and appropriate. The Policies and Procedures will be available to OIG upon request.

Within ninety (90) days of the effective date of the CIA, the relevant portions of the Policies and Procedures shall be made available to all appropriate covered persons. Compliance staff or supervisors should be available to explain any and all policies and procedures.

C. Training and Education. PennMed shall meet the following training requirements. These training requirements are cumulative (not exclusive) so that one person may be required to attend training in several substantive areas in addition to the general training. Persons providing the training must be knowledgeable about the relevant subject area. All training requirements set forth below shall be implemented within ninety (90) days of the effective date of this CIA and thereafter repeated annually during the term of the CIA.

1. *General Training*. PennMed shall provide at least two (2) hours of training to each covered person. This general training shall explain PennMed's:

a. Corporate Integrity Agreement requirements;

b. Compliance Program (including the Policies and Procedures as they pertain to general compliance issues); and

c. Code of Conduct.

The training material shall be made available to the OIG, upon request.

2. *Specific Training*. Each covered person who is involved directly or indirectly in the delivery of patient care and/or in the preparation or submission of information (including claims, bills, and reports) to any Federal health care program shall receive at least eight (8) hours of training in addition to the general training required above. This training shall include a discussion of:

a. The submission of accurate information, *e.g.*, Minimum Data Set (MDS), to Federal health care programs;

b. Policies, procedures and other requirements applicable to the documentation of medical records;

c. The personal obligation of each individual involved in the patient care, documentation, and/or reimbursement process to ensure that the information provided is accurate;

d. Applicable statutes, regulations, and program requirements and directives relevant to the person's duties;

e. The legal sanctions for improper submissions to Federal health care programs;

f. Examples of proper and improper practices related to Federal health care programs;

g. Policies and procedures related to proper billing for services to Federal health care programs and claims for payments through submission of Federal health care program cost reporting and information forms.

3. *New Persons*. Affected new covered persons shall receive the training required by this CIA within one week of the beginning of their employment or contractual relationship with PennMed or within ninety (90) days of the effective date of this CIA, whichever is later. If a new covered person is in a position for which training is required under this CIA prior to receiving all the training required for that position, a PennMed employee who has completed the substantive training shall review all of the untrained person's work related to that substantive area.

4. *Certifications and Retention.* Each person who is required to attend training shall certify, in writing, that he or she has attended the required training. The certification shall specify the type of training received and the date received. The Compliance Officer shall retain the certifications as well as the specific course materials and make all of these certifications and materials available to OIG upon request.

D. Review Procedures. PennMed shall retain an entity, such as an accounting, auditing or consulting firm (hereinafter "Independent Review Organization"), to perform review procedures to assist PennMed in assessing the adequacy of its submissions to Federal health care programs, and its compliance with this CIA. The reviews will be performed annually and will cover each of the one-year periods beginning on the effective date of this CIA or the anniversary of that date. The Independent Review Organization must have expertise in the billing, coding, reporting and other requirements of the Federal health care programs from which PennMed seeks reimbursement. The Independent Review Organization must be retained to conduct the audit of the first year within ninety (90) days of the effective date of this CIA.

The Independent Review Organization will conduct two separate engagements. One will be an analysis of PennMed's submissions to the Federal health care programs to assist PennMed and OIG in determining compliance with all applicable statutes, regulations, and directives/guidance ("submissions engagement"). The second engagement will determine whether PennMed is in compliance with this CIA ("compliance engagement").

1. *Submissions Engagement.* The submissions engagement shall consist of a review of the submissions made by each PennMed facility to Federal health care programs related to a statistically valid sample of the Federal health care program beneficiaries in residence at the PennMed facility during that year. The sample shall be designed to ensure that the findings can be projected to the total reimbursement received by the PennMed facility from Federal health care programs during the relevant year covered by the engagement. The sample size shall be determined through the use of a probe sample. The probe sample must contain at least thirty (30) sample units and cannot be used as part of the full sample. The full sample must contain a sufficient number of units so that when the sample results are projected to the full population, the projection provides a minimum 90% confidence level and a maximum precision of plus or minus 25% of the point estimate (i.e., the upper and lower bounds of the 90% confidence interval shall not exceed 125% and shall not fall below 75% of the midpoint of the confidence interval, respectively). Both the probe sample and the full sample must be selected through random number sampling. To generate the random sample, PennMed shall use OIG's Office of Audit Services Statistical Sampling Software, also known as "RAT-STATS," presently available through the Internet at "www.hhs.gov/oas/ratstat.html."

Each annual submissions engagement analysis shall include the following components in its methodology:

a. Submissions Engagement Objective: a clear statement of the objective intended to be achieved by the submissions engagement and the procedure or combination of procedures that will be applied to achieve the objective.

b. Submissions Engagement Population: the identity of the population, which is the group about which information is needed and an explanation of the methodology used to develop the population and provide the basis for this determination.

c. Sources of Data: a full description of the source of the information upon which the submissions engagement conclusions will be based, including the legal or other standards applied, documents relied upon, payment data, and/or any contractual obligations.

d. Sampling Unit: a definition of the sampling unit, which is any of the designated elements that comprise the population of interest.

e. Sampling Frame: the identity of the sampling frame, which is the totality of the sampling units from which the sample will be selected.

The submissions engagement shall provide:

a. Findings regarding PennMed's documentation (*e.g.*, cost reports, cost statements), billing, and reporting (*e.g.*, reporting of MDS and other information relevant to Resource Utilization Group (RUG)) operations (including, but not limited to, the operation of the reporting system, strengths and weaknesses of this system, internal controls, effectiveness of the system);

b. Findings regarding whether PennMed is submitting accurate claims, cost reports, resident assessments, and other submissions to the Federal health care programs;

c. Findings regarding PennMed's procedures to correct inaccurate claims, cost reports, resident assessments, and other submissions to the Federal health care programs;

d. Findings regarding whether PennMed has complied with its obligation under the Settlement Agreement: (1) not to resubmit to any Federal health care program payors any previously denied claims related to the conduct addressed in the Settlement Agreement, and its obligation not to appeal any such denials of claims; and (2) 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 and adjust any past charges of unallowable costs;

e. Findings regarding the steps PennMed is taking to bring its operations into compliance or to correct problems (including whether PennMed has effectively implemented corrective action plans to address such problems) identified by these engagements, internal or external audits, or fiscal intermediary audits; and

With respect to the entry of MDS data, the Independent Review Organization shall use its own MDS data entry software program to compare resulting outputs (i.e., RUGs).

The submission engagement shall also consist of a review of a sample of provider cost reports and home office cost statements filed for reimbursement or information with HCFA through its fiscal intermediaries. The review will consist of, at a minimum, a review of all related documentation that supports the entries on the cost reports/cost statements, statistics, revenues, costs (expenses), and any other relevant information that forms the basis of the filings. The reviews shall be conducted to ensure that the reports were filed in accordance with Federal health care program policies, procedures, and instructions. The OIG may obtain documentation from PennMed regarding the work PennMed has performed on these reviews, to assist the OIG in determining the appropriateness of the filings.

2. *Compliance Engagement.* An Independent Review Organization shall also conduct a compliance engagement that shall provide findings regarding whether PennMed's program, policies, procedures, and operations comply with the terms of this CIA. This engagement shall include section-by-section findings regarding the requirements of this CIA as well as findings regarding adherence to the requirements of paragraphs 12-20 of the Settlement Agreement and the requirements of 42 C.F.R. § 1001.1901. This engagement will also include findings as to the facts and circumstances of any mortgage refinancings by any of the PennMed nursing homes or limited partnerships and any distributions to the partners pursuant to any such refinancing. In making its findings, the Independent Review Organization shall interview appropriate employees and other individuals, inspect appropriate documents, and take such other actions as are necessary to ascertain the facts.

3. *Verification/Validation.* In the event the OIG has reason to believe that PennMed's Submissions Engagement or Compliance Engagement fail to conform to its obligations under the CIA or indicate improper submissions not otherwise adequately addressed in the audit report, and thus determines that it is necessary to conduct an independent review to determine whether or the extent to which PennMed is complying with its obligations under this CIA, PennMed agrees to pay for the reasonable cost of any such review or engagement by the OIG or any of its designated agents.

E. Confidential Disclosure Program. Within ninety (90) days after the effective date of this CIA, PennMed shall establish a Confidential Disclosure Program, which must include measures (*e.g.*, a toll-free compliance telephone line) to enable employees, contractors, agents or other individuals to disclose, to the Compliance Officer or some other person who is not in the reporting individual's chain of command, any identified issues or questions associated with PennMed's policies, practices or procedures related to the Federal health care program that the individual believes to be inappropriate. PennMed shall publicize the existence of the hotline (*e.g.*, e-mail to employees or post hotline number in prominent common areas).

The Confidential Disclosure Program shall emphasize a non-retribution, non-retaliation policy, and shall include a reporting mechanism for anonymous, confidential communication. Upon receipt of a complaint, the Compliance Officer (or designee) shall gather the information in such a way as to elicit all relevant information from the individual reporting the alleged misconduct. The Compliance Officer (or designee) shall make a preliminary good faith inquiry into the allegations set forth in every disclosure to ensure that he or she has obtained all of the information necessary to determine whether a further review should be conducted. For any disclosure that is sufficiently specific so that it reasonably: (1) permits a determination of the appropriateness of the alleged improper practice, and (2) provides an opportunity for taking corrective action, PennMed shall conduct an internal review of the allegations set forth in such a disclosure and ensure that proper follow-up is conducted.

The Compliance Officer shall maintain a confidential disclosure log, which shall include a record and summary of each allegation received, the status of the respective investigations, and any corrective action taken in response to the investigation.

F. Ineligible Persons and Criminal Background Checks.

1. *Definition*. For purposes of this CIA, an "Ineligible Person" shall be any individual or entity who: (i) is currently excluded, suspended, debarred or otherwise ineligible to participate in the Federal health care programs; or (ii) has been convicted of a criminal offense related to the provision of health care items or services and has not been reinstated in the Federal health care programs after a period of exclusion, suspension, debarment, or ineligibility.

2. *Screening Requirements*. PennMed shall not hire or engage as contractors any Ineligible Person. To prevent hiring or contracting with any Ineligible Person, PennMed shall screen all prospective employees and prospective contractors prior to engaging their services by (i) requiring applicants to disclose whether they are Ineligible Persons, and (ii) reviewing the General Services Administration's List of Parties Excluded from Federal Programs (currently available through the Internet at http://www.arnet.gov/epls) and the HHS/OIG List of Excluded Individuals/Entities (currently 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 ninety (90) days of the effective date of this CIA, PennMed will review its list of current employees and contractors against the Exclusion Lists. Thereafter, PennMed will review the list once semi-annually. If PennMed has notice that an employee, agent, or physician has become an Ineligible Person, PennMed will remove such person from responsibility for, or involvement with, PennMed'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 PennMed has notice that an employee or contractor is charged with a criminal offense related to any Federal health care program, or is suspended or proposed for exclusion during his or her employment or contract with PennMed, within 10 days of receiving such notice PennMed will remove such individual from responsibility for, or involvement with, PennMed's business operations related to the Federal health care programs until the resolution of such criminal action, suspension, or proposed exclusion.

5. *Criminal Background Checks.* PennMed shall ensure that it: (a) complies with all federal and state requirements regarding criminal background checks for covered persons; and (b) obtains the results of a criminal background check for any individual who may receive an offer of employment for a position that involves patient care, prior to extending an offer of employment.

G. Notification of Proceedings. Within thirty (30) days of discovery, PennMed 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 PennMed has committed a crime or has engaged in fraudulent activities or any other knowing misconduct. 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. PennMed shall also provide written notice to OIG within thirty (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. *Reporting of Overpayments.* If, at any time, PennMed identifies or learns of any billing, reporting or other policies, procedures and/or practices that result in an overpayment, PennMed shall notify the payor (*e.g.*, Medicare fiscal intermediary or carrier) within 30 days of discovering the overpayment 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 the overpayment is discovered as the result of any of the activities required by this CIA, the notice to the payor shall include:

a. A statement that the refund is being made pursuant to this CIA;

b. A description of the complete circumstances surrounding the overpayment;

c. The methodology by which the overpayment was determined;

d. The amount of the overpayment;

e. Any claim-specific information used to determine the overpayment (e.g., beneficiary health insurance number, claim number, service date, and payment date);

f. The Provider identification number under which the repayment is being made;

g. The cost reporting period; and

h. Any applicable Overpayment Refund Form provided and required by the payor.

2. *Reporting of Material Deficiencies*. If PennMed determines that there is a material deficiency, PennMed shall notify the OIG within 30 days of discovering the material deficiency. If the material deficiency results in an overpayment, the report to the OIG shall be made at the same time as the report to the payor and shall include all of the information required by section III.H.1 plus: (i) the payor's name, address, and contact person where the overpayment was sent; and (ii) the date of the check and identification number (or electronic transaction number) on which the overpayment was repaid. Regardless of whether the material deficiency resulted in an overpayment, the report to the OIG shall include:

a. A complete description of the material deficiency, including the relevant facts, persons involved, and legal and program authorities;

b. PennMed's actions to correct the material deficiency; and

c. Any further steps PennMed plans to take to address such material deficiency and prevent it from recurring.

3. *Definition of "Overpayment."* For purposes of this CIA, an "overpayment" shall mean the amount of money PennMed has received in excess of the amount due and payable under the Federal health care programs' statutes, regulations or program directives, including carrier and intermediary instructions.

4. *Definition of "Material Deficiency."* For purposes of this CIA, a "material deficiency" means anything that involves: (i) a substantial overpayment relating to any Federal

health care program; (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; or (iii) a violation of the obligation to provide items or services of a quality that meets professionally recognized standards of health care where such violation has occurred in one or more instances that presents an imminent danger to the health, safety, or well-being of a Federal health care program beneficiary or places the beneficiary unnecessarily in high-risk situations. A material deficiency may be the result of an isolated event or a series of occurrences.

IV. NEW LOCATION AND BUSINESS UNITS

In the event that PennMed purchases or establishes new business units after the effective date of this CIA, PennMed shall notify OIG of this fact within thirty (30) days of the date of purchase or establishment. This notification shall include the location of the new operation(s), phone number, fax number, Federal health care program Provider number(s) (if any), and the corresponding payor(s) (contractor specific) that has issued each provider number. All covered persons at such locations shall be subject to the requirements in this CIA that apply to new covered persons (*e.g.*, completing certifications and undergoing training).

V. IMPLEMENTATION AND ANNUAL REPORTS

A. Implementation Report. Within one hundred and twenty (120) days after the effective date of this CIA, PennMed 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 section III.A;

2. The names and positions of the members of the Compliance Committee required by section III.A;

3. A copy of PennMed's Code of Conduct required by section III.B.1;

4. The summary of the Policies and Procedures required by section III.B.2;

5. A description of the training programs required by section III.C including a description of the targeted audiences 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 section III.B have been developed, are being implemented, and have been distributed to all covered persons;

b. All covered persons have completed the Code of Conduct certification required by section III.B.1; and

c. All covered persons have completed the training and executed the certification required by section III.C.

7. A description of the confidential disclosure program required by section III.E;

8. The identity of the Independent Review Organization(s) and the proposed start and completion date of the first audit; and

9. A summary of personnel actions taken pursuant to section III.F.

10. A list of all of PennMed's locations and facilities owned or operated (including street and mailing addresses), the corresponding name under which each facility is doing business, the corresponding phone numbers and fax numbers, each facility's Federal health care program provider identification number(s), and the name, address, and telephone number of the payor (specific contractor) that issued each provider identification number.

B. Annual Reports. PennMed shall submit to OIG an Annual Report with respect to the status and findings of PennMed's compliance activities. The Annual Reports shall include:

1. Any change in the identity or position description of the Compliance Officer and/or members of the Compliance Committee described in section III.A;

2. A certification by the Compliance Officer that:

a. All covered persons have completed the annual Code of Conduct certification required by section III.B.1; and

b. All covered persons have completed the training and executed the certification required by section III.C.

3. Notification of any changes or amendments to the Policies and Procedures required by section III.B and the reasons for such changes (e.g., change in contractor policy);

4. A complete copy of the report prepared pursuant to the Independent Review Organization's submissions and compliance engagement, including a copy of the methodology used.

5. PennMed's response/corrective action plan to any issues raised by the Independent Review Organization.

6. A summary of material deficiencies and reported throughout the course of the previous twelve (12) months pursuant to III.D.3 and III.H.

7. A report of the aggregate overpayments that have been returned to the Federal health care programs that were discovered as a direct or indirect result of implementing this CIA. Overpayment amounts should be broken down into the following categories: Medicare, Medicaid (report each applicable state separately) and other Federal health care programs;

8. A copy of the confidential disclosure log required by section III.E;

9. A description of any personnel action (other than hiring) taken by PennMed as a result of the obligations in section III.F;

10. A summary describing any ongoing investigation or legal proceeding conducted or brought by a governmental entity involving an allegation that PennMed has committed a crime or has engaged in fraudulent activities, which have been reported pursuant to section III.G. The statement shall include a description of the allegation, the identity of the investigating or prosecuting agency, and the status of such investigation, legal proceeding or requests for information;

11. A corrective action plan to address the probable violations of law identified in section III.H; and

12. A description of all changes to the most recently provided list (as updated) of PennMed'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 Federal health care program provider identification number(s), and the name, address, and telephone number of the payor (specific contractor) that issued each provider identification number.

The first Annual Report shall be received by the OIG no later than one year and thirty (30) days after the effective date of this CIA. Subsequent Annual Reports shall be submitted 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 under penalty of perjury, that: (1) PennMed 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, upon such inquiry, the information is accurate and truthful.

VI. NOTIFICATIONS AND SUBMISSION OF REPORTS

Unless otherwise stated in writing subsequent to the effective date of this CIA, all notifications and reports required under this CIA shall be submitted to the entities listed below:

OIG:

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, SW
Washington, DC 20201
Phone: 202.619.2078
Fax: 202.205.0604

PennMed:

Verna MacGeorge
Acting Compliance Officer
PennMed Consultants, Inc.
964 Marcon Blvd, Suite 224
Allentown, PA 18102
Phone: 610 264 8000

VII. 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 PennMed's books, records, and other documents and supporting materials and/or conduct an onsite review of PennMed's operations for the purpose of verifying and evaluating: (a) PenMed's compliance with the terms of this CIA; and (b) PenMed's compliance with the requirements of the Federal health care programs in which it participates. The documentation described above shall be made available by PennMed 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 PennMed's employees, contractors, and agents who consent to be interviewed at the employee's place of business during normal business hours or at such other place and time as may be mutually agreed upon between the employee, contractor, and agent and OIG. PennMed agrees to assist OIG in contacting and arranging interviews with

such employees, contractors, and agents upon OIG's request. PennMed's employees may elect to be interviewed with or without a representative of PennMed present.

VIII. DOCUMENT AND RECORD RETENTION

PennMed shall maintain for inspection all documents and records relating to reimbursement from the Federal health care programs or to compliance with this CIA, one year longer than the term of this CIA (or longer if otherwise required by law).

IX. DISCLOSURES

Subject to HHS's Freedom of Information Act ("FOIA") procedures, set forth in 45 C.F.R. Part 5, the OIG shall make a reasonable effort to notify PennMed prior to any release by OIG of information submitted by PennMed pursuant to its obligations under this CIA and identified upon submission by PennMed as trade secrets, commercial or financial information and privileged and confidential under the FOIA rules. PennMed shall refrain from identifying any information as trade secrets, commercial or financial information and privileged and confidential that does not meet the criteria for exemption from disclosure under FOIA.

X. BREACH AND DEFAULT PROVISIONS

PennMed is expected to fully and timely comply with all of the obligations herein throughout the term of this CIA or other time frames herein agreed to.

A. Stipulated Penalties for Failure to Comply with Certain Obligations. As a contractual remedy, PennMed 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 $2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day, beginning ninety (90) days after the effective date of this CIA and concluding at the end of the term of this CIA, PennMed fails to have in place any of the following:

a. Compliance Officer;
b. Compliance Committee;
c. Written Code of Conduct;
d. Written Policies and Procedures;
e. Training program; and
f. Confidential Disclosure Program.

2. A Stipulated Penalty of $2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day PennMed fails meet any of the deadlines to submit the Implementation Report or the Annual Reports to the OIG.

3. A Stipulated Penalty of $2,000 (which shall begin to accrue on the date the failure to comply began) for each day PennMed:

a. Hires or enters into a contract with an Ineligible Person after that person has been listed by a federal agency as excluded, debarred, suspended or otherwise ineligible for participation in the Medicare, Medicaid or any other Federal health care program (as defined in 42 U.S.C. § 1320a-7b(f)) (this Stipulated Penalty shall not be demanded for any time period during which PennMed can demonstrate that it did not discover the person's exclusion or other ineligibility after making a reasonable inquiry (as described in section III.F) as to the status of the person);

b. Employs or contracts with an Ineligible Person and that person: (i) has responsibility for, or involvement with, PennMed'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 (this Stipulated Penalty shall not be demanded for any time period during which PennMed can demonstrate that it did not discover the person's exclusion or other ineligibility after making a reasonable inquiry (as described in section III.F) as to the status of the person); or

c. Employs or contracts with a person who: (i) has been charged with a criminal offense related to any Federal health care program, or (ii) is suspended or proposed for exclusion, and that person has responsibility for, or involvement with, PennMed's business operations related to the Federal health care programs (this Stipulated Penalty shall not be demanded for any time period before 10 days after PennMed received notice of the relevant matter or after the resolution of the matter).

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

5. A Stipulated Penalty of $1,000 (which shall begin to accrue ten (10) days after the date that OIG provides notice to PennMed of the failure to comply) for each day PennMed fails to comply fully and adequately with any obligation of this CIA. In its notice to PennMed, the OIG shall state the specific grounds for its determination that the PennMed has failed to comply fully and adequately with the CIA obligation(s) at issue.

B. Payment of Stipulated Penalties.

1. *Demand Letter*. Upon a finding that PennMed has failed to comply with any of the obligations described in section X.A and determining that Stipulated Penalties are appropriate, OIG shall notify PennMed by personal service or certified mail of (a) PennMed'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").

Within fifteen (15) days of the date of the Demand Letter, PennMed shall either (a) cure the breach to the OIG's satisfaction and pay the applicable stipulated penalties; or (b) request a hearing before an HHS administrative law judge ("ALJ") to dispute the OIG's determination of noncompliance, pursuant to the agreed upon provisions set forth below in section X.D. In the event PennMed elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until PennMed cures, to the 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 X.C

2. *Timely Written Requests for Extensions*. PennMed may 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 PennMed fails to meet the revised deadline as agreed to by the OIG-approved extension. 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 two (2) business days after PennMed receives OIG's written denial of such request. A "timely written request" is defined as a request in writing received by OIG at least five (5) 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.

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 VI.

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

C. Exclusion for Material Breach of this CIA

1. *Notice of Material Breach and Intent to Exclude.* The parties agree that a material breach of this CIA by PennMed constitutes an independent basis for PennMed's exclusion from participation in the Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)). Upon a determination by OIG that PennMed has materially breached this CIA and that exclusion should be imposed, the OIG shall notify PennMed by certified mail of (a) PennMed'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").

2. *Opportunity to cure.* PennMed shall have thirty five (35) days from the date of the Notice of Material Breach and Intent to Exclude Letter to demonstrate to the OIG's satisfaction that:

a. PennMed is in full compliance with this CIA;
b. The alleged material breach has been cured; or
c. The alleged material breach cannot be cured within the 35-day period, but that: (i) PennMed has begun to take action to cure the material breach, (ii) PennMed is pursuing such action with due diligence, and (iii) PennMed has provided to OIG a reasonable timetable for curing the material breach.

3. *Exclusion Letter.* If at the conclusion of the thirty five (35) day period, PennMed fails to satisfy the requirements of section X.C.2, OIG may exclude PennMed from participation in the Federal health care programs. OIG will notify PennMed in writing of its determination to excluded PennMed (this letter shall be referred to hereinafter as the "Exclusion Letter"). Subject to the Dispute Resolution provisions in section X.D, below, the exclusion shall go into effect thirty (30) days after the date of the Exclusion Letter. The exclusion shall have national effect and will also apply to all other federal procurement and non-procurement programs. If PennMed is excluded under the provisions of this CIA, PennMed may seek reinstatement pursuant to the provisions at 42 C.F.R. §§ 1001.3001-.3004.

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

a. Failure by PennMed to report a material deficiency, take corrective action and pay the appropriate refunds, as provided in section III.D;

b. Repeated or flagrant violations of the obligations under this CIA, including, but not limited to, the obligations addressed in section X.A of this CIA;

c. Failure to respond to a Demand letter concerning the payment of Stipulated Penalties in accordance with section X.B above;

d. Failure to retain and use an Independent Review Organization for review purposes in accordance with section III.D; or

e. Violation of any of the provisions of paragraphs 12-20 of the Settlement Agreement.

D. Dispute Resolution

1. *Review Rights.* Upon the OIG's delivery to PennMed of its Demand Letter or of its Exclusion Letter, and as an agreed-upon contractual remedy for the resolution of disputes arising under the obligation of this CIA, PennMed 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. § 1005 as if they applied to the Stipulated Penalties or exclusion sought pursuant to this CIA. Specifically, the OIG's determination to demand payment of Stipulated Penalties or to seek exclusion shall be subject to review by an ALJ and, in the event of an appeal, the 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 fifteen (15) days of the date of the Demand Letter and the request for a hearing involving exclusion shall be made within thirty (30) days of the date 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 PennMed was in full and timely compliance with the obligations of this CIA for which the OIG demands payment; and (b) the period of noncompliance. PennMed shall have the burden of proving its full and timely compliance and the steps taken to cure the noncompliance, if any. If the ALJ finds for the OIG with regard to a finding of a breach of this CIA and orders PennMed to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable twenty (20) days after the ALJ issues such a decision notwithstanding that PennMed may request review of the ALJ decision by the DAB.

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 PennMed was in material breach of this CIA; (b) whether such breach was continuing on the date of the Exclusion Letter; and (c) the alleged material breach cannot be cured within the 35 day period, but that (i) PennMed has begun to take action to cure the material breach, (ii) PennMed is pursuing such action with due diligence, and (iii) PennMed has provided to OIG a reasonable timetable for curing the material breach.

For purposes of the exclusion herein, exclusion shall take effect only after an ALJ decision that is favorable to the OIG. PennMed's election of its contractual right to appeal to the DAB shall not abrogate the OIG's authority to exclude PennMed upon the issuance of the ALJ's decision. If the ALJ sustains the determination of the OIG and determines that exclusion is authorized, such exclusion shall take effect twenty (20) days after the ALJ issues such a decision, notwithstanding that PennMed may request review of the ALJ decision by the 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 and PennMed agrees to waive any right it may have to appeal the decision administratively, judicially or otherwise seek review by any court or other adjudicative forum.

XI. 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, PennMed and OIG agree as follows:

A. This CIA shall be binding on the successors, assigns and transferees of PennMed, including "New Co." referred to in the Settlement Agreement; it shall be binding on the nursing facilities managed or owned by PennMed presently or in the future; and it shall be binding on any other nursing home management entity retained by any of these nursing facilities.

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. The undersigned PennMed 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.

Francis A. Hayman, Jr., individually — DATE 10/1/99

ON BEHALF OF PENNMED CONSULTANTS, INC:

Francis A. Hayman, Jr., President — DATE 10/1/99

ON BEHALF OF BRIARCLIFF NURSING CENTER ASSOCIATES:

[signature] — DATE 10/1/99

ON BEHALF OF EASTON NURSING CENTER ASSOCIATES:

Francis A. Hayman, Jr., Managing General Partner — DATE 10/1/99

ON BEHALF OF GREENRIDGE NURSING CENTER ASSOCIATES:

Francis A. Hayman, Jr., Managing General Partner — DATE 10/1/99

ON BEHALF OF LANCASTER NURSING CENTER ASSOCIATES:

Francis A. Hayman, Jr., Managing General Partner — DATE 10/1/99

ON BEHALF OF MILLVILLE NURSING CENTER ASSOCIATES:

Francis A. Hayman, Jr., Managing General Partner — DATE 10/1/99

ON BEHALF OF ORANGEVILLE NURSING CENTER ASSOCIATES:

Francis A. Hayman, Jr., Managing General Partner — DATE 10/1/99

ON BEHALF OF OVERLOOK NURSING CENTER ASSOCIATES:

Francis A. Hayman, Jr., Managing General Partner — DATE 10/1/99

ON BEHALF OF WHITE CLIFF NURSING CENTER ASSOCIATES:

Francis A. Hayman, Managing General Partner — DATE 10/1/99

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

10/1/99
DATE

AMENDMENT TO THE CORPORATE INTEGRITY AGREEMENT BETWEEN THE OFFICE OF INSPECTOR GENERAL OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES AND PENNMED

The Office of Inspector General ("OIG") of the Department of Health and Human Services and PennMed Consultants, Inc., Briarcliff Nursing Center Associates, Easton Nursing Center Associates, Greenridge Nursing Center Associates, Lancaster Nursing Center Associates, Milville Nursing Center Associates, Orangeville Nursing Center Associates, Overlook Nursing Center Associates, White Cliff Nursing Center Associates, and Francis Hayman, Jr. (hereinafter referred to collectively as "PennMed") entered into a Corporate Integrity Agreement ("CIA") on October 1, 1999.

A. Pursuant to section XI.C. of PennMed's CIA, modifications to the CIA may be made with the prior written consent of both the OIG and PennMed. Therefore, the OIG and PennMed hereby agree that PennMed'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.

The attached Appendix A is hereby added to PennMed's CIA.

B. The OIG and PennMed agree that all other sections of PennMed's CIA will remain unchanged and in effect, unless specifically amended upon the prior written consent of the OIG and PennMed.

C. The undersigned PennMed signatory represents and warrants that he is 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.

D. The effective date of this Amendment will be the date on which the final signatory of this Amendment signs this Amendment.

ON BEHALF OF PENNMED

Francis A. Hayman, Jr.
President, PennMed

5/30/02
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

6/10/02
DATE

D. Review Procedures.

1. *General Description.*

a. Retention of Independent Review Organization. Within 90 days of the effective date of this CIA, PennMed 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 PennMed 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 PennMed 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 PennMed seeks reimbursement. Each IRO shall assess, along with PennMed, 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 PennMed's billing and coding to the Federal health care programs ("Claims Review"), and shall analyze PennMed's compliance with the obligations assumed under this CIA and the Settlement Agreement ("Compliance Review" and "Settlement Agreement Compliance Review").

b. Frequency and types of Claims Reviews. The Claims Reviews 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 the annual Claims Reviews.

i. Types of reviews: For each facility to be reviewed, the IRO shall conduct a claims review of Medicare Part A, Medicare Part B and Medicaid claims.

ii. Selection of facilities: The IRO shall conduct claims reviews at five facilities each year. The facilities shall be randomly chosen using RAT-STATS. If a facility has already been reviewed in the immediately preceding year, then a replacement facility should be reviewed.

c. 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.

d. Frequency of Settlement Agreement Compliance Review. The Settlement Agreement Compliance Review shall be performed annually by the IRO.

e. Retention of Records. The IRO and PennMed 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 PennMed) related to the reviews.

2. *Claims Review.* Each 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 will conduct a discovery sample of 50 randomly selected Paid Claims per facility and will include Medicare and Medicaid payor classes. The payor class (Medicare, Medicaid) pro ration of claims in the discovery sample at each facility will approximate the percentages of the number of patient days for Medicare and for Medicaid to the total number of patient days for Medicare and Medicaid for the scope period for the randomly selected facility. Further dissection of the separate number of Medicare Part A and Medicare Part B claims to be included in the one discovery sample of 50 sample items for each facility will be based on the percentage of payments for Medicare Part A and Medicare Part B to the total payments for Medicare Parts A and B for the scope period for that facility. The Paid Claims shall be reviewed based on the supporting documentation available at PennMed or under PennMed's control and applicable billing and coding regulations and guidance to determine whether the claim submitted was correctly coded, submitted, and reimbursed.

i. If the Error Rate (as defined in Appendix A) for the Discovery Sample 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, PennMed should, as appropriate, further analyze any errors identified

in the Discovery Sample. PennMed 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 III.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 PennMed or under PennMed'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, PennMed 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 PennMed 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 PennMed's Discovery Sample identifies an Error Rate of 5% or greater, PennMed'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 PennMed the IRO's 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, PennMed 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. PennMed agrees to make available to the OIG any and all documentation that reflects the refund of the Overpayment(s) to the payor.

3. *Claims Review Report.* The IRO shall prepare a report based upon the Claims Reviews performed (the "Claims Review Report"). Information to be included in the Claims Review Report is detailed in Appendix A.

4. *Compliance Review.* The IRO shall conduct a review of PennMed's compliance activities. The Compliance Review shall consist of a review of PennMed's compliance with the obligations set forth in each section of this CIA.

5. *Compliance Review Report.* The IRO shall prepare a report based upon the Compliance Review performed. The Compliance Review Report shall include the IRO's findings and supporting rationale regarding PennMed's compliance with the terms of each section of the CIA, as applicable.

6. *Settlement Agreement Compliance Review.* The IRO shall review PennMed's adherence to the requirements of paragraphs 12-20 of the Settlement Agreement and the requirements of 42 CFR 1001.1901 (Settlement Agreement Compliance Review).

7. *Settlement Agreement Compliance Review Report.* The Settlement Agreement Compliance Review Report shall include findings regarding adherence to the requirements of paragraphs 12-20 of the Settlement Agreement and the requirements of 42 CFR 1001.1901. This report will also include findings as to the facts and circumstances of any mortgage refinancings by any of the PennMed nursing homes or limited partnerships and any distributions to the partners pursuant to any such refinancings. In making its finds, the IRO shall interview appropriate employees and other individuals, inspect appropriate documents, and take other such actions as are necessary to ascertain the facts.

8. *Validation Review.* In the event the OIG has reason to believe that: (a) PennMed's Claims Reviews or Compliance Review fails to conform to the requirements of this CIA; or (b) the IRO's findings or Claims Reviews results are inaccurate, the OIG may, at its sole discretion, conduct its own review to determine whether the Claims

Reviews or Compliance Review complied with the requirements of the CIA and/or the findings or Claims Reviews results are inaccurate ("Validation Review"). PennMed 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 PennMed's final Annual Report and any additional information requested by the OIG is received by the OIG.

Prior to initiating a Validation Review, the OIG shall notify PennMed 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, PennMed may request a meeting with the OIG to discuss the results of any Claims Reviews or Compliance Review submissions or findings; present any additional or relevant information to clarify the results of the Claims Reviews or Compliance Review or to correct the inaccuracy of the Claims Reviews; and/or propose alternatives to the Validation Review. PennMed 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 Reviews or Compliance Review issues with PennMed 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 PennMed a certification or sworn affidavit that it has evaluated its professional independence with regard to the Claims Reviews and Compliance Review and that it has concluded that it is, in fact, independent.

APPENDIX A

A. Claims Review.

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

a. Overpayment: The amount of money PennMed 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 PennMed and for which PennMed has received reimbursement from the Medicare or Medicaid program.

d. Population: All Items for which PennMed has submitted a code or line item and for which PennMed has received reimbursement from the Medicare or Medicaid program (i.e., a Paid Claim) during the 12-month period covered by the Claims Reviews. 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 net Overpayments shall be calculated by subtracting all underpayments identified in the sample from all gross Overpayments identified in the sample. (Note: 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.)

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 Reviews, any Paid Claim for which PennMed cannot produce documentation sufficient to support the Paid Claim shall be considered an error and the total reimbursement received by PennMed 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.

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. **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, if applicable.

d. A description or identification of the statistical sampling software package used to conduct the sampling.

3. **Claims Review Findings.**

a. Narrative Results.

i. A description of PennMed's billing and coding system(s), including the identification, by position description, of the personnel involved in coding and billing.

ii. A narrative explanation of the IRO's findings and supporting rationale (including reasons for errors, patterns noted, etc.) regarding each 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.

b. Quantitative Results.

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

ii. 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 PennMed.

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

iv. Error Rate in the sample.

v. Spreadsheet of each of the Claims Reviews 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. **Systems Review.** Observations, findings and recommendations on possible improvements to the system(s) and process(es) that generated the Overpayment(s).

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

Attachment 1

Claim Review Results

Federal Health Care Program Billed	Bene HIC #	Date of Service	Procedure Code Submitted	Procedure Code Reimbursed	Allowed Amount Reimbursed	Correct Procedure Code (IRO determined)	Correct Allowed Amt Reimbursed (IRO determined)	Dollar Difference between Amt Reimbursed and Correct Allowed Amt

pennmed new rev proc.march2002.wpd