ATTACHMENT B

CORPORATE INTEGRITY AGREEMENT
BETWEEN THE
OFFICE OF INSPECTOR GENERAL
OF THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND
COASTAL MED-TECH, INC. AND DALE HADLOCK

I. PREAMBLE

Coastal Med-Tech, Inc. and Dale Hadlock (collectively, "Coastal ") hereby agree to enter into this Corporate Integrity Agreement ("Agreement") with the Office of Inspector General of the United States Department of Health and Human Services ("OIG") to provide for the establishment of a Corporate Integrity Program to ensure compliance with the requirements of Medicare, Medicaid and all other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)) by Coastal, by any corporation which participates in the Federal health care programs, in which Coastal is an owner or has a control interest as defined in 42 U.S.C. § 1320a-3(a)(3), Coastal's employees, and all third parties with whom Coastal may choose to engage to act as billing or coding consultants for Coastal. Coastal's compliance with the terms and conditions in this Agreement shall constitute an element of Coastal's present responsibility with regard to participation in the Federal health care programs. Contemporaneously with this Agreement, Coastal is entering into a Stipulation and Consent Judgment with the United States, and this Agreement is incorporated by reference into the Stipulation and Consent Judgment.

II. TERM OF THE AGREEMENT

Except as otherwise provided, the period of compliance obligations assumed by Coastal under this Agreement shall be six (6) years from the date of execution of this Agreement. The effective date of this Agreement will be the date on which the final signatory of this Agreement executes this Agreement (the "effective date").

III. CORPORATE INTEGRITY OBLIGATIONS

Within ninety (90) days of the date of execution of this Agreement, Coastal agrees

to implement a Corporate Integrity Program (the "Program"), which shall include the following provisions:

A. COMPLIANCE CONTACT

Within thirty (30) days of execution of this Agreement, Coastal shall designate a person to be the contact person for purposes of the obligations herein. In the event a new contact person is appointed during the term of this Agreement, Coastal shall notify the OIG, in writing, within fifteen (15) days of such a change.

B. POSTING OF NOTICE

Within the first thirty (30) days following the effective date of this Agreement, Coastal shall post in a prominent place accessible to all customers and employees a notice detailing Coastal's commitment to comply with all applicable statutes, regulations and directives applicable to Medicare, Medicaid and all other Federal health care programs in the conduct of Coastal's business. This notice shall include a means (i.e., telephone number, address, etc.) by which instances of misconduct can be reported anonymously.

C. WRITTEN POLICIES AND PROCEDURES

Coastal agrees to develop and implement written policies and procedures within ninety (90) days of the effective date of this Agreement that address the following:

a. The proper submission of claims to the Medicare, Medicaid, and other Federal health care programs;

b. The proper documentation of services and billing information and the retention of such information in a readily retrievable form; and

c. The commitment of Coastal to adhere to honest and accurate billing practices.

D. TRAINING AND CERTIFICATION

Within ninety (90) days following the effective date of this Agreement, Coastal and all personnel involved in preparing or submitting Medicare, Medicaid, and all other Federal health care program bills for services and items provided by Coastal

or any of Coastal's agents shall be trained in the proper billing standards, methods, and procedures to ensure accurate billing for services rendered to Medicare, Medicaid, and all other Federal health care programs. The training shall be designed to ensure that Coastal and all of its employees and agents are aware of all applicable health care statutes, regulations, and program guidelines and with the standards of business conduct that such individual is expected to follow and the consequences (i.e., termination, legal sanctions, etc.) both to the individual and Coastal that will ensue from any violation of such requirements.

In addition, Coastal will arrange for all new personnel involved in billing for services to participate in such training no later than thirty (30) days after they begin working for Coastal. Until they have had the requisite training, such new employees will work under the direct supervision of an employee who has received such training. This training program shall provide for no less than six (6) hours of training annually for each person.

At a minimum, the training sessions shall cover the following topics:

1. The proper billing standards and procedures for the submission of accurate bills for services rendered and/or items provided to Medicare, Medicaid, and all other Federal health care programs to which Coastal submits claims; and

2. All applicable statutes, rules, regulations, and guidelines related to Medicare, Medicaid and other Federal health care programs billing, reimbursement, and the legal sanctions for improper billing and violating these laws.

Every employee, officer, and director will sign a certification indicating attendance at the training session and further attesting to an understanding of the provisions in the billing policy manual and all applicable Federal health care laws, including Medicare and Medicaid statutes, regulations and standards of business conduct. These certifications will be maintained by Coastal and shall be made available for inspection by OIG or its duly authorized representatives.

E. Independent Audits

Within thirty (30) days of the effective date of this Agreement, Coastal agrees to contract with a third party reviewer (e.g., audit, law or health care consulting firm)

to undertake an annual review of a statistically valid sample of the claims submitted by Coastal, its agents and/or employees to Medicare, Medicaid, and all other Federal health care programs to determine whether the claims are in compliance with the appropriate billing requirements. This review will be conducted by an independent and appropriately trained person or entity with knowledge of Federal health care statutes, regulations, program requirements, billing policies and procedures. These audits shall cover the preceding one (1) year period and shall seek to determine that the claims submitted to the Medicare, Medicaid and other Federal health care programs are medically necessary and covered services under applicable program guidelines and that the claims are appropriately coded and billed. The results of this review shall be submitted with the Annual Report, along with a corrective action plan for correcting the deficiencies found.

Generally, if any of these reviews uncovers claims processing and/or billing policies, procedures and/or practices that result in material deficiencies, Coastal shall notify the entity in charge of processing the claim for reimbursement (such as the Medicare carrier or other payor), within thirty (30) days of discovering the deficiency and take remedial steps within sixty (60) days of discovering the deficiency (or such additional time as may be agreed to by the payor) to correct the problem, and prevent the deficiency from reoccurring.

Contemporaneous with Coastal's notification to the payor as provided above, Coastal shall notify OIG of: (1) all of the information provided to the payor in returning the overpayment; (2) the name and the address of the payor to which the overpayment was sent; (3) Coastal's findings concerning the material deficiency; (4) Coastal's actions to correct such material deficiency; and (5) any further steps Coastal plans to take to address such material deficiency and prevent it and similar billing deficiencies from reoccurring.

For purposes of this Agreement, a "material deficiency" shall mean anything that involves: (i) a substantial overpayment or improper payment relating to the Medicare and/or Medicaid programs; (ii) conduct or policies that clearly violate the Medicare and/or Medicaid statutes, regulations or directives issued by the Health Care Financing Administration ("HCFA") and/or its agents; or (iii) serious quality of care implications for Federal health care beneficiaries or recipients. A material deficiency may be the result of an isolated event or a series of occurrences.

If Coastal learns of any overpayment (regardless of its size and regardless of whether it results from a material deficiency) received from a Federal health care program, Coastal shall notify the appropriate payor, make appropriate refunds and take any steps necessary to prevent the reoccurrence.

In the event that the OIG determines that it is necessary to conduct an independent review to determine whether or the extent to which Coastal is complying with its obligations under this CIA, Coastal agrees to pay for the reasonable cost of any such review or engagement by the OIG or any of its designated agents.

F. INELIGIBLE PERSONS

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.* Coastal shall not hire or engage as contractors any Ineligible Person. To prevent hiring or contracting with any Ineligible Person, Coastal 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 (available through the Internet at http://www.arnet.gov/epls) and the HHS/OIG List of Excluded Individuals/Entities (available through the Internet at http://www.dhhs.gov/progorg/oig) (these lists and reports 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, Coastal will review its list of current employees and contractors against the Exclusion Lists. Thereafter, Coastal will review the list once semi-annually. If Coastal has notice that an employee or agent has become an Ineligible Person, Coastal will remove such person from responsibility for, or involvement with, Coastal'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 Coastal 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 Coastal, within 10 days of receiving such notice Coastal will remove such individual from responsibility for, or involvement with, Coastal's business operations related to the Federal health care programs until the resolution of such criminal action, suspension, or proposed exclusion.

IV. SELF-DISCLOSURE OF PROBABLE VIOLATIONS

During the term of this Agreement, Coastal will report to OIG any reliable evidence of actions that Coastal believes constitute a probable violation of any state or Federal civil, criminal or administrative statute, regulation, or rule governing a Federal health care program. Coastal must make the required disclosure no later than thirty (30) calendar days after becoming aware of the existence of the probable violation. This disclosure shall include conduct by any of Coastal's personnel and any person or entity with a financial interest in Coastal's business.

Coastal will certify to OIG that any disclosures made under this paragraph have been fully investigated and that appropriate corrective actions have been taken to ensure that Coastal is in compliance with all state and Federal civil, criminal, and administrative statutes, regulations and rules governing all Federal health care programs. Nothing in this paragraph waives OIG's right to enforce any and all statutes and regulations governing any Federal health care program, subject to the release provisions of the Stipulation and Consent Judgment signed this same date.

V. OIG INSPECTION, AUDIT AND REVIEW RIGHTS

In addition to any other right OIG may have by statute, regulation, contract or pursuant to this Agreement, OIG or its duly authorized representative(s) may examine Coastal's place of business, Coastal's books, records, and other company documents and supporting materials for the purpose of verifying and evaluating: (i) Coastal's compliance

with the terms of this Agreement; and (ii) Coastal's compliance with the requirements of the Medicare, Medicaid and other Federal health care programs. OIG, or its duly authorized representative, may conduct unannounced on-site visits at Coastal's place of business at any time to review patient medical records and other related documentation for the purpose of verifying and evaluating Coastal's compliance with the statutory and regulatory requirements of Medicare, Medicaid and all other Federal health care programs.

VI. REPORTS

A. IMPLEMENTATION REPORT

Within one-hundred and twenty (120) days of the effective date of this Agreement, Coastal shall provide the OIG with a written report demonstrating that Coastal has complied with the Program's requirements. This report, known as the "Implementation Report," shall include:

(1) A copy of the notice Coastal posted in its place(s) of business as described in Section III.B.

(2) A certification signed by Coastal attesting that all employees have completed the initial training required by Section III.D. as well as a summary of what the training included and the proposed schedule for the next year. The training materials will be made available to OIG upon request.

(3) A copy of the written policies and procedures required by section III.C. of this Agreement.

(4) A certification from the Coastal stating that Dale Hadlock has reviewed the Implementation Report, he has made a reasonable inquiry regarding its content and believes that the information is accurate and truthful.

B. ANNUAL REPORTS

Coastal shall make annual written reports (each one of which is referred to throughout this Agreement as the "Annual Report") to OIG describing the measures Coastal has taken to implement and maintain the Program and ensure compliance with the terms of this Agreement. In accordance with the provisions above, the Annual Report shall include:

(1) A description, schedule and topic outline of the training programs implemented pursuant to section III.D. of this Agreement, and a written certification from all appropriate personnel that they received training pursuant to the requirements set forth in section III.D. of this Agreement.

(2) A copy of the audits and reviews conducted pursuant to section III.E. of this Agreement relating to the year covered by the Annual Report; a complete description of the findings made during the reviews and audits; copies of the disclosure or notice documents made by Coastal pursuant to this section; and any future corrective actions Coastal plans to initiate and when.

(3) A certification signed by Dale Hadlock certifying that he has reviewed the Annual Report, he has made a reasonable inquiry regarding its content and believes that the information is accurate and truthful.

(4) a description of any personnel action (other than hiring) taken as a result of the obligations in section III. F.

The first Annual Report shall be submitted no later than one year and thirty (30) days after the effective date of this Agreement. Subsequent Annual Reports will be submitted on the anniversary date of the date of submission of the first Annual Report.

VII. NOTIFICATIONS AND SUBMISSION OF REPORTS

Unless otherwise stated subsequent to the execution of this Agreement, all notifications and reports required under the terms of this Agreement shall be submitted to the entities listed below:

To 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
330 Independence Avenue, SW
Cohen Building, Room 5527
Washington, DC 20201
Tel: 202.619.2078
Fax: 202.205.0604

To Coastal: Dale Hadlock
RR1 Box 479 B
Hancock, Maine 04640
Tel: -207.667.6589
Fax: 207.667.2589

VIII. <u>BREACH AND DEFAULT PROVISIONS</u>

Full and timely compliance by Coastal shall be expected throughout the duration of this Agreement with respect to all of the obligations herein agreed to by Coastal.

A. <u>REMEDIES FOR MATERIAL BREACH OF THIS AGREEMENT</u>

If Coastal engages in conduct that OIG considers to be a material breach, defined below, of this Agreement, OIG may seek exclusion of Coastal from participation in the Medicare, Medicaid and any other Federal health care programs. Upon making its determination, OIG shall notify Coastal of the alleged material breach by certified mail and of its intent to exclude as a result thereof (this notice shall be referred to hereinafter as the "Intent to Exclude Letter"). Coastal shall have thirty-five (35) days from the date of the letter to:

(1) cure the alleged material breach; or

(2) demonstrate to the OIG's satisfaction that the alleged material breach cannot be cured within the thirty-five (35) day period, but that Coastal has begun to take action to cure the material breach and that Coastal will pursue such action with due diligence. Coastal shall, at this time, submit a timetable for curing the material breach for the OIG's approval.

If at the conclusion of the thirty-five (35) day period (or other specific period as

subsequently agreed by OIG and Coastal), Coastal fails to act in accordance with provisions (1) and (2) above, OIG may exclude Coastal from participation in the Medicare, Medicaid and all other Federal health care programs. OIG will notify Coastal in writing of its determination to exclude Coastal (this letter shall be referred to hereinafter as the "Exclusion Letter").

B. Dispute Resolution

Upon OIG's delivery to Coastal of its Exclusion Letter, and as an agreed upon contractual remedy for the resolution of disputes arising under the obligations in this Agreement, the OIG may initiate proceedings to undertake appropriate administrative action, including exclusion, for a material breach of this Agreement. Coastal shall be afforded certain review rights comparable to those that are provided in 42 U.S.C. § 1320a-7(f) and 42 C.F.R. part 1005. Specifically, the OIG's determination to seek exclusion shall be subject to review by an HHS Administrative Law Judge ("ALJ") in a manner consistent with the provisions in 42 C.F.R. §§ 1005.2-1005.21. The ALJ's decision, in turn, may be appealed to the HHS Departmental Appeals Board ("DAB") in a manner consistent with the provisions in 42 C.F.R. § 1005.21. However, Coastal agrees that the decision by the DAB, if any, shall constitute the final decision and no appeal right shall be afforded to any Federal or state court.

For purposes of this section, a "material breach" shall mean: (i) a failure to report a material deficiency, take corrective action and pay the appropriate refunds, as provided in section III.E of this Agreement; (ii) repeated or flagrant violations of the obligations under this Agreement, including, but not limited to, the obligations addressed in section VI.A and VI.B of this Agreement; or (iii) a failure to retain and use an Independent Review Organization for review purposes in accordance with section III.E.

IX. New Locations

In the event that Coastal purchases or establishes new business units, which participate in the Federal health care programs, after the effective date of this CIA, Coastal 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 employees at such locations shall be subject to the requirements in this CIA that apply to

new employees (e.g., completing certifications and undergoing training).

X. EFFECTIVE AND BINDING AGREEMENT

Consistent with the provisions in the Stipulation and Consent Judgment pursuant to which this Agreement is entered, and into which this Agreement is incorporated, Coastal and the OIG agree as follows:

(1) this Agreement shall be binding on the successors, assigns and transferees of Coastal;

(2) this Agreement shall become final and binding only upon signing by each respective party hereto; and

(3) any modifications to this Agreement shall be made with the prior written consent of the parties to this Agreement.

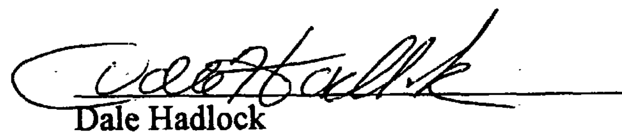
IN WITNESS WHEREOF, the parties hereto affix their signatures:

COASTAL MED- TECH INC. AND DALE HADLOCK

Sept. 14, 1999
Date

President
Coastal Med-Tech, Inc.

Sept. 14, 1999
Date



Dale Hadlock

OFFICE OF INSPECTOR GENERAL OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES

9/20/99
Date

Lewis Morris, Esquire
Assistant Inspector General for Legal Affairs
Office of Counsel to the Inspector General
Office of Inspector General
U. S. Department of Health and Human Services

AMENDMENT TO THE CORPORATE INTEGRITY AGREEMENT
BETWEEN THE
OFFICE OF INSPECTOR GENERAL OF THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND
COASTAL MED-TECH, INC. AND DALE HADLOCK

The Office of Inspector General ("OIG") of the Department of Health and Human Services and Coastal Med-Tech, Inc. and Dale Hadlock ("Coastal") entered into a Corporate Integrity Agreement ("CIA") on September 20, 1999.

A. Pursuant to section X.3 of Coastal's CIA, modifications to the CIA may be made with the prior written consent of both the OIG and Coastal. Therefore, the OIG and Coastal hereby agree that Coastal's CIA will be amended as follows:

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

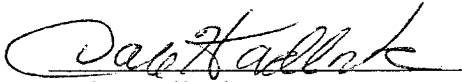
   The attached Appendix A is hereby added to Coastal's CIA.

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

C. The undersigned Coastal 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. This effective date of this Amendment will be the date on which the final signatory of this Amendment signs this Amendment.

ON BEHALF OF COASTAL MED-TECH, INC. AND DALE HADLOCK



Dale Hadlock
President

9-16-02
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

9/9/02
DATE

E. Review Procedures.

1. *General Description.*

a. Retention of Independent Review Organization. Within 90 days of the effective date of this CIA, Coastal 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 Coastal in assessing and evaluating its billing and coding practices and systems, pursuant to this CIA and the Settlement Agreement. Each IRO retained by Coastal 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 Coastal seeks reimbursement. Each IRO shall assess, along with Coastal, 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 Coastal's billing and coding to the Federal health care programs ("Claims 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. Retention of Records. The IRO and Coastal 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 Coastal) 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 Coastal. The Paid Claims shall be reviewed based on the supporting documentation available at Coastal or under Coastal'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, Coastal should, as appropriate, further analyze any errors identified in the Discovery Sample. Coastal 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.E.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' ("CMS") statistical sampling for overpayment estimation guidelines. The Paid Claims shall be reviewed based on supporting documentation available at Coastal or under Coastal'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, Coastal 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 Coastal 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 Coastal's Discovery Sample identifies an Error Rate of 5% or greater, Coastal'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 Coastal 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. Coastal 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. Coastal agrees to make available to the OIG any and all documentation that reflects the refund of the Overpayment(s) to the payor.

e. Reporting of Overpayments. If Coastal learns of any overpayments (regardless of its size and regardless of whether it results from a material deficiency and/or the Discovery or Full Sample) received from a Federal health care program, Coastal shall notify the appropriate payor, make appropriate refunds and take any necessary steps to prevent the reoccurrence. Contemporaneous with Coastal's notification to the payor, Coastal shall notify OIG of: (1) all of the information provided to the payor in returning the overpayment; (2) the name and the address of the payor to which the overpayment was sent; (3) Coastal's finding concerning the material deficiency; (4) Coastal's actions to correct such material deficiency; and (5) any further steps Coastal plans to take to address such material deficiency and prevent it and similar billing deficiencies from recurring.

f. Material Deficiency. For purposes of this Agreement, a "material deficiency" shall mean anything that involves: (i) a substantial overpayment or improper payment relating to the Medicare and/or Medicaid programs; (ii) conduct or policies that clearly violate the Medicare and/or Medicaid statutes, regulations or directives issued by CMS and/or its agents; or (iii) serious quality of care implications for Federal health care beneficiaries or recipients. A material deficiency may be the result of an isolated event or a series of occurrences.

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. *Validation Review.* In the event the OIG has reason to believe that: (a) Coastal's Claims 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"). Coastal 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 Coastal'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 Coastal 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, Coastal may request a meeting with the OIG to discuss the results of any Claims Review submissions or findings; present any additional or relevant information to clarify the results of the Claims Review or to correct the inaccuracy of the Claims Review; and/or propose alternatives to the Validation Review. Coastal 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 issues with Coastal 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.* The IRO shall include in its report(s) to Coastal a certification or sworn affidavit that it has evaluated its professional independence with regard to the Claims 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 Review, the following definitions shall be used:

a. Overpayment: The amount of money Coastal 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 Coastal and for which Coastal has received reimbursement from the Medicare, Medicaid or any other Federal health care program.

d. Population: All Items for which Coastal has submitted a code or line item and for which Coastal has received reimbursement from the Medicare, Medicaid, or any other Federal health care program (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 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 Review, any Paid Claim for which Coastal cannot produce documentation sufficient to support the Paid Claim shall be considered an error and the total reimbursement received by Coastal 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 Coastal'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 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.

b. Quantitative Results.

i. Total number and percentage of instances in which the IRO determined that the Paid Claims submitted by Coastal ("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 Coastal.

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. 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. **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 Review; and (2) performed the Claims Review.