# CERTIFICATION OF COMPLIANCE AGREEMENT BETWEEN THE OFFICE OF INSPECTOR GENERAL OF THE

# DEPARTMENT OF HEALTH AND HUMAN SERVICES AND

CORAM, INC. AND CORAM ALTERNATE SITE SERVICES

#### I. PREAMBLE

Coram, Inc., a Delaware corporation, and Coram Alternate Site Services (Coram) hereby enter into this Certification of Compliance Agreement (CCA) with the Office of Inspector General (OIG) of the United States Department of Health and Human Services (HHS). Contemporaneously with this CCA, Coram is entering into a Settlement Agreement with the United States.

The effective date of this CCA shall be the date on which the final signatory of this CCA executes this CCA (Effective Date). Each one-year period, beginning with the one-year period following the Effective Date, shall be referred to as a "Reporting Period."

#### II. INTEGRITY REQUIREMENTS

Coram shall, for a period of three years from the Effective Date of this CCA:

- A. Continued Implementation of Compliance Program. Coram shall continue to implement its Compliance Program, as described in the attached Declaration (which is incorporated by reference as Appendix A), and continue to provide, at a minimum, the same level of resources currently provided, throughout this time period; provided, however, that in the event that a change in circumstances would justify a reduction in that level of resources Coram may seek consent from OIG for such reduction by submitting a revised budget and a written explanation for the reduction. Coram may amend its Compliance Program as it deems necessary, so long as those amendments are consistent with the overall objective of ensuring compliance with the requirements of Medicare, Medicaid, and all other Federal health care programs, as defined in 42 U.S.C. § 1320a-7b(f).
- B. Reporting of Overpayments. Coram shall promptly refund to the appropriate Federal health care program payor any identified Overpayment(s). For purposes of this CCA, an "Overpayment" shall mean the amount of money Coram has received in excess of the amount due and payable under any Federal health care program requirements. If, at any time, Coram identifies or learns of any Overpayment, Coram shall notify the payor

CCA - Coram

- (e.g., Medicare fiscal intermediary or carrier) within 30 days after identification of the Overpayment and take remedial steps within 60 days after identification (or such additional time as may be agreed to by the payor) to correct the problem, including preventing the underlying problem and the Overpayment from recurring. Also, within 30 days after identification of the Overpayment, Coram shall repay the Overpayment to the appropriate payor to the extent such Overpayment has been quantified. If not yet quantified, within 30 days after identification, Coram shall notify the payor of its efforts to quantify the Overpayment amount along with a schedule of when such work is expected to be completed. Notification and repayment to the payor shall be done in accordance with the payor's policies and, for Medicare contractors, shall include the information contained on the Overpayment Refund Form, provided as Appendix B to this CCA. Notwithstanding the above, notification and repayment of any Overpayment amount that is routinely reconciled or adjusted pursuant to policies and procedures established by the payor should be handled in accordance with such policies and procedures.
- C. Reportable Events. Coram shall report to OIG in writing within 30 days after making a determination (after a reasonable opportunity to conduct an appropriate review or investigation of the allegations) that there is a Reportable Event, which shall mean anything that involves: (1) a substantial Overpayment, (2) a matter that a reasonable person would consider a probable violation of criminal, civil, or administrative laws applicable to any Federal health care program for which penalties or exclusion may be authorized; or (3) the filing of a bankruptcy petition by Coram. In such report, Coram shall include the following information:
  - 1. if the Reportable Event results in an Overpayment, the report to OIG shall be made at the same time as the notification to the payor required in Section II.B, and shall include all of the information on the Overpayment Refund Form, as well as:
    - a. the payor's name, address, and contact person to whom the Overpayment was sent, and
    - b. the date of the check and identification number (or electronic transaction number) by which the Overpayment was repaid/refunded;
  - 2. a complete description of the Reportable Event, including the relevant facts, persons involved, and legal and Federal health care program authorities implicated;

- 3. a description of Coram's actions taken to correct the Reportable Event;
- 4. any further steps Coram plans to take to address the Reportable Event and prevent it from recurring; and
- 5. if the Reportable Events involves the filing of a bankruptcy petition, the report to the OIG shall include documentation of the filing and a description of any Federal health care program authorities implicated.
- D. Notification of Government Investigation or Legal Proceedings. Within 30 days after the matter is discovered by senior management, Coram shall notify OIG, in writing, of any ongoing investigation or legal proceeding known to Coram conducted or brought by a governmental entity or its agents involving an allegation that Coram has committed a crime or has engaged in fraudulent activities. This notification shall include a description of the allegation, the identity of the investigating or prosecuting agency, and the status of such investigation or legal proceeding. Coram shall also provide written notice to OIG within 30 days after the resolution of the matter; and shall provide OIG with a description of the findings and/or results of the investigation or proceedings, if any.
- E. Annual Reporting Requirements. Coram shall submit to OIG annually a report that sets forth the following information for each Reporting Period (Annual Report):
  - 1. a description of any material amendments to its Compliance Program and the reasons for such changes;
  - 2. any decrease to the level of resources dedicated to its Compliance Program and the reasons for such decrease;
  - 3. a summary of all internal or external reviews, audits, or analyses related to completion of Certificates of Medical Necessity (CMNs) and DME MAC Information Forms (DIFs) (including, at a minimum, the objective of the review, audit, or analysis; the protocol or methodology for the review, audit, or analysis; and the results of the review, audit, or analysis) and any corrective action plans developed in response to such reviews, audits, or analyses;
  - 4. a summary of all internal or external reviews, audits, or analyses related to Federal health care programs (including, at a minimum, the objective of the review, audit, or analysis, the protocol or methodology for the review, audit, or analysis; and the results of the review, audit, or analysis) and any

corrective action plans developed in response to such reviews, audits, or analyses;

- 5. a report of the aggregate Overpayments that have been returned to the Federal health care programs. Overpayment amounts shall be broken down into the following categories: outpatient Medicare, Medicaid (report each state separately, if applicable), and other Federal health care programs. Overpayment amounts that are routinely reconciled or adjusted pursuant to policies and procedures established by the payor do not need to be included in this aggregate Overpayment report; and
- 6. a certification by the Compliance Officer that: (a) to the best of her knowledge, except as otherwise described in the Annual Report, Coram is in compliance with the requirements of this Section II, and (b) she has reviewed the Annual Report and has made reasonable inquiry regarding its content and believes that the information in the Annual Report is accurate and truthful.

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

F. <u>Notifications and Submission of Annual Reports</u>. Unless otherwise specified in writing after the Effective Date, all notifications and Annual Reports required under this CCA shall be submitted to the following addresses:

#### OIG:

Administrative and Civil Remedies Branch
Office of Counsel to the Inspector General
Office of Inspector General
U.S. Department of Health and Human Services
Cohen Building, Room 5527
330 Independence Avenue, S.W.
Washington, DC 20201
Telephone: 202-619-2078
Facsimile: 202-205-0604

Coram:

Margaret F. Brown

Corporate Compliance Officer

CCA - Coram

Senior Vice President, Quality, Ethics and Compliance

Coram, Inc.

1471 Business Center Drive, Suite 400

Mt. Prospect, IL 60056

Copies to:

Jonathan L. Diesenhaus

Counsel for Coram

HOGAN & HARTSON, LLP

Columbia Square, 555 Thirteenth Street, NW

Washington, DC 20004 Telephone: 202-637-5416 Facsimile: 202-637-5910

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

- G. OIG Inspection, Audit, and Review Rights. In addition to any other rights OIG may have by statute, regulation, or contract, OIG or its duly authorized representative(s) may examine or request copies of Coram's books, records, and other documents and supporting materials and/or conduct on-site reviews of any of Coram's locations for the purpose of verifying and evaluating: (a) Coram's compliance with the terms of this CCA; and (b) Coram's compliance with the requirements of the Federal health care programs in which it participates. The documentation described above shall be made available by Coram 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 Coram's employees, contractors, or agents who consent to be interviewed at the individual's place of business during normal business hours or at such other place and time as may be mutually agreed upon between the individual and OIG. Coram shall assist OIG or its duly authorized representative(s) in contacting and arranging interviews with such individuals upon OIG's request. Coram's employees may elect to be interviewed with or without a representative of Coram present.
- H. <u>Document and Record Retention</u>. Coram shall maintain for inspection all documents and records relating to reimbursement from the Federal health care programs, or to compliance with this CCA, for four years (or longer if otherwise required by law) from the Effective Date.

#### III. BREACH AND DEFAULT PROVISIONS

Coram is expected to fully and timely comply with all of the Integrity Requirements set forth in this CCA.

- A. <u>Stipulated Penalties for Failure to Comply with Certain Obligations</u>. As a contractual remedy, Coram and OIG hereby agree that failure to comply with the Integrity Requirements set forth in this CCA 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 Coram fails to establish and implement any of the following compliance program elements as described in Section II and the Declaration attached to this CCA as Appendix A:
  - a. a Compliance Officer;
  - b. a Compliance Committee;
  - c. a written Code of Conduct,
  - d. written Policies and Procedures;
  - e. the annual training of employees, officers, directors, contractors, subcontractors, agents, and other persons who provide patient care items or services or who perform billing or coding functions on behalf of Coram;<sup>1</sup>
  - f. an internal reimbursement compliance audit department that performs periodic reviews to monitor Coram's compliance with Federal health care program requirements;
  - g. a Disclosure Program;
  - h. Ineligible Persons screening and removal requirements, and

Annual training is not required for part-time or per diem employees, contractors, subcontractors, agents and other persons who are not reasonably expected to work for Coram more than 160 hours per year. Such individuals shall be required to receive the compliance training, however, at the point when they work more than 160 hours during the calendar year.

- i. notification of government investigations and legal proceedings, pursuant to Section II.D.
- 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 Coram fails to submit the Annual Reports to OIG in accordance with the requirements of Section II.E by the stated deadlines for submission.
- 3. A Stipulated Penalty of \$1,500 for each day Coram fails to grant access as required in Section II.G of this CCA. (This Stipulated Penalty shall begin to accrue on the date Coram fails to grant access.)
- 4. A Stipulated Penalty of \$5,000 for each false certification submitted by or on behalf of Coram as part of its Annual Reports or otherwise required by this CCA.
- 5. A Stipulated Penalty of \$1,000 for each day Coram fails to comply fully and adequately with any Integrity Requirements of this CCA. OIG shall provide notice to Coram stating the specific grounds for its determination that Coram has failed to comply fully and adequately with the Integrity Requirement(s) at issue and steps Coram shall take to comply with the Integrity Requirements of this CCA. (This Stipulated Penalty shall begin to accrue 10 days after Coram receives notice from OIG of the failure to comply.) A Stipulated Penalty as described in this Subsection shall not be demanded for any violation for which OIG has sought a Stipulated Penalty under Subsections 1-4 of this Section III.A.
- B. <u>Timely Written Requests for Extensions</u>. Coram may, in advance of the due date, submit a timely written request for an extension of time to perform any act or file any notification or report required by this CCA. 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 Coram fails to meet the revised deadline set by OIG. Notwithstanding any other provision in this Section, if OIG denies such a timely written request, Stipulated Penalties for failure to perform the act or file the notification or report shall not begin to accrue until three business days after Coram receives OIG's written denial of such request or the original due date, whichever is later. A "timely written request" is defined as a request in writing received by OIG at least five business days prior to the date by which any act is due to be performed or any notification or report is due to be filed.
  - C. Payment of Stipulated Penalties.

- 1. Demand Letter. Upon a finding that Coram has failed to comply with any of the obligations described in Section III. A and after determining that Stipulated Penalties are appropriate, OIG shall notify Coram of: (a) Coram's failure to comply; and (b) OIG's exercise of its contractual right to demand payment of the Stipulated Penalties (this notification is referred to as the "Demand Letter").
- 2. Response to Demand Letter. Within 10 days after the receipt of the Demand Letter, Coram shall either: (a) cure the breach to OIG's satisfaction and pay the applicable Stipulated Penalties or (b) request a hearing before an HHS administrative law judge (ALJ) to dispute OIG's determination of noncompliance, pursuant to the agreed upon provisions set forth below in Section III.E. In the event Coram elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until Coram cures, to OIG's satisfaction, the alleged breach in dispute. Failure to respond to the Demand Letter in one of these two manners within the allowed time period shall be considered a material breach of this CCA and shall be grounds for exclusion under Section III.D.
- 3. Form of Payment. Payment of the Stipulated Penalties shall be made by certified or cashier's check, payable to: "Secretary of the Department of Health and Human Services," and submitted to OIG at the address set forth in Section II.F.
- 4. Independence from Material Breach Determination. Except as set forth in Section III.D. 1.c, these provisions for payment of Stipulated Penalties shall not affect or otherwise set a standard for OIG's decision that Coram has materially breached this CCA, which decision shall be made at OIG's discretion and shall be governed by the provisions in Section III.D, below.

#### D. Exclusion for Material Breach of this CCA.

- 1. Definition of Material Breach. A material breach of this CCA means:
  - a. a failure by Coram to report a Reportable Event, take corrective action, and make the appropriate refunds, as required in Section II.C,
  - b. a repeated or flagrant violation of the obligations under this CCA, including, but not limited to, the obligations addressed in Section III.A, or
  - c. a failure to respond to a Demand Letter concerning the payment of Stipulated Penalties in accordance with Section III.C.

- 2. Notice of Material Breach and Intent to Exclude. The parties agree that a material breach of this CCA by Coram constitutes an independent basis for Coram's exclusion from participation in the Federal health care programs. Upon a determination by OIG that Coram has materially breached this CCA and that exclusion is the appropriate remedy, OIG shall notify Coram of: (a) Coram's material breach, and (b) OIG's intent to exercise its contractual right to impose exclusion (this notification is referred to as the "Notice of Material Breach and Intent to Exclude").
- 3. Opportunity to Cure. Coram shall have 30 days from the date of receipt of the Notice of Material Breach and Intent to Exclude to demonstrate to OIG's satisfaction that:
  - a. Coram is in compliance with the requirements of the CCA cited by OIG as being the basis for the material breach;
  - b. the alleged material breach has been cured, or
  - c. the alleged material breach cannot be cured within the 30-day period, but that: (i) Coram has begun to take action to cure the material breach; (ii) Coram is pursuing such action with due diligence; and (iii) Coram has provided to OIG a reasonable timetable for curing the material breach.
- 4. Exclusion Letter. If, at the conclusion of the 30-day period, Coram fails to satisfy the requirements of Section III.D.3, OIG may exclude Coram from participation in the Federal health care programs. OIG shall notify Coram in writing of its determination to exclude Coram (this letter shall be referred to as the "Exclusion Letter"). Subject to the Dispute Resolution provisions in Section III.E, below, the exclusion shall go into effect 30 days after the date of Coram's receipt of the Exclusion Letter. The exclusion shall have national effect and shall also apply to all other Federal procurement and nonprocurement programs. Reinstatement to program participation is not automatic. After the end of the period of exclusion, Coram may apply for reinstatement by submitting a written request for reinstatement in accordance with the provisions at 42 C.F.R. §§ 1001.3001-.3004.

#### E. Dispute Resolution.

- 1. Review Rights. Upon OIG's delivery to Coram of its Demand Letter or of its Exclusion Letter, and as an agreed-upon contractual remedy for the resolution of disputes arising under this CCA, Coram shall be afforded certain review rights comparable to the ones that are provided in 42 U.S.C. §1320a-7(f) and 42 C.F.R. Part 1005 as if they applied to the Stipulated Penalties or exclusion sought pursuant to this CCA. Specifically, OIG's determination to demand payment of Stipulated Penalties or to seek exclusion shall be subject to review by an HHS ALJ and, in the event of an appeal, the HHS Departmental Appeals Board (DAB), in a manner consistent with the provisions in 42 C.F.R. §§ 1005.2-1005.21. Notwithstanding the language in 42 C.F.R. § 1005.2(c), the request for a hearing involving Stipulated Penalties shall be made within 10 days after receipt of the Demand Letter and the request for a hearing involving exclusion shall be made within 25 days after receipt of the Exclusion Letter.
- 2. Stipulated Penalties Review. Notwithstanding any provision of Title 42 of the United States Code or Title 42 of the Code of Federal Regulations, the only issues in a proceeding for Stipulated Penalties under this CCA shall be: (a) whether Coram was in full and timely compliance with the requirements of this CCA for which OIG demands payment; and (b) the period of noncompliance. Coram shall have the burden of proving its full and timely compliance and the steps taken to cure the noncompliance, if any. OIG shall not have the right to appeal to the DAB an adverse ALJ decision related to Stipulated Penalties. If the ALJ agrees with OIG with regard to a finding of a breach of this CCA and orders Coram to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable 20 days after the ALJ issues such a decision unless Coram requests review of the ALJ decision by the DAB. If the ALJ decision is properly appealed to the DAB and the DAB upholds the determination of OIG, the Stipulated Penalties shall become due and payable 20 days after the DAB issues its decision.
- 3. Exclusion Review. Notwithstanding any provision of Title 42 of the United States Code or Title 42 of the Code of Federal Regulations, the only issues in a proceeding for exclusion based on a material breach of this CCA shall be:
  - a. whether Coram was in material breach of this CCA;
  - b. whether such breach was continuing on the date of the Exclusion Letter; and
  - c. whether the alleged material breach could not have been cured within the 30-day period, but that: (i) Coram had begun to take

action to cure the material breach within that period; (ii) Coram has pursued and is pursuing such action with due diligence; and (iii) Coram provided to OIG within that period a reasonable timetable for curing the material breach and Coram has followed the timetable.

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

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 CCA agree that the DAB's decision (or the ALJ's decision if not appealed) shall be considered final for all purposes under this CCA.

#### IV. EFFECTIVE AND BINDING AGREEMENT

Coram and OIG agree as follows:

- A. This CCA shall be binding on the successors, assigns, and transferees of Coram;
- B. This CCA shall become final and binding on the date the final signature is obtained on the CCA;
- C. This CCA constitutes the complete agreement between the parties and may not be amended except by written consent of the parties to this CCA;
- D. OIG may agree to a suspension of Coram's obligations under this CCA in the event of Coram's cessation of participation in Federal health care programs. If Coram withdraws from participation in Federal health care programs and is relieved of its CCA obligations by OIG, Coram shall notify OIG at least 30 days in advance of Coram's

11

intent to reapply as a participating provider or supplier with any Federal health care program. Upon receipt of such notification, OIG shall evaluate whether the CCA should be reactivated or modified.

- E. The undersigned Coram signatories represent and warrant that they are authorized to execute this CCA. The undersigned OIG signatory represents that he is signing this CCA in his official capacity and that he is authorized to execute this CCA.
- F. This CCA may be executed in counterparts, each of which constitutes an original and all of which constitute one and the same CCA. Facsimiles of signatures shall constitute acceptable, binding signatures for purposes of this CCA.

# ON BEHALF OF CORAM, INC.

Margare	t & Brown
MARCARETI	CDDOUNI

MARGARET F. BROWN

Corporate Compliance Officer Senior Vice President, Quality, Ethics and Compliance

JONATHAN L. DIESENHAUS HOGAN & HARTSON, LLP COUNSEL FOR CORAM, INC.

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

GREGORY E. DEMSKE

Assistant Inspector General for Legal Affairs Office of Inspector General

United States Department of Health and Human Services

14

### Appendix A

#### **DECLARATION**

The declarant is currently the Corporate Compliance Officer of Coram, Inc. and has personal knowledge of the facts stated herein. The following describes the compliance program (Program) currently in place at Coram.

- 1. Compliance Budget. The annual budget for the Program is attached hereto as Exhibit 1 and Coram shall sustain, at a minimum, the levels of funding reflected therein for three years subsequent to the Effective Date; provided, however, that in the event that a change in circumstances would justify a reduction in that level of resources Coram may seek consent from OIG for such reduction by submitting a revised budget and a written explanation for the reduction.
- 2. Compliance Officer. The Program includes a Compliance Officer who is responsible for developing and implementing policies, procedures, and practices designed to ensure compliance with Federal health care program requirements. The Compliance Officer also is responsible for monitoring the day-to-day compliance activities of Coram. The Compliance Officer is a member of senior management of Coram and is not subordinate to the General Counsel or Chief Financial Officer. The Compliance Officer makes periodic (at least quarterly) reports regarding compliance matters directly to the Board of Directors of Coram and is authorized to report on such matters to the Board of Directors at any time.
- 3. Compliance Committee. The Program includes an Executive Compliance Steering Committee that is chaired by the Compliance Officer and that is made up of other members of senior management necessary to support the Compliance Officer in fulfilling her responsibilities under the Program (e.g., senior executives of relevant departments, such as billing, clinical, human resources, audit, and operations).
- 4. Code of Conduct. Coram has in place a Code of Business Ethics and Conduct that includes: (a) Coram's commitment to full compliance with all Federal health care program requirements, including its commitment to prepare and submit accurate claims consistent with such requirements; (b) Coram's requirement that all of its personnel are expected to comply with all Federal health care program requirements and with the Policies and Procedures described in Paragraph 5 below; (c) the requirement that all of Coram's personnel are expected to report to the Compliance Officer or other appropriate individual designated by Coram suspected violations of any Federal health care program requirements or of Coram's own Policies and Procedures; (d) the possible consequences to both Coram and its personnel of failure to comply with Federal health care program

requirements and with Coram's own Policies and Procedures and the failure to report such noncompliance; and (e) the right of Coram's personnel to use the Disclosure Program described in Paragraph 8 below and Coram's commitment to nonretaliation and to maintain, as appropriate, confidentiality and anonymity with respect to such disclosures. Each officer, director, and employee, contractor, subcontractor, agent, and other persons who provide patient care items or services or who perform billing or coding functions on behalf of Coram is required to certify in writing that he or she has received, read, understood, and will abide by the Code of Business Ethics and Conduct.<sup>2</sup>

- 5. Compliance Policies and Procedures. Coram has in place Policies and Procedures regarding the operation of the Program and Coram's compliance with Federal health care program requirements, which include but are not limited to policies and procedures on Certificates of Medical Necessity (CMNs) and DME MAC Information Forms (DIFs), reimbursement compliance audits, and exclusion checks. The Policies and Procedures are made available to all relevant Coram personnel whose job functions relate to the policies and procedures. At least annually (and more frequently, if appropriate), Coram reviews and updates as necessary these Policies and Procedures and, if revisions are made, makes available the revised Policies and Procedures to all Coram personnel whose job functions relate to the revised Policies and Procedures.
- 6. Compliance Training. Coram has in place an annual training program that requires all officers, directors, employees, contractors, subcontractors, agents, and other persons who provide patient care items or services or who perform billing or coding functions on behalf of Coram to attend at least one hour of annual compliance training that addresses Coram's Code of Business Ethics and Conduct and the operation of the Program. Coram's training program also requires additional hours of training for all employees, contractors, subcontractors, agents, and other persons who provide patient care items or services or who perform billing or claims submission functions on behalf of Coram. Such additional training addresses: (a) the Federal health care program requirements regarding the accurate submission of claims; (b) policies, procedures, and

<sup>&</sup>lt;sup>2</sup> Certification need not be required of part-time or per diem employees, contractors, subcontractors, agents and other persons who are not reasonably expected to work for Coram more than 160 hours per year. Such individuals shall be required to receive the compliance training, however, at the point when they work more than 160 hours during the calendar year.

Annual training is not required for part-time or per diem employees, contractors, subcontractors, agents and other persons who are not reasonably expected to work for Coram more than 160 hours per year. Such individuals shall be required to receive the compliance training, however, at the point when they work more than 160 hours during the calendar year.

other requirements applicable to the documentation of medical records; (c) the personal obligation of each individual involved in the claims submission process to ensure that such claims are accurate; (d) applicable reimbursement statutes, regulations, and program requirements and directives; (e) the legal sanctions for violations of Federal health care program requirements; and (f) use of billing systems for proper claims submission. Coram maintains written or electronic records that identify the type of training provided, the date(s) of the training, and the attendees. Persons providing the training are knowledgeable about the subject area. Coram reviews the training content on an annual basis and, as appropriate, updates the training to reflect changes in Federal health care program requirements and/or any issues discovered during the internal audits described in Paragraph 7 below.

- 7. Auditing and Monitoring. Coram has in place an internal reimbursement compliance audit department that performs periodic reviews to monitor Coram's compliance with Federal health care program requirements, including focused reviews relating to specific risk areas identified by the OIG and/or through the Program. The reimbursement compliance audit department prepares an annual workplan that is reviewed and approved by the Compliance Officer. The current workplan provides for an on-site audit to be conducted by December 31, 2007 at each of its six billing centers that submit claims to Federal health care programs. The internal reimbursement compliance audit department conducts audits through a process that includes analysis of clinical and financial records and employee interviews. Coram has a director and at least two full-time qualified employees in its internal reimbursement compliance audit department who are assigned to review Coram's compliance with Federal health care program requirements.
- 8. Disclosure Program. Coram maintains a Disclosure Program that includes a mechanism to enable individuals to disclose, to the Compliance Officer or some other person who is not in the disclosing individual's chain of command, any identified issues or questions associated with Coram's policies, conduct, practices, or procedures with respect to a Federal health care program believed by the individual to be a potential violation of criminal, civil, or administrative law. Coram publicizes the existence of the disclosure mechanism to all personnel.

The Disclosure Program emphasizes a nonretribution, nonretaliation policy and includes a reporting mechanism for anonymous communications for which appropriate confidentiality is maintained. Each disclosure is reviewed by the Compliance Officer and the Compliance Officer or in her absence her designee either investigates the disclosure or refers the disclosure to the relevant department or manager for follow up and any appropriate corrective action.

The Compliance Officer (or designee) maintains a disclosure log, which includes a record and summary of each disclosure received (whether anonymous or not), the status of Coram's internal review of the allegations, and any corrective action taken in response to the internal review.

9. Exclusion Checks. Coram has in place a policy and procedure for screening all prospective owners, officers, directors, and employees, and contractors who supply reimbursable items and services to, or who provide sales or marketing services for, Coram, to ensure that they are not Ineligible Persons<sup>4</sup> by: (a) requiring such persons to disclose whether they are an Ineligible Person; and (b) appropriately querying the General Services Administration's List of Parties Excluded from Federal Programs (available through the Internet at http://epls.arnet.gov) and the HHS/OIG List of Excluded Individuals/Entities (available through the Internet at http://oig.hhs.gov) (these lists shall hereinafter be referred to as the "Exclusion Lists"). Coram also performs annual screening of its current officers, directors, employees, and contractors who supply reimbursable items and services to, or who provide sales or marketing services for, Coram, against the Exclusion Lists and requires all officers, directors, employees, and contractors who supply reimbursable items and services to, or who provide sales or marketing services for, Coram, to disclose immediately any debarment, exclusion, suspension, or other event that makes that person an Ineligible Person.

Coram also has a policy in place that, if Coram has actual notice that an officer, director, employee, or contractors who supply reimbursable items and services to, or who provide sales or marketing services for, Coram, has become an Ineligible Person, Coram will remove such person from responsibility for, or involvement with, Coram's business operations related to the Federal health care programs and will remove such person from any position for which the person's compensation or items or services furnished, ordered, or prescribed by the person are paid in whole or in 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. (Nothing in this Declaration affects the responsibility of Coram to refrain from billing Federal health care programs for items or services furnished, ordered, or prescribed by excluded individuals or Coram's liability for overpayments received by Coram as a result of billing any Federal health care program for such items or services.)

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<sup>&</sup>lt;sup>4</sup> An "Ineligible Person" is an individual or entity who: (i) is currently excluded, debarred, suspended, or otherwise ineligible to participate in the Federal health care programs or in Federal procurement or nonprocurement programs; or (ii) has been convicted of a criminal offense that falls within the ambit of 42 U.S.C. § 1320a-7(a), but has not yet been excluded, debarred, suspended, or otherwise declared ineligible.

The undersigned signatory represents and warrants that she is authorized to execute this declaration on behalf of Coram.

I declare under penalty of perjury that the foregoing is true and correct.

Margaret F. Brown

Corporate Compliance Officer

Margaret & Brown

Senior Vice President, Quality, Ethics and

Compliance

Coram, Inc.

# APPENDIX B

# OVERPAYMENT REFUND

	COMPLETED BY MEDICARE	CONTRACTOR	
Date:			
Contractor Deposit Control #	Date of Deposit: Phone #	·	
Contractor Contact Name:	Phone #		
Contractor Address:			
Contractor Fax:	ribite #	<u>.</u>	
		•	
TO RE	OMDI ETED BY PROVIDER/P	HVSICIAN/STIP	PTTER
Diagra complete and forward to	Madiagra Contractor This form	or a similar docum	tout containing the following
Piease compiete ana jorwara i	COMPLETED BY PROVIDER/P o Medicare Contractor. This form, by every voluntary refund so that rec	or a similar aocam	ieni coniaining ine joliowing
injormation, snouta accompan	y every votuntary rejuna so that rec	eipi oj cneck is pro	sperty recoraea ana appitea.
			·
PROVIDER/PHYSICIAN/SUPPLIE			
ADDRESS	A 115 A 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1		
PROVIDER/PHYSICIAN/SUPPLIE	R # CHECK NUMBI	3R#	
CONTACT PERSON:	PHONE #		<del></del>
AMOUNT OF CHECK \$	CHECK NUMBI PHONE # CHECK DATE	<del></del>	
	REFUND INFORMAT	10N	
For each Claim, provide the	following:		
D. C. C. N. L.	T T	IC #	
Medicare Claim Number	Claim Amount Refunde	4.\$	<del></del>
Reason Code for Claim Adjustment:	Claim Amount Refunde (Select reason code from list below	Use one reason per c	laim)
Trousen cour for claim ringularion.	(		,
(Dlagga ligt a	ull claim numbers involved. Attach	congrato shoot if	'nacassaru)
(Tieuse usi <u>u</u>	ii cimin numbers mvoived. Amacii	separate succe, g	necessary)
N . FOR IN D .: JUNG	1/01 in 11/01 in Amount date and ma	ailabla fou all alaiw	and to Statistical Samplina
Note: IJ Specific Patient/HIC.	/Claim #/Claim Amount data not ave hodology and formula used	madie jor an ciaim	s aue io siansucai sampung
please indicate met	hodology and formula used	to determine an	nount ana reason joi
overpayment:			
1 7			
For Institutional Facilities O	inly.		
Cost Papart Vaar(s)	<u>,</u> .		
Cost Report Tear(s)	re involved, provide a breakdown b	ar amount and car	cononding cost report year
(if multiple cost report years a	re myorved, provide a breakdown t	by annount and con	esponding cost report year.)
For OIG Reporting Require	ments:		
Do you have a Corporate Integ	grity Agreement with OIG?	Yes	No
Reason Codes:			
Billing/Clerical Error	MSP/Other Paver Involvement	Miscellaneous	
01 - Corrected Date of Service	MSP/Other Payer Involvement 08 - MSP Group Health Plan Insurance	13 - Insufficient Doc	cumentation
02 - Duplicate	09 - MSP No Fault Insurance	14 - Patient Enrolled	in an HMO
03 - Corrected CPT Code	09 - MSP No Fault Insurance 10 - MSP Liability Insurance 11 - MSP, Workers Comp.(Including	15 - Services Not Re	
04 - Not Our Patient(s)	11 - MSP Workers Comp (Including	16 - Medical Necess	
05 - Modifier Added/Removed	Black Lung	17 - Other (Please S)	necify)
06 - Billed in Error	12 - Veterans Administration	Olici (2 10000 0)	; <i>)</i> /
107 - Corrected CPT Code	12 - Votorans / taministration		
O/ - Corrected Cr 1 Code			
	<u></u>		
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