CORPORATE INTEGRITY AGREEMENT
BETWEEN THE
OFFICE OF INSPECTOR GENERAL
OF THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND
SYMPHONY DIAGNOSTIC SERVICES, INC.

I. PREAMBLE

Symphony Diagnostic Services, Inc., ("SYMPHONY") hereby enters 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 promote compliance by SYMPHONY (as this term is defined herein), and by all Covered Persons and Covered Contractors (as these terms are defined herein) with the requirements of Medicare, Medicaid, and all other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f))("Federal health care program requirements"). SYMPHONY's compliance with the terms and conditions in this CIA shall constitute an element of SYMPHONY's present responsibility with regard to participation in the Federal health care programs. Contemporaneously with this CIA, SYMPHONY is entering into a Settlement Agreement with the United States, and this CIA is incorporated by reference into that Settlement Agreement, as embodied in a Plan of Reorganization to be filed in SYMPHONY's Chapter 11 of the Bankruptcy Code proceeding in the United States Bankruptcy Court for the District of Delaware (the "Bankruptcy Court"). The scope of this CIA shall be governed by the following definitions:

A. "SYMPHONY": means Symphony Diagnostic Services, Inc. and any corporation, subsidiary, affiliate, joint venture or other organization or entity in which SYMPHONY owns greater than 50%, or which SYMPHONY operates, performs billing functions, or has a management contract or arrangement to provide management and administrative services that give it control over the day-to-day operations of the organization or entity (hereinafter "related entity").

B. "Covered Persons": includes all officers, directors, and employees. The term also includes those employees of contractors and agents who, on a regular basis, (i.e., more often than two weeks over a 52-week period):

1. Are involved in patient or resident care to Federal health care program beneficiaries;

2. Participate in SYMPHONY's billing or related submissions to the Federal health care programs; or

3. Otherwise carry out the duties and responsibilities of this CIA (excluding the Independent Review Organization ("IRO")).

C. "Covered Contractor": any entity or individual with whom SYMPHONY has entered into a contract or other arrangement and does not fall within the definition of "Covered Persons."

II. TERM OF THE CIA.

The period of the compliance obligations assumed by SYMPHONY 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 same as the Effective Date of the Settlement Agreement into which this CIA is incorporated by reference (the "Effective Date").

Sections VII, VIII, IX, X and XI shall remain in effect until the OIG has completed its review of the final Annual Report and any additional materials submitted by SYMPHONY pursuant to OIG's request, which request must be made within one year of the OIG's receipt of SYMPHONY's final Annual Report.

III. CORPORATE INTEGRITY OBLIGATIONS.

Prior to the execution of this CIA, SYMPHONY established a Compliance Program and hereby agrees to maintain its Compliance Program for the duration of this CIA. In addition, to the extent not already implemented and for the duration of this CIA, SYMPHONY agrees to supplement its Compliance Program by adhering to the obligations contained in this CIA, including the maintenance of a Compliance Program that includes the following elements:

A. Program Infrastructure.

1. *Compliance Committee.* SYMPHONY shall maintain a Compliance Committee that reports to its Compliance Officer. During the term of this CIA, this committee shall:

a. Review SYMPHONY's system of internal controls, accounting policies, financial reporting practices, and the quality and integrity of SYMPHONY's financial reporting to Federal health care programs; and

b. Ensure that SYMPHONY adopts and implements policies and procedures designed to ensure that SYMPHONY complies with all applicable statutes, regulations, policies, and this CIA.

The individuals who serve on the Compliance Committee shall be available to the IRO required under this CIA, to respond to any issues or questions that might arise. The names of the Committee members and the Charter for the committee shall be provided to the OIG within 150 days of the Effective Date of this CIA. When new members are appointed, or the

responsibilities or authorities of the Committee are substantially changed, SYMPHONY shall notify OIG, in writing, within 30 days of such a change.

2. *Compliance Officer.* SYMPHONY has appointed a Compliance Officer who is responsible for developing and implementing policies, procedures, and practices designed to promote 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 SYMPHONY (i.e., not subordinate to SYMPHONY's general counsel or chief financial officer), shall make regular (at least quarterly) reports regarding compliance matters directly to the CEO and the Board of Directors. The Compliance Officer shall be authorized to report to the Board of Directors at any time. The Compliance Officer shall remain responsible for monitoring the day-to-day activities engaged in by SYMPHONY to further its compliance objectives as well as any reporting obligations created under this CIA. The Compliance Officer or his or her designees shall also ensure that financial or quality of care issues are appropriately identified and addressed through corrective action plans. In the event a new Compliance Officer is appointed during the term of this CIA, SYMPHONY shall notify OIG, in writing, within 15 days of such a change.

3. *Reserved.*

4. *Internal Audit Functions.* SYMPHONY shall create a program for performing internal audits. The internal audit function shall:

a. Make findings of whether the claims, and submissions to Federal health care programs that affect reimbursement are accurate and in accordance with applicable law;

b. Conduct an annual billing review of claims submitted by SYMPHONY; and

c. Perform other internal audits designed to ensure that this CIA is being appropriately implemented and to ensure that SYMPHONY is meeting its obligations under applicable law.

B. Written Standards.

1. *Standards of Conduct.* SYMPHONY has established Standards of Conduct. Within 120 days of the Effective Date of this CIA, the Standards of Conduct shall be reviewed by the Compliance Officer to ensure they meet the requirements set forth herein.

a. Contents. The Standards of Conduct shall, at a minimum, include:

i. SYMPHONY's commitment to compliance with all statutes, regulations, directives, and guidelines applicable to Federal health

care programs, including its commitment to prepare and submit accurate billings consistent with Federal health care program requirements, which includes procedures or instructions communicated by appropriate regulatory agencies, e.g., the Centers for Medicare and Medicaid Services (formerly known as the Health Care Financing Administration or HCFA) (hereinafter "CMS") and fiscal intermediaries or carriers;

ii. SYMPHONY's requirement that all of its Covered Persons shall be expected to comply with all Federal health care program requirements and with SYMPHONY's own Policies and Procedures (including the requirements of this CIA);

iii. The requirement that all Covered Persons shall be expected to report suspected violations of any Federal health care program requirements or of SYMPHONY's own Policies and Procedures;

iv. The possible consequences to both SYMPHONY and to any Covered Person for failure to comply with all Federal health care program requirements and with SYMPHONY's own Policies and Procedures or for failure to report such non-compliance; and

v. The right of all individuals to use the Disclosure Program, as well as SYMPHONY's commitment to confidentiality and non-retaliation with respect to disclosures.

b. Distribution and Certification. SYMPHONY shall distribute the Standards of Conduct to all employees during each employee's orientation, and thereafter, as revisions occur. Within 120 days of the Effective Date of this CIA, SYMPHONY shall distribute the Standards of Conduct to all Covered Persons who have not already received a copy that reflects the required contents as set forth herein. Within 120 days of the Effective Date of this CIA, each Covered Person who has not already done so shall certify, in writing, that he or she has received, read, understood, and will abide by SYMPHONY's Standards of Conduct.

New Covered Persons shall receive the Standards of Conduct during orientation or at the time of their appointment, employment or contract, or within 120 days of the Effective Date of the CIA, whichever is later. All Covered Persons shall complete the required certification within 30 days after the commencement of their appointment, employment, or contract or within 120 days of the Effective Date of the CIA, whichever is later. SYMPHONY shall continue to make the promotion of, and adherence to, the Standards of Conduct an element in evaluating the performance of employees.

SYMPHONY shall annually review the Standards of Conduct and will revise or supplement it as necessary. SYMPHONY shall distribute revisions or supplements of the Standards of Conduct to Covered Persons within 30 days of such changes being completed. Covered Persons shall certify on an annual basis that they have received, read, understood and will abide by the Standards of Conduct that is currently in place.

c. Covered Contractor Requirements. For each of its Covered Contractors, SYMPHONY shall: i) require in its contract with the Covered Contractor that the Covered Contractor acknowledges SYMPHONY's Compliance Program and Standards of Conduct; ii) for any Covered Contractor with whom SYMPHONY has an existing contract, SYMPHONY shall in good faith seek to reform the contract to require the Covered Contractor to acknowledge the Compliance Program and Standards of Conduct; and iii) ensure that the Standards of Conduct is provided (either by SYMPHONY or the Covered Contractor) to all Covered Contractor employees.

2. *Policies and Procedures*. SYMPHONY has established written Policies and Procedures regarding its Compliance Program and its compliance with relevant federal and state requirements, including, but not limited to, the requirements of Federal health care programs. SYMPHONY shall continue to assess and update as necessary the Policies and Procedures at least annually and more frequently, as appropriate. The Policies and Procedures shall be available to the OIG upon request. To the extent not already accomplished, SYMPHONY shall ensure that the relevant portions of its Policies and Procedures are available to the appropriate Covered Persons within 120 days of the Effective Date of this CIA. The Compliance Officer shall continue to be available to explain any and all Policies and Procedures. Within 120 days of the Effective Date of this CIA, SYMPHONY shall review and analyze its Polices and Procedures to ensure that, at a minimum, such Policies and Procedures specifically address and/or include:

a. Measures designed to ensure that SYMPHONY fully complies with applicable portions of Titles XVIII and XIX of the Social Security Act, 42 U.S.C. §§ 1395-1395ggg and 1396-1396v, and all regulations, directives, and guidelines promulgated pursuant to these statutes, including, but not limited to, 42 C.F.R. Parts 424, 482, and 483, and any other state or local statutes, regulations, directives, or guidelines applicable to long term care facilities or hospitals;

b. Measures designed to ensure that individuals and entities who fall within the ambit of the Covered Contractor definition are appropriately supervised to ensure that the Covered Contractor is acting within the parameters of SYMPHONY's Policies and Procedures and the requirements of Federal health care programs;

c. Measures designed to ensure that the internal audits are performed by appropriate and qualified individuals;

d. Non-retaliation policies and methods for employees to make disclosures or otherwise report on compliance issues through the Disclosure Program required by section III.E; and

e. Disciplinary guidelines to reflect the Standards of Conduct requirements as specified in Section III.B.1.

C. Training and Education.

Prior to the execution of this CIA, SYMPHONY established a training program for all its Covered Persons and agrees that it shall continue to conduct training programs that meet the requirements of this CIA. Persons providing the training must be knowledgeable about the subject area covered by the training.

1. *General Compliance Training.* SYMPHONY shall provide at least one hour of general compliance training to each Covered Person. This general training, at a minimum, shall explain SYMPHONY's:

a. Corporate Integrity Agreement requirements; and

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

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

New Covered Persons shall receive the general training described above during orientation, but not later than 30 days after the beginning of their employment or within 120 days after the Effective Date of this CIA, whichever is later. During the term of this CIA, every Covered Person shall receive such general training on an annual basis.

2. *Specific Training.* Within 120 days of the Effective Date of this CIA, SYMPHONY shall initiate specific training of certain designated Covered Persons, as set forth in this Section. Each Covered Person who is involved in the delivery of patient or resident care (including individuals who are responsible for quality assurance, setting policies or procedures, or making staffing decisions), the preparation or submission of claims for reimbursement or the assignment of procedure codes or other diagnostic assessments that might affect reimbursement, for any Federal health care programs (hereinafter, "Relevant Covered Persons") shall receive at least 2 hours of specific training pertinent to his or her responsibilities (as described below) in addition to the general training required above. This training shall be conducted at least annually thereafter, and

shall include a discussion of the policies and procedures set forth in Section III.B.2, including, but not limited to:

a. The submission of accurate information (e.g., claims and bills) for services rendered to Medicare or Medicaid beneficiaries;

b. Policies, procedures and other requirements applicable to the documentation of medical records, if relevant to the person's duties;

c. The personal obligation of each individual involved in the patient or resident care, documentation, or reimbursement processes to ensure that such submissions are accurate;

d. Applicable Federal health care program requirements, if relevant to the person's duties;

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

f. Examples of relevant reimbursement practices related to Federal health care programs found to have been improper, if relevant to the person's duties.

Affected new Relevant Covered Persons shall receive this training within 60 days of the beginning of their employment or contract, or within 120 days after the effective date of this CIA, whichever is later. New Relevant Covered Persons involved in the delivery of patient or resident care or in the preparation or submission of information (including, but not limited to, claims and bills) to any Federal health care program shall be adequately supervised by trained employees until they have completed the specific training relevant to their duties. Each Relevant Covered Person shall receive the appropriate Specific Training on an annual basis.

3. *Certification.* Each Covered Person 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 (or his/her designee) shall retain the certifications, along with specific course materials. These shall be made available to OIG upon request.

4. *Prior Training.* Training of any type provided to affected Covered Persons within 6 months prior to the Effective Date of this Agreement that meets with the requirements of Section III.C.2 shall be deemed to meet the timeframe obligations for initial training imposed by this Section, but does not obviate the requirement for attendance certifications.

D. Review Procedures.

1. *Financial Reviews.*

a. General Description

i. Retention of Independent Review Organization. Within 120 days of the Effective Date of this CIA, SYMPHONY shall engage an entity, such as an accounting, auditing or consulting firm (hereinafter "Independent Review Organization" or "IRO"), to assist SYMPHONY in assessing and evaluating its billing, coding and claims submission practices pursuant to this CIA and the Settlement Agreement. The IRO retained by SYMPHONY 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 SYMPHONY seeks reimbursement. The IRO(s) review shall address and analyze SYMPHONY's billing and coding to the Federal health care programs ("SYMPHONY Claims Review"). The IRO shall assess, along with SYMPHONY, whether it can perform the IRO engagements in a professionally independent fashion, taking into account any other business relationships or other engagements that may exist.

ii. Frequency of SYMPHONY Claims Reviews. The SYMPHONY 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 ("Reporting Period"). SYMPHONY and/or the IRO, as appropriate, shall conduct the Claims Review in accordance with Section III.D.2.e. and Appendix A to this CIA.

iii. Retention of Records. SYMPHONY and the IRO shall retain and make available to the OIG, upon request, all work papers, supporting documentation, correspondence and draft reports, if any, (those exchanged between the IRO and SYMPHONY) related to the review for at least one year after expiration of the CIA.

iv. Independence Certification. The IRO shall include in its report(s) to SYMPHONY a certification or sworn affidavit that it has evaluated its professional independence with regard to the SYMPHONY Claims Reviews and that it has concluded that it was, in fact, independent.

b. SYMPHONY Claims Review.

i. Internal Claims Review Option. For the first Reporting Period (as defined in Section III.D.2.a.iv.), SYMPHONY may conduct an internal review of

its billing and coding practices with respect to SYMPHONY's billing to the Federal health care programs, which review shall comply with all of the requirements outlined in Section III.D.2.f. and in Appendix A to this CIA ("SYMPHONY Claims Review"). Following its review of SYMPHONY's most recently submitted Annual report, if, in its sole discretion, OIG determines that SYMPHONY's internal SYMPHONY Claims Review satisfactorily establishes the adequacy of SYMPHONY's billing and compliance practices pursuant to this CIA, OIG may allow SYMPHONY to continue to perform the internal SYMPHONY Claims Review in conformance with the requirements of Section III.D and Appendix A to this CIA for Reporting Periods two through five of this CIA. To the extent that OIG permits SYMPHONY to perform internal SYMPHONY Claims Reviews, SYMPHONY shall submit all information required by the provisions outlined in Section III.D and in Appendix A to this CIA.

ii. IRO Verification of SYMPHONY Claims Review

(A) For the first Reporting Period, the IRO shall conduct a review of at least 20% of the sampling units reviewed by SYMPHONY in its internal SYMPHONY Claims Review ("SYMPHONY Verification Review").

(B) If SYMPHONY is permitted to perform the internal SYMPHONY Claims Review, after the first Reporting Period, the IRO shall conduct a SYMPHONY Verification Review for each of those successive years of the CIA.

(C) If the OIG does not allow SYMPHONY to perform the SYMPHONY Claims Review internally after the first Reporting Period, the IRO shall conduct the Symphony Claims Review for each successive year of the CIA.

As part of SYMPHONY's Annual Report, the IRO shall submit a report that verifies that the requirements outlined in Section III.D.2.f. and in Appendix A to this CIA have been satisfied and shall report the results, sampling unit by sampling unit, of any SYMPHONY Verification Review or SYMPHONY Claims Review performed.

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

(A) Discovery Samples. SYMPHONY or the IRO shall randomly select and review a sample of 50 Medicare Paid Claims submitted by or on behalf of SYMPHONY for each of the SYMPHONY dispatch locations where customer orders are taken. The Paid Claims shall be reviewed based on the supporting documentation available at SYMPHONY or under SYMPHONY's control and applicable billing and coding regulations and guidance to determine whether the claim submitted was correctly coded, submitted, and reimbursed.

(B) Results of Discovery Samples. If the Error Rate (as defined in Appendix A) for a Discovery Sample is less than 5%, no additional sampling is required, nor is a Systems Review required. (Note: The threshold listed above does not imply that this is an acceptable error rate. Accordingly, SYMPHONY should, as appropriate, further analyze any errors identified in the Discovery Sample. SYMPHONY 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.)

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

(D) Full Sample. If necessary, as determined by procedures set forth in III.D.2.f.iii., SYMPHONY and/or the IRO shall perform an additional sample of Paid Claims using commonly accepted sampling methods and in accordance with Appendix A to this CIA. The Full Sample should be designed to (i) 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 (ii) conform to 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 SYMPHONY or under SYMPHONY'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, SYMPHONY 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 SYMPHONY 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.

(E) Systems Review. If a Discovery Sample identifies an Error Rate of 5% or greater, SYMPHONY or the IRO, as determined by the procedures set forth in section III.D.1.c., shall also conduct a Systems Review. Specifically, for each claim in the Discovery Sample and Full Sample that resulted in an Overpayment, SYMPHONY or the IRO shall 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. SYMPHONY or the IRO shall report its observations of the Systems Review and shall develop recommendations on suggested improvements to the system(s) and the process(es) that generated the claim.

(F) Repayment of Identified Overpayments. In accordance with Section III.H.1, SYMPHONY shall 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. SYMPHONY shall make available to the OIG any and all documentation that reflects the refund of the Overpayment(s) to the payor and the associated documentation.

(G) SYMPHONY Claims Review Report. Depending on whether SYMPHONY conducted an internal SYMPHONY Claims Review with an IRO Verification Review or the IRO conducted the SYMPHONY Claims Review, SYMPHONY and/or the IRO shall prepare a report based upon the Claims Review performed (the "SYMPHONY Claims Review Report"). Information to be included in the SYMPHONY Claims Review Report is detailed in Appendix A to this CIA.

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

SYMPHONY Claims Review complied with the requirements of the CIA and/or the findings or SYMPHONY Claims Review results are inaccurate ("Validation Review"). SYMPHONY 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 SYMPHONY's final submission (as described in section II) is received by the OIG.

Prior to initiating a Validation Review, the OIG shall notify SYMPHONY 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, SYMPHONY may request a meeting with the OIG to discuss the results of any SYMPHONY Claims Review submissions or findings; present any additional or relevant information to clarify the results of the SYMPHONY Claims Reviews to correct the inaccuracy of the SYMPHONY Claims Review; and/or propose alternatives to the proposed Validation Review. SYMPHONY 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 SYMPHONY Claims Review with SYMPHONY 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.

E. Disclosure Program.

SYMPHONY has established a Disclosure Program that includes a toll free hotline. Within 120 days of the Effective Date of this CIA, SYMPHONY shall review its Disclosure Program and ensure that it is in compliance with the requirements of this Section. The Disclosure Program shall include mechanisms (e.g., a toll-free compliance telephone line) to enable any individual 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 SYMPHONY's policies, practices, or procedures with respect to quality of care or a Federal health care program, believed by the individual to be inappropriate. SYMPHONY shall publicize the existence of the disclosure mechanism, and, at a minimum, shall post it prominently in each of its locations and publicize it in training and newsletters to employees.

The Disclosure Program shall emphasize a non-retribution, non-retaliation policy, and shall include a reporting mechanism for anonymous, confidential communication. Upon receipt of a disclosure, the Compliance Officer (or designee) shall gather all relevant information from the disclosing individual. 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 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, SYMPHONY 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 disclosure log, which shall include a record and summary of each disclosure received (whether anonymous or not), the status of the respective internal review, and any corrective action taken in response to the internal review. The disclosure log shall be made available to OIG upon request.

F. Ineligible Persons.

1. *Definition.* For purposes of this CIA, an "Ineligible Person" shall be any individual or entity who: (a) is currently excluded, suspended, debarred or otherwise ineligible to participate in the Federal health care programs or in federal procurement or non-procurement programs; or (b) has been convicted of a criminal offense that falls within the ambit of 42 U.S.C. § 1320a-7(a), but has not yet been excluded, suspended, debarred or otherwise declared ineligible.

2. *Screening Requirements.* SYMPHONY shall not hire as employees, engage as contractors, or grant staff privileges to any Ineligible Person. To prevent hiring, contracting, or granting staff privileges with or to any Ineligible Person, SYMPHONY shall screen all prospective employees and contractors prior to engaging their services by: (a) requiring applicants to disclose whether they are Ineligible Persons; 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 and reports will hereinafter be referred to as the "Exclusion Lists"). Nothing in this section affects the responsibility of (or liability for) SYMPHONY to refrain from billing Federal health care programs for services of Ineligible Persons.

3. *Review and Removal Requirement.* Within 120 days of the Effective Date of this CIA, SYMPHONY will review its list of current employees, agents, contractors, and physicians with staff privileges against the Exclusion Lists. Thereafter, SYMPHONY shall review its current employees and contracts against the Exclusion Lists annually. In addition, SYMPHONY shall require employees and contractors to disclose immediately any debarment, suspension, exclusion, or other event that makes the employee an Ineligible Person.

If SYMPHONY has actual notice that an employee, agent, contractor, or physician with staff privileges has become an Ineligible Person, SYMPHONY will remove such person from responsibility for, or involvement with, SYMPHONY'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 SYMPHONY has actual notice that an employee, agent, or contractor is charged with a criminal offense related to any Federal health care program, or is proposed for exclusion during his or her employment or contract, SYMPHONY shall take all appropriate actions to ensure that the responsibilities of that employee, agent, contractor, or physician do not adversely affect the quality of care rendered to any patient or resident or the accuracy of any claims submitted to any Federal health care program.

G. Notification of Proceedings.

Within 30 days of discovery, SYMPHONY shall notify the OIG, in writing, of any ongoing investigation known to SYMPHONY or legal proceeding conducted or brought by a governmental entity or its agents involving an allegation that SYMPHONY 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. SYMPHONY shall also provide written notice to the OIG within 30 days of the resolution of the matter, and shall provide the OIG with a description of the findings and/or results of the proceedings, if any.

H. Reporting.

1. *Overpayments*

a. Definition of "Overpayment." For purposes of this CIA, an "Overpayment" shall mean the amount of money SYMPHONY has received in excess of the amount due and payable under the Federal health care program requirements.

b. Reporting of Overpayments. If, at any time, SYMPHONY identifies or learns of any overpayments, SYMPHONY shall notify the payor (e.g., Medicare fiscal intermediary or carrier) within 30 days of identification of the overpayment and take remedial steps within 60 days of identification (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. Also, within 30 days of identification of the overpayment, SYMPHONY shall repay the overpayment to the appropriate payor to the extent such overpayment has been quantified. If not yet quantified, within 30 days of identification, SYMPHONY shall notify the payor of its efforts to quantify the overpayment amount along with a schedule of when such work is expected to be completed.

Notification and repayment to the payor should be done in accordance with the payor's policies, and for Medicare contractors, must include the information contained on the Overpayment Refund Form, provided as Appendix C to this CIA. Notwithstanding the above, notification and repayment of any overpayment amount that routinely is reconciled or adjusted pursuant to policies and procedures established by the payor should be handled in accordance with such policies and procedures.

2. *Material Deficiencies*

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

(i) a substantial Overpayment; or

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

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

b. Reporting of Material Deficiencies. If SYMPHONY determines through any means that there is a Material Deficiency (as defined herein), SYMPHONY shall notify the OIG in writing within 30 days of making the determination that the Material Deficiency exists. The report to the OIG shall include the following information:

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

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

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

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

iii. a description of SYMPHONY's actions taken to correct the Material Deficiency;

iv. Any further steps SYMPHONY plans to take to address the Material Deficiency prevent it from recurring.

IV. NEW BUSINESS UNITS OR LOCATIONS

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

V. IMPLEMENTATION AND ANNUAL REPORTS

A. Implementation Report. Within 150 days after the Effective Date of this CIA, SYMPHONY shall submit a written report to the 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 all individuals in positions described in Section III.A;

2. the Charter for the Compliance Committee as required in Section III.A.1;

3. a description of all training required by section III.C, including a description of the targeted audiences, length of sessions, which sessions were mandatory and for whom, percentage of attendance, and a schedule of when the training sessions were held. A copy of all training materials shall be made available to the OIG upon request.

4. a certification by the Compliance Officer that:

   a. the Policies and Procedures required by section III.B.2 have been developed, are being implemented, and have been made available to all appropriate Covered Persons;

   b. all Covered Persons have completed the Standards of Conduct certification required by Section III.B.1; and

   c. all Covered Persons have completed the applicable training and executed the certification required by Section III.C;

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

5. the identity of the Independent Review Organization(s) and the proposed start and completion date of the engagements for the first year;

6. a summary of personnel actions taken pursuant to Section III.F;

7. a list of all of SYMPHONY's locations (including locations and mailing addresses), the corresponding name under which each location is doing business, the corresponding telephone numbers and facsimile numbers, each location's Federal health care program provider identification numbers(s), and the name, address, and telephone number of the payor (specific contractor) that issued each provider identification number; and

8. The certification required by section V.C.

B. Annual Reports. SYMPHONY shall submit to the OIG Annual Reports with respect to the status of, and findings regarding, SYMPHONY's compliance activities for each of the five one-year periods beginning on the Effective Date of the CIA (The one year period

covered by each Annual Report shall be referred to as "the Reporting Period"). Each Annual Reports shall include:

1. any change in the identity or position description of individuals in positions described in Section III.A, a change in any of the committees' structure or charter, any change in the internal audit and review program, or any change in the quality of care infrastructure;

2. a certification by the Compliance Officer that:

a. all Covered Persons and Covered Contractors have completed the annual Standards of Conduct certification required by Section III.B.1;

b. all Covered Persons have completed the training and executed the certification required by Section III.C;

c. SYMPHONY has complied with its obligations under the Settlement Agreement: (i) not to resubmit to any Federal health care program payors any previously denied claims related to covered conduct addressed in the Settlement Agreement, and its obligation not to appeal any such denials of claims; and (ii) not to charge to or otherwise seek payment from federal or state payors for unallowable costs (as defined in the Settlement Agreement) and its obligation to identify and adjust any past charges or claims for unallowable costs;

d. SYMPHONY has effectively implemented all plans of correction related to problems identified under this CIA, SYMPHONY's Compliance Program, or internal audits or reviews;

3. a summary of any changes or amendments to the Policies and Procedures required by Section III.B.2 and the reasons for such changes (e.g., change in contractor policy);

4. a description of all training conducted during the Reporting Period, including a description of the targeted audiences, length of sessions, which sessions were mandatory and for whom, percentage of attendance, and a schedule of when the training sessions were held. A copy of all training materials used for the training required by section III.C. shall be made available to the OIG upon request;

5. a summary of the facilities audited or reviewed pursuant to SYMPHONY's internal audit and review program, a summary of the findings of such audit or

review, and a summary of the corrective actions taken under the program for internal audits and reviews;

6. a complete copy of all reports prepared pursuant to the IRO engagements, including all the information required in Section III.D, a copy of the methodology used, and a copy of any IRO engagement letters;

7. SYMPHONY's response/corrective action plan to any issues raised by the IRO;

8. a revised summary/description of all engagements between SYMPHONY and the IRO, including, but not limited to, any outside financial audits, compliance program engagements, or reimbursement consulting, if different from what was submitted as part of the Implementation Report;

9. A certification from the IRO regarding its professional independence from SYMPHONY;

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

11. 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: Medicare, Medicaid (report each applicable state separately), 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;

12. a summary of the disclosure in the disclosures log required by Section III.E that related to Federal health care programs;

13. a description of any personnel actions (other than hiring) taken by SYMPHONY as a result of the obligations in Section III.F, and the name, title, and responsibilities of any person who falls within the ambit of Section III.F.3 and 4, and the actions taken in response to the obligations set forth in that Section;

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

15. a description of all changes to the most recently provided list (as updated) of SYMPHONY's locations (including locations and mailing addresses) as required by section V.A.7, the corresponding name under which each location is doing business, the corresponding telephone numbers and facsimile numbers, each location's

Federal health care program provider identification numbers(s), and the name, address, and telephone number of the payor (specific contractor) that issued each provider identification number; and

16. the certification required by section V.C.

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

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

D. Designation of Information: SYMPHONY shall clearly identify any portions of its submissions that it believes are trade secrets, or information that is commercial or financial and privileged or confidential, and therefore potentially exempt from disclosure under the Freedom of Information Act ("FOIA"), 5 U.S.C. § 552. SYMPHONY shall refrain from identifying any information as exempt from disclosure if that information does not meet the criteria for exemption from disclosure under FOIA.

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:

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, SW
Washington, DC 20201
Phone: 202-619-2457
Fax: 202-205-0604

SYMPHONY: Mary Johnson
Symphony Diagnostic Services, Inc.
185 Witmer Road
Horsham, Pennsylvania 19044
Phone: 215- 442-0660
Fax: 215-957-2640

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

VII. OIG INSPECTION, AUDIT AND REVIEW RIGHTS

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

VIII. DOCUMENT AND RECORD RETENTION

SYMPHONY shall maintain for inspection all documents and records relating to reimbursement from the Federal health care programs, or to compliance with this CIA for six years (or longer if otherwise required by law).

IX. DISCLOSURES AND PRIVILEGES

Nothing in this CIA, or any communication or report made pursuant to this CIA, shall constitute or be construed as a waiver by SYMPHONY of its attorney-client, work product, peer review, or other applicable privileges. Notwithstanding that fact, the existence of any such privilege does not affect SYMPHONY's obligations to comply with the provisions of this CIA.

Consistent with 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 SYMPHONY prior to any release by the OIG of information submitted by SYMPHONY pursuant to its obligations under this CIA and identified upon submission by SYMPHONY as trade secrets, commercial or financial information and privileged and confidential under the FOIA rules. With respect to the disclosure of information, SYMPHONY shall have the rights set forth in 45 C.F.R. § 5.65(d). SYMPHONY shall refrain from identifying any information as exempt from release if that information does not meet the criteria for exemption from disclosure under FOIA.

X. BREACH AND DEFAULT PROVISIONS

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

A. Stipulated Penalties for Failure to Comply with Certain Obligations. As a contractual remedy, SYMPHONY and the 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 SYMPHONY fails to have in place any of the following:

a. a Compliance Officer;

b. Compliance Committees;

c. a program for performing internal audits and reviews;

d. a written Standards of Conduct;

e. written Policies and Procedures;

f. a requirement that Covered Persons be trained; and

g. a 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 SYMPHONY fails to retain an IRO, as required by section III.D.

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

4. A Stipulated Penalty of $2,000 (which shall begin to accrue on the date the failure to comply began) for each day SYMPHONY employs or contracts with or grants staff privileges to an Ineligible Person and that person: (i) has responsibility for, or involvement with, SYMPHONY's business operations related to the Federal health care programs; or (ii) is in a position for which the person's salary or the items or services rendered, ordered, or prescribed by the person are paid in whole or part, directly or indirectly, by Federal health care programs or otherwise with federal funds (the Stipulated Penalty described in this paragraph shall not be demanded for any time period during which SYMPHONY 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).

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

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

B. Timely Written Requests for Extensions. SYMPHONY may, in advance of the due date, submit a timely written request for an extension of time to perform any act or file any notification or report required by this CIA. Notwithstanding any other provision in this section, if OIG grants the timely written request with respect to an act, notification, or report, Stipulated Penalties for failure to perform the act or file the notification or report shall not begin to accrue until one day after SYMPHONY 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 SYMPHONY 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 SYMPHONY has failed to comply with any of the obligations described in Section X.A and determining that Stipulated Penalties are appropriate, the OIG shall notify SYMPHONY of: (a) SYMPHONY's failure to comply; and (b) the OIG's exercise of its contractual right to demand payment of the Stipulated Penalties (this notification is hereinafter referred to as the "Demand Letter").

2. *Response to Demand Letter.* Within 15 days of the date of the Demand Letter, SYMPHONY 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 OIG's determination of noncompliance, pursuant to the agreed upon provisions set forth below in Section X.E. In the event SYMPHONY elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until SYMPHONY 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.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 the 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 SYMPHONY has materially breached this CIA, which decision shall be made at the OIG's discretion and governed by the provisions in Section X.D, below.

D. Exclusion for Material Breach of this CIA

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

a. a failure by SYMPHONY to report a material deficiency, take corrective action and pay the appropriate refunds, as provided in Section III.H;

b. repeated, systemic, 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. a failure to respond to a Demand Letter concerning the payment of Stipulated Penalties in accordance with Section X.C above; or

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

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

3. *Opportunity to Cure.* SYMPHONY shall have 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. SYMPHONY is in full compliance with these obligations of the CIA cited by the OIG as being the basis for the Material Breach;

b. the alleged Material Breach has been cured; or

c. the alleged Material Breach cannot be cured within the 35 day period, but that: (i) SYMPHONY has begun to take action to cure the Material Breach; (ii) SYMPHONY is pursuing such action with due diligence; and (iii) SYMPHONY has provided to the OIG a reasonable timetable for curing the Material Breach.

4. *Exclusion Letter.* If at the conclusion of the thirty-five (35) day period, SYMPHONY fails to satisfy the requirements of Section X.D.3, the OIG may exclude SYMPHONY from participation in the Federal health care programs. The OIG will notify SYMPHONY in writing of its determination to exclude SYMPHONY (this letter shall be referred

to hereinafter as the "Exclusion Letter"). Subject to the Dispute Resolution provisions in Section X.E, below, the exclusion shall go into effect 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. Reinstatement to program participation is not automatic. If at the end of the period of exclusion, SYMPHONY wishes to apply for reinstatement, SYMPHONY must submit a written request for reinstatement in accordance with the provisions at 42 C.F.R. §§ 1001.3001-.3004.

D. Dispute Resolution

1. *Review Rights.* Upon the OIG's delivery to SYMPHONY of its Demand Letter or its Exclusion Letter, and as an agreed-upon contractual remedy for the resolution of disputes arising under this CIA, SYMPHONY shall be afforded certain review rights comparable to the ones that are provided in 42 U.S.C. § 1320a-7(f) and 42 C.F.R. Part 1005 as if they applied to the Stipulated Penalties or exclusion sought pursuant to this CIA. Specifically, OIG's determination to demand payment of Stipulated Penalties or to seek exclusion shall be subject to review by an 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), a request for a hearing involving Stipulated Penalties shall be made within 15 days of the date of the Demand Letter, and the request for a hearing involving exclusion shall be made within 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 SYMPHONY was in full and timely compliance with the obligations of this CIA for which OIG demands payment; (b) the period of noncompliance. SYMPHONY shall have the burden of proving its full and timely compliance and the steps taken to cure the noncompliance, if any. The OIG shall not have the right to appeal to the DAB an adverse ALJ decision related to Stipulated Penalties. If the ALJ agrees with the OIG with regard to a finding of a breach of this CIA and orders SYMPHONY to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable 20 days after the ALJ issues such a decision unless SYMPHONY requests review of the ALJ decision by the DAB. If the ALJ decision is properly appealed to the DAB and the DAB upholds the determination of OIG, the Stipulated Penalties shall become due and payable 20 days after the DAB issues its decision.

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

(a) whether SYMPHONY was in Material Breach of this CIA;

(b) whether such breach was continuing on the date of the Exclusion Letter;

(c) whether the alleged Material Breach could not be cured within the 35 day period, but that

(i) SYMPHONY had begun to take action to cure the Material Breach within that period,

(ii) SYMPHONY has pursued and is pursuing such action with due diligence, and

(iii) SYMPHONY provided to OIG within that period a reasonable timetable for curing the Material Breach and SYMPHONY has followed the timetable.

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

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, SYMPHONY and the OIG agree as follows:

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

B.This CIA shall become final and binding on the same date as the Effective Date of the Settlement Agreement in which this CIA is incorporated by reference.

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

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

E. Nothing in this CIA precludes SYMPHONY from lawfully contesting the legality, enforceability or applicability of any Federal health care program requirement.

F. The undersigned SYMPHONY signatory represents and warrants that he/she is 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.

ON BEHALF OF SYMPHONY DIAGNOSTIC SERVICES, INC.

DATED: August 28, 2003 BY: William J. Illyes
SENIOR VICE-PRESIDENT

DATED: August 28, 2003 BY: Mary A. Johnson
COMPLIANCE OFFICER

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

DATED: August 25, 2003

LARRY J. GOLDBERG
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

APPENDIX A – SYMPHONY CLAIMS REVIEW

A. Claims Review.

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

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

d. Population: All Items for which Symphony has submitted a code or line item and for which Symphony has received reimbursement from the Medicare 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 Symphony cannot produce documentation sufficient to support the Paid Claim shall be considered an error and the total reimbursement received by Symphony 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 or IHS 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 Symphony'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 or IHS determined that the Paid Claims submitted by Symphony ("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 Symphony.

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 or IHS), correct allowed amount (as determined by the IRO or IHS), and 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: (a) designed the statistical sampling procedures and the review methodology utilized for the Claims Review; and (b) performed the Claims Review.

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)

APPENDIX B

A. Claims Review.

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

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

d. Population: All Items for which Symphony has submitted a code or line item and for which Symphony has received reimbursement from the Medicare 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 Symphony cannot produce documentation sufficient to support the Paid Claim shall be considered an error and the total reimbursement received by Symphony 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 or IHS 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 Symphony'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 or IHS determined that the Paid Claims submitted by Symphony ("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 Symphony.

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 or IHS), correct allowed amount (as determined by the IRO or IHS), and 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: (a) designed the statistical sampling procedures and the review methodology utilized for the Claims Review; and (b) performed the Claims Review.

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

