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CORPORATE INTEGRITY AGREEMENT BETWEEN THE OFFICE OF INSPECTOR GENERAL OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES AND BETH ISRAEL MEDICAL CENTER

I. PREAMBLE

Beth Israel Medical Center (Beth Israel) 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 with the statutes, regulations, and written directives 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). Contemporaneously with this CIA, Beth Israel is entering into a Stipulation and Order of Settlement and Dismissal with the United States, and this CIA is incorporated by reference into the Stipulation and Order of Settlement and Dismissal.

Prior to the execution of this CIA, Beth Israel voluntarily established a compliance plan, also known as the "Compliance Program," which provides for integrity policies and procedures and which, as represented by Beth Israel in this CIA, is aimed at ensuring that its participation in the Federal health care programs (which includes any requests for payments) conforms with the statutes, regulations and other directives applicable to the Federal health care programs. Therefore, pursuant to this CIA, Beth Israel hereby agrees to maintain in full operation the Compliance Program for the term of this CIA. The Compliance Program may be modified by Beth Israel as appropriate, but at a minimum, shall comply with the integrity obligations in this Agreement.

II. TERM AND SCOPE OF THE CIA

A. The period of the compliance obligations assumed by Beth Israel under this CIA shall be five and one half (5.5) years from the Effective Date of this CIA, unless otherwise specified. However, should Beth Israel pay the full Settlement Amount, as defined in the Stipulation and Order of Settlement and Dismissal, prior to the end of the fifth year of this CIA, then the term of this CIA shall be five years. The Effective Date shall be the date on which the final signatory of this CIA executes this CIA (Effective

- Date). Each one-year period (except that, the last period may be one and one half years), beginning with the one-year period following the Effective Date, shall be referred to as a "Reporting Period."
- B. Sections VII, VIII, IX, X, and XI shall expire no later than 120 days after OIG's receipt of: (1) Beth Israel's final annual report; or (2) any additional materials submitted by Beth Israel pursuant to OIG's request, whichever is later.
 - C. The scope of this CIA shall be governed by the following definitions:
 - 1. "Covered Persons" includes:
 - a. all owners, officers, trustees, and employees of Beth Israel, except food services employees, housekeeping staff, laundry staff, maintenance employees, grounds keepers, and mailroom staff;
 - b. all contractors, subcontractors, agents, and other persons who provide patient care items or services or who perform billing or coding functions on behalf of Beth Israel; and
 - c. all of Beth Israel's employed medical staff.

Notwithstanding the above, this term does not include part-time or per diem employees, contractors, subcontractors, agents, and other persons who are not reasonably expected to work more than 160 hours per year, except that any such individuals shall become "Covered Persons" at the point when they work more than 160 hours during the calendar year.

2. "Relevant Covered Persons" includes all persons involved in the preparation or submission of cost reports to any Federal health care program.

III. CORPORATE INTEGRITY OBLIGATIONS

Beth Israel shall establish and maintain a Compliance Program that includes the following elements:

A. Compliance Officer and Committee.

1. Compliance Officer. To the extent Beth Israel has not already done so, within 90 days after the Effective Date, Beth Israel shall appoint an individual to serve as its Compliance Officer and shall maintain a Compliance Officer for the term of the CIA. The Compliance Officer shall continue to be responsible for developing and implementing policies, procedures, and practices designed to ensure compliance with the requirements set forth in this CIA and with Federal health care program requirements. The Compliance Officer shall continue to be a member of senior management of Beth Israel, shall make periodic (at least quarterly) reports regarding compliance matters directly to the Board of Trustees of Beth Israel, and shall be authorized to report on such matters to the Board of Trustees at any time. The Compliance Officer shall not be or be subordinate to the General Counsel or Chief Financial Officer. The Compliance Officer shall be responsible for monitoring the day-to-day compliance activities engaged in by Beth Israel as well as for any reporting obligations created under this CIA.

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

2. Compliance Committee. To the extent it has not already done so, within 90 days after the Effective Date, Beth Israel shall appoint a Compliance Committee. The Compliance Committee shall, at a minimum, include the Compliance Officer, Trustees, and other members of senior management necessary to meet the requirements of this CIA. The Compliance Officer shall be a member of the Compliance Committee and the Committee shall support the Compliance Officer in fulfilling his/her responsibilities (e.g., shall assist in the analysis of the organization's risk areas and shall oversee monitoring of internal and external audits and investigations).

Beth Israel shall report to OIG, in writing, any changes in the composition of the Compliance Committee, or any actions or changes that would affect the Compliance Committee's ability to perform the duties necessary to meet the obligations in this CIA, within 15 days after such a change.

B. Written Standards.

- 1. Code of Conduct. To the extent Beth Israel has not already done so, within 150 days after the Effective Date, Beth Israel shall develop, implement, and distribute a written Code of Conduct to all Covered Persons. Beth Israel shall make the promotion of, and adherence to, the Code of Conduct an element in evaluating the performance of all employees. The Code of Conduct shall, at a minimum, continue to set forth:
 - a. Beth Israel'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. Beth Israel's requirement that all of its Covered Persons shall be expected to comply with all Federal health care program requirements and with Beth Israel's own Policies and Procedures as implemented pursuant to this Section III.B (including the requirements of this CIA);
 - c. the requirement that all of Beth Israel's Covered Persons shall be expected to report to the Compliance Officer or other appropriate individual designated by Beth Israel suspected violations of any Federal health care program requirements or of Beth Israel's own Policies and Procedures;
 - d. the possible consequences to both Beth Israel and Covered Persons of failure to comply with Federal health care program requirements and with Beth Israel's own Policies and Procedures and the failure to report such noncompliance; and
 - e. the right of all individuals to use the Disclosure Program described in Section III.E, and Beth Israel's commitment to nonretaliation and to maintain, as appropriate, confidentiality and anonymity with respect to such disclosures.

Within 150 days after the Effective Date, each Covered Person shall certify, in writing, that he or she has received, read, understood, and shall abide by Beth Israel's

Code of Conduct. New Covered Persons shall receive the Code of Conduct and shall complete the required certification within 30 days after becoming a Covered Person or within 150 days after the Effective Date, whichever is later.

Beth Israel shall periodically review the Code of Conduct to determine if revisions are appropriate and shall make any necessary revisions based on such review. Any revised Code of Conduct shall be distributed within 30 days after any revisions are finalized. Each Covered Person shall certify, in writing, that he or she has received, read, understood, and shall abide by the revised Code of Conduct within 30 days after the distribution of the revised Code of Conduct.

- 2. Policies and Procedures. To the extent Beth Israel has not already done so, within 150 days after the Effective Date, Beth Israel shall implement written Policies and Procedures regarding the operation of Beth Israel's compliance program and its compliance with Federal health care program requirements. At a minimum, the Policies and Procedures shall address:
 - a. the subjects relating to the Code of Conduct identified in Section III.B.1;
 - b. the need for compliance in connection with all cost report and other submissions to Federal health care programs;
 - c. the establishment and maintenance of Beth Israel's Compliance Program; and
 - d. Beth Israel's commitment to the honest and accurate submission of cost reports and other claims in accordance with Federal health care program requirements.

To the extent Beth Israel has not already done so, within 150 days after the Effective Date, the relevant portions of the Policies and Procedures shall be posted on the Corporate Compliance intranet or distributed to all individuals whose job functions relate to those Policies and Procedures. Appropriate and knowledgeable staff shall be available to explain the Policies and Procedures.

At least annually (and more frequently, if appropriate), Beth Israel shall assess and update as necessary the Policies and Procedures. Within 30 days after the effective date

of any revisions, the relevant portions of any such revised Policies and Procedures shall be posted on the Corporate Compliance intranet or distributed to all individuals whose job functions relate to those Policies and Procedures.

C. Training and Education.

- 1. General Training. Within 150 days after the Effective Date, Beth Israel shall provide at least one hour of General Training to each Covered Person. This training, at a minimum, shall explain Beth Israel's:
 - a. CIA requirements; and
 - b. Beth Israel's Compliance Program (including the Code of Conduct and the Policies and Procedures as they pertain to general compliance issues).

New Covered Persons shall receive the General Training described above within 30 days after becoming a Covered Person or within 150 days after the Effective Date, whichever is later. Beginning the year after receiving the initial General Training described above, each Covered Person shall receive at least one hour of General Training annually.

- 2. Specific Training. Within 150 days after the Effective Date, each Relevant Covered Person shall receive at least three hours of Specific Training in addition to the General Training required above. This Specific Training shall include a discussion of:
 - a. the Federal health care program requirements regarding the accurate preparation and submission of cost reports;
 - b. policies, procedures, and other requirements applicable to the submission of cost reports to Federal health care programs;
 - c. the personal obligation of each individual involved in the preparation of cost report process to ensure that such cost reports and claims are accurate;

- d. applicable reimbursement statutes, regulations, and program requirements and directives;
- e. the legal sanctions for violations of the Federal health care program requirements; and
- f. examples of proper and improper cost report practices.

Relevant Covered Persons shall receive this training within 30 days after the beginning of their employment or becoming Relevant Covered Persons, or within 150 days after the Effective Date, whichever is later. A Beth Israel employee who has completed the Specific Training shall review a new Relevant Covered Person's work, to the extent that the work relates to the preparation or submission of cost reports from any Federal health care program, until such time as the new Relevant Covered Person completes his or her Specific Training.

Beginning the year after receiving the initial Specific Training described in this Section, each Relevant Covered Person shall receive at least three hours of Specific Training annually.

- 3. Certification. Each individual who is required to attend training shall certify, in writing, or in electronic form, if applicable, that he or she has received the required training. The certification shall specify the type of training received and the date received. The Compliance Officer (or designee) shall retain the certifications, along with all course materials. These shall be made available to OIG, upon request.
- 4. Qualifications of Trainer. Persons providing the training shall be knowledgeable about the subject area.
- 5. Update of Training. Beth Israel shall annually review the training, and, where appropriate, update the training to reflect changes in Federal health care program requirements, any issues discovered during internal audits or the IRO Claims Review, Unallowable Cost Review, and any other relevant information.
- 6. Computer-based Training. Beth Israel may provide the training required under this CIA through appropriate computer-based training approaches. If Beth Israel chooses to provide computer-based training, it shall make available appropriately

qualified and knowledgeable staff or trainers to answer questions or provide additional information to the individuals receiving such training.

D. Review Procedures.

1. General Description.

a. Engagement of Independent Review Organization. Within 90 days after the Effective Date, Beth Israel shall engage an entity (or entities), such as an accounting, auditing, or consulting firm (hereinafter "Independent Review Organization" or "IRO"), to perform reviews to assist Beth Israel in assessing and evaluating its cost reporting practices and certain other obligations pursuant to this Agreement and the Stipulation and Order of Settlement and Dismissal. The applicable requirements relating to the IRO are outlined in Appendix A to this Agreement, which is incorporated by reference.

Each IRO engaged by Beth Israel shall have expertise in the cost reporting and other requirements of hospitals and in the general requirements of the Federal health care program(s) from which Beth Israel seeks reimbursement. Each IRO shall assess, along with Beth Israel, whether it can perform the IRO review in a professionally independent and/or objective fashion, as appropriate to the nature of the engagement, taking into account any other business relationships or other engagements that may exist.

The IRO(s) review shall evaluate and analyze Beth Israel's cost report submissions to the Federal health care programs (Cost Reporting Review), and shall analyze whether Beth Israel sought payment for certain unallowable costs (Unallowable Cost Review).

b. Frequency of Cost Reporting Review. The Cost Reporting Review shall be performed annually and shall cover each of the Reporting Periods. The IRO(s) shall perform all components of each annual Cost Reporting Review.

- c. Frequency of Unallowable Cost Review. If applicable, the IRO shall perform the Unallowable Costs Review for the first Reporting Period.
- d. Retention of Records. The IRO and Beth Israel shall retain and make available to OIG, upon request, all work papers, supporting documentation, correspondence, and draft reports (those exchanged between the IRO and Beth Israel) related to the reviews.
- 2. Cost Reporting Review. The Cost Reporting Review shall consist of the following:
 - a. Cost Report Systems Review. The IRO shall, through observation and inquiry, gain an understanding of Beth Israel's cost report preparation process ("Cost Report Systems Engagement"). The engagement shall be designed to compare Beth Israel's practices with best practices among similarly situated hospitals in the industry and shall be designed to produce findings and recommendations aimed at improving Beth Israel's cost report preparation process. The specific focus of the engagement shall be to document and, if applicable, recommend improvements to the steps Beth Israel takes to ensure that the proper information is being recorded on such submissions to the Medicare program and that controls are reasonably designed to ensure that allowable costs and amounts are submitted for reimbursement. The IRO shall conduct interviews and review policies and procedures to present findings and recommendations on Beth Israel's cost report preparation policies, procedures, and process ("Cost Report Systems Findings"). The Cost Report Systems Engagement shall consist of interviews with key Beth Israel cost reporting personnel, as well as an analysis of cost report preparation policies and procedures. The IRO's findings and recommendations shall include an analysis of the internal controls related to the allocation of costs and the derivation of dollar amounts.
 - b. Cost Reporting Review. The IRO shall perform an analysis of all costs charged directly to those departments of Beth Israel for which payment is made based upon a hospital-specific cost as reported on

Medicare cost reports during the Reporting Period (the "Cost Reporting Review"), to evaluate their compliance with Medicare requirements. Specifically, the IRO shall test all hospital expenses for: (i) costs concerning Beth Israel's Faculty Practice Plans; (ii) advertising and marketing costs; (iii) overhead costs; (iv) depreciation expenses; and (v) administrative and general expenses. The IRO's testing of such expenses shall demonstrate that the costs claimed reflect services actually rendered and that such costs are supported by documentation in compliance with applicable Medicare requirements.

- c. Cost Reporting Review Report. The IRO shall prepare a report based upon the Cost Reporting Engagement and appropriate consulting standards. The Report shall include the IRO's findings and supporting rationale regarding (i) the weaknesses in Beth Israel's cost report, cost statement, information statement, and payment request preparation process relating to any and all costs submitted to the Medicare program covered by the Cost Reporting Systems Engagement in the period being audited; (ii) any recommendations the IRO may have to improve any of these systems, operations, and processes; and (iii) a summary of the conclusions from the Cost Reporting Review.
- 3. Unallowable Cost Review. The IRO shall conduct a review of Beth Israel's compliance with the unallowable cost provisions of the Stipulation and Order of Settlement and Dismissal. The IRO shall determine whether Beth Israel has complied with its obligations not to charge to, or otherwise seek payment from, federal or state payors for unallowable costs (as defined in the Stipulation and Order of Settlement and Dismissal) and its obligation to identify to applicable federal or state payors any unallowable costs included in payments previously sought from the United States, or any state Medicaid program. This unallowable cost analysis shall include, but not be limited to, payments sought in any cost reports, cost statements, information reports, or payment requests already submitted by Beth Israel or any affiliates. To the extent that such cost reports, cost statements, information reports, or payment requests, even if already settled, have been adjusted to account for the effect of the inclusion of the unallowable costs, the IRO shall determine if such adjustments were proper. In making this determination, the IRO may need to review cost reports and/or financial statements from the year in which

the Stipulation and Order of Settlement and Dismissal was executed, as well as from previous years.

- 4. <u>Unallowable Cost Review Report</u>. The IRO shall prepare a report based upon the Unallowable Cost Review performed. The Unallowable Cost Review Report shall include the IRO's findings and supporting rationale regarding the Unallowable Cost Review and whether Beth Israel has complied with its obligation not to charge to, or otherwise seek payment from, federal or state payors for unallowable costs (as defined in the Stipulation and Order of Settlement and Dismissal) and its obligation to identify to applicable federal or state payors any unallowable costs included in payments previously sought from such payor.
- 5. <u>Validation Review</u>. In the event OIG has reason to believe that: (a) Beth Israel's Cost Reporting Review or Unallowable Cost Review fails to conform to the requirements of this CIA; or (b) the IRO's findings or Cost Reporting Review results or Unallowable Cost Review results are inaccurate, OIG may, at its sole discretion, conduct its own review to determine whether the Cost Reporting Review or Unallowable Cost Review complied with the requirements of the Agreement and/or the findings or Cost Reporting Review results or Unallowable Cost Review results are inaccurate (Validation Review). Beth Israel shall pay for the reasonable cost of any such review performed by OIG or any of its designated agents. Any Validation Review of Reports submitted as part of Beth Israel's final Annual Report must be initiated no later than one year after Beth Israel's final submission (as described in Section II) is received by OIG.

Prior to initiating a Validation Review, OIG shall notify Beth Israel of its intent to do so and provide a written explanation of why OIG believes such a review is necessary. To resolve any concerns raised by OIG, Beth Israel may request a meeting with OIG to: (a) discuss the results of any Cost Reporting Review or Unallowable Cost Review submissions or findings; (b) present any additional information to clarify the results of the Cost Reporting Review or Unallowable Cost Review or to correct the inaccuracy of the Cost Reporting Review or Unallowable Cost Review; and/or (c) propose alternatives to the proposed Validation Review. Beth Israel agrees to provide any additional information as may be requested by OIG under this Section in an expedited manner. OIG will attempt in good faith to resolve any Cost Reporting Review or Unallowable Cost Review issues with Beth Israel 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 OIG.

6. Independence/Objectivity Certification. The IRO shall include in its report(s) to Beth Israel a certification or sworn affidavit that it has evaluated its professional independence and/or objectivity, as appropriate to the nature of the engagement, with regard to the Cost Reporting Review or Unallowable Cost Review and that it has concluded that it is, in fact, independent and/or objective.

E. Disclosure Program.

Beth Israel represents to OIG that it has established a Disclosure Program that includes a mechanism (e.g., a toll-free compliance telephone line) 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 Beth Israel'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. Beth Israel shall continue to appropriately publicize the existence of the disclosure mechanism (e.g., via periodic e-mails to employees or by posting the information in prominent common areas).

The Disclosure Program shall continue to emphasize a nonretribution, nonretaliation policy, and shall include a reporting mechanism for anonymous communications for which appropriate confidentiality shall be maintained. 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 a further review should be conducted. For any disclosure that is sufficiently specific so that it reasonably: (1) permits a determination of the appropriateness of the alleged improper practice; and (2) provides an opportunity for taking corrective action, Beth Israel shall conduct an internal review of the allegations set forth in the disclosure and ensure that proper follow-up is conducted.

The Compliance Officer (or designee) 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 reviews, and any corrective action taken in response to the internal reviews. The disclosure log shall be made available to OIG upon request.

F. Ineligible Persons.

- 1. Definitions. For purposes of this CIA:
 - a. an "Ineligible Person" shall include 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.
 - b. "Exclusion Lists" include:
 - i. the HHS/OIG List of Excluded Individuals/Entities (available through the Internet at http://oig.hhs.gov); and
 - ii. the General Services Administration's List of Parties Excluded from Federal Programs (available through the Internet at http://epls.arnet.gov).
 - c. "Screened Persons" include prospective and current owners, officers, directors, employees, contractors, and agents of Beth Israel.
- 2. Screening Requirements. Beth Israel shall ensure that all Screened Persons are not Ineligible Persons, by implementing or maintaining the following screening requirements.
 - a. Beth Israel shall continue to screen all Screened Persons against the Exclusion Lists prior to engaging their services and, as part of the hiring or contracting process, shall continue to require such persons to disclose whether they are an Ineligible Person.

- b. Beth Israel shall screen all Screened Persons against the Exclusion Lists within 90 days after the Effective Date and on an annual basis thereafter.
- c. Beth Israel shall implement or maintain a policy requiring all Screened Persons to disclose immediately any debarment, exclusion, suspension, or other event that makes that person an Ineligible Person.

Nothing in this Section affects the responsibility of (or liability for) Beth Israel to refrain from billing Federal health care programs for items or services furnished, ordered, or prescribed by an Ineligible Person.

- 3. Removal Requirement. If Beth Israel has actual notice that a Screened Person has become an Ineligible Person, Beth Israel shall remove such person from responsibility for, or involvement with, Beth Israel's business operations related to the Federal health care programs and shall remove such person from any position for which the person's compensation or the items or services furnished, 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 Beth Israel has actual notice that a Screened Person is charged with a criminal offense that falls within the ambit of 42 U.S.C. §§ 1320a-7(a), 1320a-7(b)(1)-(3), or is proposed for exclusion during his or her employment or contract term or, in the case of a physician, during the term of the physician's medical staff privileges, Beth Israel shall take all appropriate actions to ensure that the responsibilities of that person have not and shall not adversely affect the quality of care rendered to any beneficiary, patient, or resident, or the accuracy of any claims submitted to any Federal health care program.

G. Notification of Government Investigation or Legal Proceedings.

Within 30 days after discovery, Beth Israel shall notify OIG, in writing, of any ongoing investigation or legal proceeding known to Beth Israel conducted or brought by a governmental entity or its agents involving an allegation that Beth Israel 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. Beth Israel 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.

H. Reporting.

1. Overpayments.

- a. <u>Definition of Overpayments</u>. For purposes of this CIA, an "Overpayment" shall mean the amount of money Beth Israel has received in excess of the amount due and payable under any Federal health care program requirements.
- b. Reporting of Overpayments. If, at any time, Beth Israel identifies or learns of any Overpayment, Beth Israel shall notify the payor (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, Beth Israel 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, Beth Israel 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 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. Reportable Events.

- a. <u>Definition of Reportable Event</u>. For purposes of this CIA, a "Reportable Event" 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 Reportable Event may be the result of an isolated event or a series of occurrences.

- b. Reporting of Reportable Events. If Beth Israel determines (after a reasonable opportunity to conduct an appropriate review or investigation of the allegations) through any means that there is a Reportable Event, Beth Israel shall notify OIG, in writing, within 30 days after making the determination that the Reportable Event exists. The report to OIG shall include the following information:
 - i. 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 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 Reportable Event, including the relevant facts, persons involved, and legal and Federal health care program authorities implicated;

iii. a description of Beth Israel's actions taken to correct the Reportable Event; and

iv. any further steps Beth Israel plans to take to address the Reportable Event and prevent it from recurring.

IV. NEW BUSINESS UNITS OR LOCATIONS

In the event that, after the Effective Date, Beth Israel changes locations or sells, closes, purchases, or establishes a new business unit or location related to the furnishing of items or services that may be reimbursed by Federal health care programs, Beth Israel shall notify OIG of this fact as soon as possible, but no later than within 30 days after the date of change of location, sale, closure, purchase, or establishment. This notification shall include the address of the new business unit or location, phone number, fax number, Medicare Provider number, provider identification number and/or supplier number, and the corresponding contractor's name and address that has issued each Medicare number. Each new business unit or location shall be subject to all the requirements of this CIA.

V. <u>IMPLEMENTATION AND ANNUAL REPORTS</u>

- A. <u>Implementation Report</u>. Within 180 days after the Effective Date, Beth Israel shall submit a written report to OIG summarizing the status of its implementation of the requirements of this CIA (Implementation Report). The Implementation Report shall, at a minimum, include:
- 1. the name, address, phone number, and position description of the Compliance Officer required by Section III.A, and a summary of other noncompliance job responsibilities the Compliance Officer may have;
- 2. the names and positions of the members of the Compliance Committee required by Section III.A;
 - 3. a copy of Beth Israel's Code of Conduct required by Section III.B.1;
 - 4. a copy of all Policies and Procedures required by Section III.B.2;
- 5. the number of individuals required to complete the Code of Conduct certification required by Section III.B.1, the percentage of individuals who have

completed such certification, and an explanation of any exceptions (the documentation supporting this information shall be available to OIG, upon request);

- 6. the following information regarding each type of training required by Section III.C:
 - a. a description of such training, including a summary of the topics covered, the length of sessions and a schedule of training sessions;
 - b. number of individuals required to be trained, percentage of individuals actually trained, and an explanation of any exceptions.

A copy of all training materials and the documentation supporting this information shall be available to OIG, upon request.

- 7. a description of the Disclosure Program required by Section III.E;
- 8. the following information regarding the IRO(s): (a) identity, address, and phone number; (b) a copy of the engagement letter; (c) a summary and description of any and all current and prior engagements and agreements between Beth Israel and the IRO; and (d) the proposed start and completion dates of the Cost Reporting Review and Unallowable Cost Review;
- 9. a certification from the IRO regarding its professional independence and/or objectivity with respect to Beth Israel;
- 10. a description of the process by which Beth Israel fulfills the requirements of Section III.F regarding Ineligible Persons;
- 11. the name, title, and responsibilities of any person who is determined to be an Ineligible Person under Section III.F; the actions taken in response to the screening and removal obligations set forth in Section III.F; and the actions taken to identify, quantify, and repay any overpayments to Federal health care programs relating to items or services furnished, ordered or prescribed by an Ineligible Person;
- 12. a list of all of Beth Israel's locations (including locations and mailing addresses); the corresponding name under which each location is doing business; the corresponding phone numbers and fax numbers; each location's Medicare Provider

number(s), provider identification number(s), and/or supplier number(s); and the name and address of each Medicare contractor to which Beth Israel currently submits cost reports or other claims;

- 13. to the extent not already provided to OIG, a description of Beth Israel's corporate structure, including identification of any parent and sister companies, subsidiaries, and their respective lines of business; and
 - 14. the certifications required by Section V.C.
- B. <u>Annual Reports</u>. Beth Israel shall submit to OIG annually a report with respect to the status of, and findings regarding, Beth Israel's compliance activities for each of the first four Reporting Periods, except that the final Annual Report shall cover the final one and one half years of this CIA (Annual Report).

Each Annual Report shall include, at a minimum:

- 1. any change in the identity, position description, or other noncompliance job responsibilities of the Compliance Officer and any change in the membership of the Compliance Committee described in Section III.A;
- 2. a summary of any significant changes or amendments to the Policies and Procedures required by Section III.B and the reasons for such changes (e.g., change in contractor policy) and copies of any compliance-related Policies and Procedures;
- 3. the number of individuals required to complete the Code of Conduct certification required by Section III.B.1, the percentage of individuals who have completed such certification, and an explanation of any exceptions (the documentation supporting this information shall be available to OIG, upon request);
- 4. the following information regarding each type of training required by Section III.C:
 - a. a description of such training, including a summary of the topics covered, the length of sessions and a schedule of training sessions;
 - b. number of individuals required to be trained, percentage of individuals actually trained, and an explanation of any exceptions.

A copy of all training materials and the documentation supporting this information shall be available to OIG, upon request.

- 5. a complete copy of all reports prepared pursuant to Section III.D, along with a copy of the IRO's engagement letter (if applicable);
- 6. Beth Israel's response and corrective action plan(s) related to any issues raised by the reports prepared pursuant to Section III.D;
- 7. a summary and description of any and all current and prior engagements and agreements between Beth Israel and the IRO, if different from what was submitted as part of the Implementation Report;
- 8. a certification from the IRO regarding its professional independence and/or objectivity with respect to Beth Israel;
- 9. a summary of Reportable Events (as defined in Section III.H) identified during the Reporting Period and the status of any corrective and preventative action relating to all such Reportable Events;
- 10. 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: inpatient Medicare, outpatient Medicare, Medicaid (report each applicable 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;
- 11. a summary of the disclosures in the disclosure log required by Section III.E that: (a) relate to Federal health care programs; or (b) allege abuse or neglect of patients;
- 12. any changes to the process by which Beth Israel fulfills the requirements of Section III.F regarding Ineligible Persons;
- 13. the name, title, and responsibilities of any person who is determined to be an Ineligible Person under Section III.F; the actions taken by Beth Israel in response to the screening and removal obligations set forth in Section III.F; and the actions taken to

identify, quantify, and repay any overpayments to Federal health care programs relating to items or services relating to items or services furnished, ordered or prescribed by an Ineligible Person;

- 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 of Beth Israel's locations (including addresses) as required by Section V.A.11; the corresponding name under which each location is doing business; the corresponding phone numbers and fax numbers; each location's Medicare Provider number(s), provider identification number(s), and/or supplier number(s); and the name and address of each Medicare contractor to which Beth Israel currently submits cost reports or claims; and
 - 16. the certifications required by Section V.C.

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.

- C. <u>Certifications</u>. The Implementation Report and Annual Reports shall include a certification by the Compliance Officer that:
- 1. to the best of his or her knowledge, except as otherwise described in the applicable report, Beth Israel is in compliance with all of the requirements of this CIA;
- 2. he or she has reviewed the Report and has made reasonable inquiry regarding its content and believes that the information in the Report is accurate and truthful; and
- 3. Beth Israel has complied with its obligations under the Stipulation and Order of Settlement and Dismissal: (a) not to resubmit to any Federal health care program payors any previously denied claims related to the Covered Conduct addressed in the Stipulation and Order of Settlement and Dismissal, and not to appeal any such denials of claims; (b) not to charge to or otherwise seek payment from federal or state payors for unallowable costs (as defined in the Stipulation and Order of Settlement and

Dismissal); and (c) to identify and adjust any past charges or claims for unallowable costs;

D. <u>Designation of Information</u>. Beth Israel 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. Beth Israel 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 after the Effective Date, all notifications and reports required under this CIA shall be submitted to the following entities:

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

Beth Israel:

Louis I. Schenkel
Corporate Compliance Officer
Continuum Health Partners, Inc.
555 West 57th Street, 18th Floor
New York, New York 10019
Ph. 212-523-2162
Fax 212-523-3935

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 OIG may have by statute, regulation, or contract. OIG or its duly authorized representative(s) may examine or request copies of Beth Israel's books, records, and other documents and supporting materials and/or conduct onsite reviews of any of Beth Israel's locations for the purpose of verifying and evaluating: (a) Beth Israel's compliance with the terms of this CIA; and (b) Beth Israel's compliance with the requirements of the Federal health care programs in which it participates. The documentation described above shall be made available by Beth Israel 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 Beth Israel'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. In the event OIG determines that it wishes to interview any of Beth Israel's employees, contractors, or agents, OIG shall contact Beth Israel and Beth Israel shall assist OIG or its duly authorized representative(s) in contacting and arranging interviews with such individuals upon OIG's request. Beth Israel's employees may elect to be interviewed with or without a representative of Beth Israel present.

VIII. DOCUMENT AND RECORD RETENTION

Beth Israel 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 and one half years (6.5) (or longer if otherwise required by law).

IX. DISCLOSURES

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

X. Breach and Default Provisions

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

- A. <u>Stipulated Penalties for Failure to Comply with Certain Obligations</u>. As a contractual remedy, Beth Israel and OIG hereby agree that failure to comply with certain obligations as 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 Beth Israel fails to establish and implement any of the following obligations as described in Section III:
 - a. a Compliance Officer;
 - b. a Compliance Committee;
 - c. a written Code of Conduct;
 - d. written Policies and Procedures;
 - e. the training of Covered Persons;
 - f. a Disclosure Program;
 - g. Ineligible Persons screening and removal requirements; and
 - h. Notification of Government investigations or legal proceedings.
- 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 Beth Israel fails to engage an IRO, as required in Section III.D and Appendix A.
- 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 Beth Israel fails to submit the Implementation Report or the Annual Reports to OIG in accordance with the requirements of Section V by the deadlines for submission.

- 4. A Stipulated Penalty of \$2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day Beth Israel fails to submit the annual Cost Reporting Review Report and any other required Review in accordance with the requirements of Section III.D.
- 5. A Stipulated Penalty of \$1,500 for each day Beth Israel fails to grant access to the information or documentation as required in Section VII. (This Stipulated Penalty shall begin to accrue on the date Beth Israel fails to grant access.)
- 6. A Stipulated Penalty of \$5,000 for each false certification submitted by or on behalf of Beth Israel as part of its Implementation Report, Annual Report, additional documentation to a report (as requested by the OIG), or otherwise required by this CIA.
- 7. A Stipulated Penalty of \$1,000 for each day Beth Israel fails to comply fully and adequately with any obligation of this CIA. OIG shall provide notice to Beth Israel, stating the specific grounds for its determination that Beth Israel has failed to comply fully and adequately with the CIA obligation(s) at issue and steps Beth Israel shall take to comply with the CIA. (This Stipulated Penalty shall begin to accrue 10 days after Beth Israel receives this 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 1-6 of this Section.
- B. <u>Timely Written Requests for Extensions</u>. Beth Israel 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 Beth Israel 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 Beth Israel 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 Beth Israel has failed to comply with any of the obligations described in Section X.A and after determining that Stipulated Penalties are appropriate, OIG shall notify Beth Israel of: (a) Beth Israel'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, Beth Israel 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 X.E. In the event Beth Israel elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until Beth Israel cures, to OIG's satisfaction, the alleged breach in dispute. Failure to respond to the Demand Letter in one of these two manners within the allowed time period shall be considered a material breach of this CIA and shall be grounds for exclusion under Section 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 OIG at the address set forth in Section VI.
- 4. Independence from Material Breach Determination. Except as set forth in Section X.D.1.c, these provisions for payment of Stipulated Penalties shall not affect or otherwise set a standard for OIG's decision that Beth Israel has materially breached this CIA, which decision shall be made at OIG's discretion and shall be 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 Beth Israel to report a Reportable Event, take corrective action, and make the appropriate refunds, as required in Section III.H;
 - b. a repeated or flagrant violation of the obligations under this CIA, including, but not limited to, the obligations addressed in Section

X.A;

- c. a failure to respond to a Demand Letter concerning the payment of Stipulated Penalties in accordance with Section X.C; or
- d. a failure to engage and use an IRO 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 Beth Israel constitutes an independent basis for Beth Israel's exclusion from participation in the Federal health care programs. Upon a determination by OIG that Beth Israel has materially breached this CIA and that exclusion is the appropriate remedy, OIG shall notify Beth Israel of: (a) Beth Israel's material breach; and (b) OIG's intent to exercise its contractual right to impose exclusion (this notification is hereinafter referred to as the "Notice of Material Breach and Intent to Exclude").
- 3. Opportunity to Cure. Beth Israel 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. Beth Israel is in compliance with the obligations of the CIA 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) Beth Israel has begun to take action to cure the material breach; (ii) Beth Israel is pursuing such action with due diligence; and (iii) Beth Israel has provided to OIG a reasonable timetable for curing the material breach.
- 4. Exclusion Letter. If, at the conclusion of the 30-day period, Beth Israel fails to satisfy the requirements of Section X.D.3, OIG may exclude Beth Israel from participation in the Federal health care programs. OIG shall notify Beth Israel in writing of its determination to exclude Beth Israel (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 Beth Israel'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, Beth Israel 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. <u>Dispute Resolution</u>

- 1. Review Rights. Upon OIG's delivery to Beth Israel of its Demand Letter or of its Exclusion Letter, and as an agreed-upon contractual remedy for the resolution of disputes arising under this CIA, Beth Israel shall be afforded certain review rights comparable to the ones that are provided in 42 U.S.C. § 1320a-7(f) and 42 C.F.R. Part 1005 as if they applied to the Stipulated Penalties or exclusion sought pursuant to this CIA. Specifically, OIG's determination to demand payment of Stipulated Penalties or to seek exclusion shall be subject to review by an HHS ALJ and, in the event of an appeal, the HHS Departmental Appeals Board (DAB), in a manner consistent with the provisions in 42 C.F.R. §§ 1005.2-1005.21. Notwithstanding the language in 42 C.F.R. § 1005.2©, 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 CIA shall be: (a) whether Beth Israel was in full and timely compliance with the obligations of this CIA for which OIG demands payment; and (b) the period of noncompliance. Beth Israel 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 CIA and orders Beth Israel to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable 20 days after the ALJ issues such a decision unless Beth Israel 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 CIA shall be:

- a. whether Beth Israel was in material breach of this CIA;
- b. whether such breach was continuing on the date of the Exclusion Letter; and
- c. whether the alleged material breach could not have been cured within the 30-day period, but that: (i) Beth Israel had begun to take action to cure the material breach within that period; (ii) Beth Israel has pursued and is pursuing such action with due diligence; and (iii) Beth Israel provided to OIG within that period a reasonable timetable for curing the material breach and Beth Israel 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 Beth Israel, only after a DAB decision in favor of OIG. Beth Israel's election of its contractual right to appeal to the DAB shall not abrogate OIG's authority to exclude Beth Israel 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 Beth Israel 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. Beth Israel 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 Beth Israel, Beth Israel 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 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 Stipulation and Order of Settlement and Dismissal pursuant to which this CIA is entered, and into which this CIA is incorporated, Beth Israel and OIG agree as follows:

- A. This CIA shall be binding on the successors, assigns, and transferees of Beth Israel;
- B. This CIA shall become final and binding on the date the final signature is obtained on the CIA;
- C. Any modifications to this CIA shall be made with the prior written consent of the Parties to this CIA;
- D. OIG may agree to a suspension of Beth Israel's obligations under the CIA in the event of Beth Israel's cessation of participation in Federal health care programs. If Beth Israel withdraws from participation in Federal health care programs and is relieved of its CIA obligations by OIG, Beth Israel shall notify OIG at least 30 days in advance of Beth Israel's 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 CIA should be reactivated or modified.
- E. The undersigned Beth Israel signatories represent and warrant that they are authorized to execute this CIA. The undersigned OIG signatory represents that he is signing this CIA in his official capacity and that he is authorized to execute this CIA.

ON BEHALF OF BETH ISRAEL MEDICAL CENTER

David Schulkin, M.D. Chief Executive Officer DATE

Kathryn C. Meyer, Esq.

Counsel for Beth Israel Medical Center.

11/29/05 DATE

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

LEWIS MORRIS

Chief Counsel to the Inspector General

Office of Inspector General

U. S. Department of Health and Human Services

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APPENDIX A INDEPENDENT REVIEW ORGANIZATION

This Appendix contains the requirements relating to the Independent Review Organization (IRO) required by Section III.D of the CIA.

A. IRO Engagement.

Beth Israel shall engage an IRO that possesses the qualifications set forth in Paragraph B, below, to perform the responsibilities in Paragraph C, below. The IRO shall conduct the review in a professionally independent and/or objective fashion, as set forth in Paragraph D. Within 30 days after OIG receives written notice of the identity of the selected IRO, OIG will notify Beth Israel if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, Beth Israel may continue to engage the IRO.

If Beth Israel engages a new IRO during the term of the CIA, this IRO shall also meet the requirements of this Appendix. If a new IRO is engaged, Beth Israel shall submit the information identified in Section V.A.8 to OIG within 30 days of engagement of the IRO. Within 30 days after OIG receives written notice of the identity of the selected IRO, OIG will notify Beth Israel if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, Beth Israel may continue to engage the IRO.

B. IRO Qualifications.

The IRO shall:

- 1. assign individuals to conduct the Cost Reporting Review and Unallowable Cost Review engagements who have expertise in the billing, coding, reporting, and other requirements of the cost reporting process and in the general requirements of the Federal health care program(s) from which Beth Israel seeks reimbursement;
- 2. assign individuals to design and select the Cost Reporting Review procedures who are knowledgeable about the appropriate cost reporting process; and
- 3. have sufficient staff and resources to conduct the reviews required by the CIA on a timely basis.

C. <u>IRO Responsibilities</u>.

The IRO shall:

- 1. perform each Cost Reporting Review and Unallowable Cost Review in accordance with the specific requirements of the CIA;
- 2. follow all applicable Federal health care programs rules in making assessments in the Cost Reporting Review;
- 3. if in doubt of the application of a particular Federal health care program policy or regulation, request clarification from the appropriate authority (e.g., fiscal intermediary or carrier);
 - 4. respond to all OIG inquires in a prompt, objective, and factual manner; and
- 5. prepare timely, clear, well-written reports that include all the information required by Appendix B.

D. <u>IRO Independence/Objectivity</u>.

The IRO must perform the Cost Reporting Review in a professionally independent and/or objective fashion, as appropriate to the nature of the engagement, taking into account any other business relationships or engagements that may exist between the IRO and Beth Israel.

E. IRO Removal/Termination.

- 1. Provider. If Beth Israel terminates its IRO during the course of the engagement, Beth Israel must submit a notice explaining its reasons to OIG no later than 30 days after termination. Beth Israel must engage a new IRO in accordance with Paragraph A of this Appendix.
- 2. OIG Removal of IRO. In the event OIG has reason to believe that the IRO does not possess the qualifications described in Paragraph B, is not independent and/or objective as set forth in Paragraph D, or has failed to carry out its responsibilities as described in Paragraph C, OIG may, at its sole discretion, require Beth Israel to engage a new IRO in accordance with Paragraph A of this Appendix.

Prior to requiring Beth Israel to engage a new IRO, OIG shall notify Beth Israel of its intent to do so and provide a written explanation of why OIG believes such a step is necessary. To resolve any concerns raised by OIG, Beth Israel may request a meeting with OIG to discuss any aspect of the IRO's qualifications, independence or performance of its responsibilities and to present additional information regarding these matters. Beth Israel shall provide any additional information as may be requested by OIG under this Paragraph in an expedited manner. OIG will attempt in good faith to resolve any differences regarding the IRO with Beth Israel prior to requiring Beth Israel to terminate

the IRO. However, the final determination as to whether or not to require Beth Israel to engage a new IRO shall be made at the sole discretion of OIG.

OVERPAYMENT REFUND

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| 02 - Duplicate | 09 - MSP No Fault Insurance | 14 - Patient Enrolled in an HM | (O |
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