CORPORATE INTEGRITY AGREEMENT

BETWEEN THE
OFFICE OF INSPECTOR GENERAL

OF THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES

AND

LIFEPOINT HOSPITALS, INC.

I. PREAMBLE

LifePoint Hospitals, Inc. ("LifePoint") 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 its subsidiaries, and their officers, directors, employees, physicians, contractors and agents 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").

Upon its formation and prior to the execution of this CIA, LifePoint voluntarily established a compliance program (the "Compliance Program") which is designed to ensure that its participation in the Federal health care programs is in conformity with Federal health care program requirements. The Compliance Program includes specifically LifePoint's Code of Conduct, as well as policies and procedures designed to implement the Code of Conduct. Therefore, during the term of this CIA, LifePoint hereby agrees to maintain a compliance program in accordance with the requirements of this CIA. The Compliance Program may be modified by LifePoint as appropriate, but at a minimum, shall always comply with the integrity obligations enumerated in this CIA.

II. TERM OF THE CIA, DEFINITION, AND CONTINGENT RELEASE

A. <u>Term.</u> The period of the compliance obligations assumed by LifePoint under this CIA shall be five years from the effective date of this CIA (unless otherwise specified). The effective date of this CIA shall be the date on which the final signatory of this CIA executes this CIA. Sections VII, VIII, IX, X and XII shall remain in effect until OIG has completed its review of the final annual report and any additional materials submitted by LifePoint pursuant to OIG's request.

B. <u>Definition of Covered Person</u>. For the purposes of this CIA, a Covered Person means any: (i) officer, director, or employee of LifePoint; or (ii) agent or other individual

who furnishes health care items or services at a LifePoint owned or operated location for which LifePoint claims reimbursement from any Federal health care program or who participates in the preparation or submission of claims for payment on behalf of LifePoint with respect to items or services for which LifePoint claims reimbursement from any Federal health care program (regardless of where such activity takes place). Notwithstanding the above, part-time or per diem agents or employees who work less than 160 hours per year are not Covered Persons.

C. HCA Investigation and Contingent Release. LifePoint is entering this Agreement in connection with the investigation by the United States of HCA - The Healthcare Company ("HCA"). HCA and the United States may enter into a settlement agreement or agreements to resolve that investigation. LifePoint's hospitals were formerly owned by HCA and LifePoint and its subsidiaries may be subject to permissive exclusion pursuant to 42 U.S.C. § 1320a-7(b)(7) for conduct that occurred while the hospitals were owned by HCA. Once this CIA is effective and the United States releases claims under the False Claims Act, 31 U.S.C. §§ 3729-3733, against HCA for conduct described in a settlement agreement between the United States and HCA ("Covered Conduct"), the OIG agrees to release and refrain from instituting any action seeking exclusion from the Medicare, Medicaid or other Federal health care programs against LifePoint and its subsidiaries under 42 U.S.C. § 1320a-7a (Civil Monetary Penalties Law), or 42 U.S.C. § 1320a-7(b) (permissive exclusion), for the Covered Conduct. The release described in this paragraph is subject to the same limitations and conditions with respect to LifePoint as apply to the parallel release granted to HCA for the Covered Conduct; provided, however, that the terms of such release shall not impose additional obligations on LifePoint beyond those contained in this CIA.

III. CORPORATE INTEGRITY OBLIGATIONS

LifePoint hereby agrees to maintain its Compliance Program so that it includes the following elements for the term of this CIA:

A. Compliance Officers and Committees.

1. Audit and Compliance Committee of the Board of Directors. LifePoint currently has an Audit and Compliance Committee of the Board of Directors ("Board Committee") comprised of at least three outside directors of LifePoint. The Board Committee is responsible for the review of matters related to the Compliance Program, this CIA, and compliance with Federal health care program requirements. The Board Committee shall meet at least four times each year. When new members of the Board Committee are appointed or the responsibilities or authorities of the Board Committee are

substantially changed, LifePoint shall notify the OIG, in writing, within 15 days of such a change.

- 2. Compliance Officer. LifePoint has, pursuant to its Compliance Program, created a position known as the Vice President, Audit & Compliance and appointed an individual to serve in that capacity ("Compliance Officer"). The Compliance Officer is 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 is charged with the responsibility for the day-to-day compliance activities in furtherance of the integrity obligations assumed herein, as well as for any reporting obligations established under this Agreement. The Compliance Officer, who is a member of senior management, has the authority and ability to report directly to the Chief Executive Officer and the Board Committee at any time and shall report to the CEO and/or Board Committee at least quarterly on compliance issues. Any changes in the identity or position description of the Compliance Officer, or any actions or changes that would reasonably be expected to affect the Compliance Officer's ability to perform the duties necessary to meet the obligations in this CIA, must be reported to OIG, in writing, within 15 days of such a change.
- 3. Internal Audit and Compliance Department. LifePoint currently has an Internal Audit and Compliance Department ("Compliance Department"). The Compliance Department is managed by the Compliance Officer and is responsible for the operation of the Compliance Program and for compliance with this CIA and Federal health care program requirements. In the event the responsibilities or authorities of the Compliance Department are substantially changed, LifePoint shall notify the OIG, in writing, within 15 days of such a change.
- 4. Local Ethics and Compliance Officers. LifePoint currently has a Local Ethics and Compliance Officer ("ECO") at each of its hospitals. Each ECO shall have sufficient management responsibility so as permit the effective performance of his or her duties. Each ECO is and shall remain responsible for implementation and oversight of the Ethics and Compliance Program at the hospital and for the hospital's compliance with this CIA and Federal health care program requirements. LifePoint shall make proper execution of ECO duties a component of the performance evaluations of ECOs. In the event any substantial change in the responsibilities or authorities of the ECOs relating to LifePoint's Compliance Program is made, LifePoint shall notify the OIG in writing within 15 days of such change.

- 5. Corporate Compliance Committee. LifePoint currently has a Corporate Compliance Committee ("Compliance Committee"). The Compliance Committee is chaired by the Compliance Officer and includes the CEO, COO, CFO, General Counsel, SVP-Human Resources, and presidents of LifePoint's two divisions. The Compliance Committee is responsible for overseeing the implementation and operation of the Compliance Program and with LifePoint's compliance with this CIA and with Federal health care program requirements. The Compliance Committee shall conduct at least 10 meetings per year and shall keep a record of its proceedings that shall be available to the OIG upon request.
- 6. Hospital Compliance Committees. Each Hospital shall have a Hospital Ethics and Compliance Committee ("Hospital Committee"). The Hospital Committee shall be chaired by the ECO of the facility and, generally, shall include the heads of each of the facility's major departments, such as billing, Health Information Management ("HIM"), quality, risk management, finance, and human resources. The Hospital Committee shall be responsible for assisting the ECO in implementing the Compliance Program, and ensuring compliance by the facility with this CIA and Federal health care program requirements.

B. Written Standards.

1. Code of Conduct. LifePoint currently has a Code of Conduct. LifePoint has implemented a program to distribute the Code of Conduct to Covered Persons. LifePoint shall continue to make the promotion of, and adherence to, the Code of Conduct an element in evaluating the performance of the Compliance Officer and each ECO. All employees who violate the Code of Conduct are, and shall continue to be, subject to discipline, up to and including termination. LifePoint has implemented a program to obtain an acknowledgment from each Covered Person that he or she has received LifePoint's Code of Conduct and understands that it represents the mandatory policies of the organization. Within 90 days of the effective date of this CIA, LifePoint shall have obtained a certification from each of its facilities and corporate office that, based on information and belief, this distribution and acknowledgment process is complete. New Covered Persons shall receive the Code of Conduct and shall complete the required acknowledgment within 30 days after becoming a Covered Person. LifePoint currently plans to make non-substantive revisions to its current Code of Conduct and distribute the revised Code of Conduct to Covered Persons during the next annual cycle of general training. For the distribution of this revised Code of Conduct and any future revisions, LifePoint shall implement a program to obtain an acknowledgment from each Covered Person that he or she has received the revised Code of Conduct, understands that it represents the mandatory policies of the organization, and agrees to abide by it. Future

revisions shall be distributed as expeditiously as possible after initiating such a change and no later than 60 days after the effective date of the revised Code of Conduct. Within 90 days of the effective date of the revised Code of Conduct, LifePoint shall obtain a certification from each of its facilities and corporate office that, based on information and belief, this distribution and acknowledgment process is complete. LifePoint shall obtain the acknowledgments and certifications described in the preceding two sentences every time that a revised Code of Conduct is distributed.

- 2. Policies and Procedures. LifePoint represents that it has developed. distributed to its employees, and placed into effect written policies and procedures regarding the operation of its Compliance Program and its overall compliance with Federal health care program requirements. LifePoint shall, during the term of this CIA. maintain policies and procedures, which shall at a minimum specifically address: (a) the need for compliance in connection with all submissions for reimbursement for inpatient and outpatient procedures; (b) the need for compliance in connection with all submissions for cost based reimbursement; (c) medical record documentation requirements; (d) a process for reasonable verification of compliance with these requirements; and (e) methods for employees to make disclosures or otherwise report on compliance issues to management and/or supervisors through the Confidential Disclosure mechanisms outlined in Section III.E. LifePoint shall assess and update the policies and procedures annually or more frequently, as appropriate. At a minimum, a summary of the policies and procedures will be provided to OIG in the Implementation Report, as provided in Section V.A. The policies and procedures will be available to OIG upon request. Within 90 days of the effective date of the CIA, LifePoint shall provide to all Covered Persons, to the extent it has not already done so, the policies and procedures that are relevant to their respective tasks and responsibilities in connection with LifePoint's participation in the Federal health care programs. LifePoint will continue to take actions that it considers reasonable and effective to communicate these policies to Covered Persons. Appropriate compliance officers or supervisory personnel are available to explain policies and procedures.
- C. <u>Training and Education</u>. LifePoint shall meet the following training requirements. The training requirements are cumulative, <u>i.e.</u>, not exclusive, so that one person may be required to attend training in several substantive areas in addition to the general training. All training requirements set forth below in paragraphs 1 to 5 shall be implemented within 90 days of the effective date of this CIA and conducted as specified below. Subject to paragraphs 1 through 5 below, with respect to the initial training required during the first 90 days after the effective date of this CIA, LifePoint need not provide such training to persons who have received training after January 1, 2000, if the

training provided meets all the subject matter and duration requirements that would apply to the initial training under the CIA. All training shall be conducted as specified below:

- 1. General Training. Throughout the term of this CIA, LifePoint shall provide at least one hour of training initially to each Covered Person and one hour of refresher training annually thereafter. This general training shall cover the Compliance Program, the Code of Conduct, and this CIA. Covered Persons who have received LifePoint's general compliance training in the past shall be considered to have completed the initial general training requirement notwithstanding the fact that such training did not cover the CIA. Covered Persons who have not received initial general training prior to the effective date of this CIA shall receive such training within 90 days after the effective date of this CIA. New Covered Persons shall receive the general training described above within 30 days of becoming a Covered Person or within 90 days after the effective date of this CIA, whichever is later. After receiving the initial training described above, each Covered Person shall receive at least one hour of general training annually.
- 2. Coding Training. Throughout the term of this CIA, LifePoint shall continue to provide at least 10 hours per year of continuing education for all Covered Persons with responsibility for coding, including coding directors and coders.
- 3. Billing Training. Throughout the term of this CIA, LifePoint shall continue to provide at least 8 hours of continuing education per year for individuals responsible for billing, including members of billing departments and laboratory and business office directors. This training provides information on essential rules of billing for Federal health care programs.
- 4. Cost Report Training. Throughout the term of this CIA, LifePoint shall continue to require at least 20 hours of continuing education for Covered Persons in the Reimbursement Department (and others who engage in the preparation of cost reports) annually which includes cost report preparation and other job-related training.
- 5. New Persons. Affected new Covered Persons shall receive the training required by this CIA promptly (but in no event later than 30 days after: (i) the person becomes a Covered Person; or (ii) the person begins work on the matter for which they must be trained, whichever is later) so that the persons are fully qualified by virtue of such training to perform whatever responsibilities may be assigned to them. With respect to initial training of new Covered Persons, training provided to that Covered Person in the six-month period prior to becoming a Covered Person will count toward meeting the hourly training requirements of this CIA if the training provided meets all the subject matter requirements that would apply to the initial training of a new Covered Person

under the CIA. In any situation where training requirements have not been completed, a fully trained LifePoint employee shall carefully monitor the work of the untrained person.

6. Certifications and Retention. LifePoint shall continue to maintain sufficient records to demonstrate that required training has occurred. These records shall include certifications from Covered Persons that they have attended the required training. The certifications may be acquired through: attendance/sign-in sheets for in-person group training sessions; computer attestations for computer-based training; or similar mechanisms for other forms of training. The Compliance Officer shall retain training records in a manner that permits reporting about the training, along with specific course materials to the OIG upon request. The Compliance Officer may delegate the maintenance of such materials.

D. Review Procedures.

1. General Description.

- a. Retention of Independent Review Organization. Within 90 days of the effective date of this CIA, LifePoint shall retain an entity (or entities), such as an accounting, auditing or consulting firm (hereinafter "Independent Review Organization" or "IRO"), to perform review engagements to assist LifePoint in evaluating its billing and coding practices and its compliance obligations pursuant to this CIA. Each Independent Review Organization retained by LifePoint shall have expertise in the billing, coding, reporting and other requirements of the particular sector of the health care industry pertaining to matters that the IRO is reviewing and in the general requirements of the Federal health care program(s) from which LifePoint seeks reimbursement.
- b. Types of Engagements. LifePoint's Internal Audit and Compliance Department (references to "LifePoint" in the review procedures described in this CIA and the incorporated appendices refer to this department) and the Independent Review Organization(s) shall conduct the following engagements. One engagement shall address LifePoint's billing and coding to the Federal health care programs ("Billing Engagement") and shall include a review of DRG and laboratory claims. The second engagement shall address LifePoint's compliance with the obligations assumed under this CIA ("Compliance Engagement").

- c. Frequency of Billing and Compliance Engagements. The Billing Engagement shall be performed annually and shall cover each of the calendar years 2001 through 2005. The Compliance Engagement shall be performed by the IRO for the calendar year 2001.
- d. Retention of records. The IRO and LifePoint shall retain and make available to the OIG upon request all work papers related to the engagements (including, but not limited to, all substantive correspondence exchanged regarding the reports) and all draft and final reports delivered to LifePoint.
- 2. Billing Engagement. The Billing Engagement shall be composed of the following types of reviews: a "DRG Claims Review," a "Laboratory Claims Review," a "Systems Review," and an Operations DRG Review." The Claims Reviews and corresponding Reports are discussed in detail in Appendices A, B, and C to this CIA, which are incorporated by reference.

a. DRG Claims Review.

- i. DRG Claims Review. LifePoint shall perform a Claims Review to identify any overpayments through an appraisal of inpatient discharges paid by Medicare DRG to LifePoint. The Claims Reviews shall be performed in accordance with the procedures set forth in Appendix A to this CIA. The Claims Reviews shall cover the two six-month periods during each year covered by the Billing Engagement. LifePoint will perform Claims Reviews at a minimum of two hospitals during each six-month period (for a minimum of four hospitals each year.) The hospitals, and the DRGs to be reviewed at each hospital, will be chosen as set forth in section III.D.2.c.
- ii. DRG Claims Review Report. LifePoint shall prepare a report based upon each Claims Review performed ("Claims Review Report"). The Claims Review Report shall be created in accordance with the procedures set forth in Appendix A to this CIA.

- iii. IRO Review. With respect to LifePoint's Claims Reviews, the IRO will prepare a report documenting the IRO's findings with respect to the following procedures:
 - A. The IRO will obtain LifePoint's workpapers and perform procedures to test concurrence with the criteria included in section III.D.2.c.
 - B. The IRO will select a random sample of a minimum of 10% of the Items reviewed by LifePoint pursuant to the DRG Claims Review and reperform LifePoint's workplan steps.
- b. Laboratory Claims Review.
 - i. Claims Review. LifePoint shall perform a Claims Review to identify any overpayments through an appraisal of outpatient laboratory claims submitted by LifePoint to the Medicare program and paid by Medicare. The Claims Reviews shall be performed in accordance with the procedures set forth in Appendix A to this CIA. The Claims Reviews shall cover the two six-month periods during each year covered by the Billing Engagement. LifePoint will perform Claims Reviews at a minimum of two hospitals during each six-month period (for a minimum of four hospitals each year.) The hospitals, and the tests to be reviewed at each hospital, will be chosen as set forth in section III.D.2.c.
 - ii. Laboratory Claims Review Report. LifePoint shall prepare a report based upon each Laboratory Claims Review performed ("Claims Review Report"). The Claims Review Report shall be created in accordance with the procedures set forth in Appendix A to this CIA.
 - iii. IRO Review. With respect to LifePoint's Laboratory Claims Review, the IRO will prepare a report documenting the IRO's findings with respect to the following procedures:

- A. The IRO will obtain LifePoint's workpapers and perform procedures to test concurrence with the criteria set forth in section III.D.2.c.
- B. The IRO will select a random sample of a minimum of 10% of the Items reviewed pursuant to the Laboratory Review and re-perform LifePoint's workplan steps.
- c. Selection of Hospitals for Claims Reviews.
 - i. DRG Claims Review Hospital Selection. LifePoint shall select the two hospitals subject to review during each sixmonth period as follows:
 - A. The hospital that has the highest percentage of Medicare focused DRGs, as compared to total Medicare DRGs, during the relevant six month period under review, will be chosen. (However, if a hospital has already been selected under this process during any of the immediately preceding two reviews then the hospital with the next highest percentage shall be chosen instead).
 - B. One hospital will be randomly selected using RAT-STATS. A replacement hospitals should be generated in case the hospital randomly selected has already been identified under section III.d.2.C.i.A.
 - ii. Laboratory Claims Review Hospital Selection. LifePoint shall select the two hospitals subject to review during each six-month period as follows:
 - A. The hospital that has the highest percentage of Medicare outpatient laboratory services revenue, as compared to total Medicare outpatient services revenue, during the relevant six month period, will be chosen. (However, if a hospital has already been selected under this process during any of the immediately preceding two reviews then the hospital

with the next highest percentage shall be chosen instead).

- B. One hospital will be randomly selected using RATSTATS. A replacement hospital should be generated in case the hospital randomly selected has already been identified under section III.d.2.C.ii.A..
- d. Systems Review. LifePoint shall review LifePoint's billing and coding systems and/or operations (the "Systems Review"). The Systems Review shall include the reviews described in Appendix B for at least four hospitals. The Systems Review shall consist of a thorough review of the following as more specifically described in Appendix B:
 - i. LifePoint's billing systems and/or operations relating to claims submitted to all Federal health care programs (including, but not limited to, the operation of the billing system, safeguards to ensure proper claim submission and billing, and procedures to correct inaccurate billing); and
 - ii. LifePoint's coding systems and/or operations relating to claims submitted to all Federal health care programs (including, but not limited to, the process by which claims are coded, safeguards to ensure proper coding, and procedures to correct inaccurate coding).
- e. Systems Review Report. LifePoint shall prepare a report based upon each Systems Review performed ("Systems Review Report"). The Systems Review Report shall include LifePoint's findings and supporting rationale regarding:
 - i. all findings and recommendations regarding LifePoint's billing systems and/or operations;
 - ii. all findings and recommendations regarding LifePoint's coding systems and/or operations; and
 - iii. any recommendations LifePoint may have to improve any of these systems, operations, and processes.

- f. Operational DRG Review. LifePoint shall review LifePoint's DRG coding for hospital inpatients (the "Operational DRG Review"). The Operational DRG Review shall include the reviews described in Appendix C for at least eight hospitals. The Operational DRG Review shall consist of a thorough review of the DRG coding operations (including a review of at least 50 DRG claims at each hospital) as more specifically described in Appendix C. Except for the fact that the review of claims need not meet the statistical confidence and precision parameters set forth in Appendix A, the Operational DRG Review shall be conducted in a manner consistent with Appendix A, e.g., paid claims without supporting documentation shall be considered an error and the total reimbursement received by LifePoint for such Paid Claim shall be deemed an Overpayment.
- g. Operational DRG Review Report. LifePoint shall provide to the OIG in its Annual Reports the Executive Summaries related to the Operational DRG Reviews. The Executive Summaries shall include a summary of the Medicare and other Federal health care program overpayments (including number of overpayments, dollar amount of overpayments, and percentage of paid dollars attributable to overpayments) identified in each Operational DRG Review. All other documents related to the Operational DRG Reviews shall be available to the OIG upon request.

3. Compliance Engagement.

- a. Compliance Review. The IRO shall conduct a review of LifePoint's compliance activities ("Compliance Review"). The Compliance Review shall consist of a review of LifePoint's compliance with the obligations set forth in each section of this CIA.
- b. Compliance Review Report. The IRO shall prepare a report based upon the Compliance Review performed (the "Compliance Review Report"). The Compliance Review Report shall include the IRO's findings, supporting rationale, and a summary of such findings and rationale regarding LifePoint's compliance with the terms of each section of the CIA, as applicable.

- 4. Validation Review. In the event the OIG has reason to believe that: (a) LifePoint's Billing or Compliance Engagement fails to conform to the requirements of this CIA or (b) the findings or Claims Review results are inaccurate, the OIG may, at its sole discretion, conduct its own review to determine whether the Billing and Compliance Engagement comply with the requirements of the CIA and/or the findings or Claims Review results are inaccurate. LifePoint 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 the final submission (as described in section II) is received by the OIG.
- E. <u>Confidential Disclosure Program</u>. LifePoint, pursuant to its Compliance Program, has established a confidential disclosure program which includes its Compliance Hotline, a toll-free telephone line, as a means to enable individuals to report instances of noncompliance and/or make inquiries on compliance issues. LifePoint shall continue to maintain a confidential disclosure program, including a mechanism such as the Compliance Hotline, which shall be available to all individuals for the purpose of reporting or inquiring on matters of compliance with the Compliance Program, this CIA, and Federal health care program requirements.

The Confidential Disclosure Program shall continue to have a non-retribution, non-retaliation policy, and allow anonymous, confidential communications. Upon receipt of a disclosure, the Compliance Officer (or designee) shall continue to gather all information believed to be relevant from the disclosing individual. The Compliance Officer (or designee) shall continue to make a preliminary, good faith inquiry into the allegations set forth in every disclosure in order to obtain 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, LifePoint shall continue to conduct an internal review of the allegations set forth in such a disclosure and ensure that proper follow-up is conducted.

The Compliance Officer (or his or her designee) shall maintain a confidential disclosure log, which shall include a record and summary of each disclosure received, the status of the respective internal reviews, and any corrective action taken in response to the internal reviews. The confidential disclosure log shall be 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, 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 related to the provision of health care items or services, but has not yet been excluded, debarred or otherwise declared ineligible.
- 2. Screening Requirements. LifePoint shall not hire or engage as contractors or grant staff privileges to any Ineligible Person. To prevent hiring or contracting with any Ineligible Person, LifePoint shall screen all prospective employees and prospective contractors prior to engaging their services and screen physicians prior to granting staff privileges by: (a) requiring applicants to disclose whether they are Ineligible Persons; and (b) reviewing 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://www.hhs.gov/oig) (these lists will hereinafter be referred to as the "Exclusion Lists").
- 3. Review and Removal Requirement. Within 90 days of the effective date of this CIA, LifePoint shall review its list of current employees and contractors and physicians with staff privileges against the Exclusion Lists. Thereafter, LifePoint shall review the list semi-annually. In addition, within 90 days of the effective date of this CIA, LifePoint shall require employees, new or renewed contractors, and physicians with staff privileges to disclose immediately any debarment, exclusion or other event that makes the person an Ineligible Person. If LifePoint has notice that an employee, contractor or physician with staff privileges has become an Ineligible Person, LifePoint shall remove such person from responsibility for, or involvement with, LifePoint'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 LifePoint has notice that an employee 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, LifePoint shall take all appropriate actions to ensure that the responsibilities of that employee or contractor 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 of discovery, LifePoint shall notify OIG, in writing, of any ongoing investigation or legal proceeding conducted or brought by a governmental entity or its agents involving an allegation that LifePoint 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. LifePoint shall also provide written notice to OIG within 30 days of the resolution of the matter, and shall provide OIG with a description of the findings and/or results of the proceedings, if any.

H. Reporting.

1. Overpayments

- a. Definition of Overpayments. For purposes of this CIA, an "overpayment" shall mean the amount of money LifePoint has received in excess of the amount due and payable under any Federal health care program requirements. LifePoint may not subtract any underpayments for purposes of determining the amount of relevant "overpayments."
- b. Reporting of Overpayments. If, at any time, LifePoint identifies or learns of any overpayments, LifePoint shall notify the payor (e.g., Medicare fiscal intermediary or carrier) and repay any identified overpayments within 30 days of identification 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, LifePoint shall repay the overpayment to the appropriate payor to the extent such overpayment has been quantified (submission of corrected bills in conformance with payor policy within 30 days fulfills this requirement). If not yet quantified, within 30 days of identification, LifePoint 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 contractor should be done in accordance with the contractor policies. For Medicare overpayments the notice to the contractor must include the information contained on the Overpayment Refund Form, attached to this CIA, unless such information is not required by the contractor.

2. Reportable Events.

- a. Definition of Reportable Event. 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 potential 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 LifePoint determines that there is a Reportable Event, LifePoint shall notify OIG, in writing, within 30 days of making the determination that the Reportable Event exists. The report to the OIG shall include the following information:
 - (i) If the Reportable Event 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, provided as Appendix E to this CIA, 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) on 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 LifePoint's actions taken to correct the Reportable Event; and
- (iv) any further steps LifePoint plans to take to address the Reportable Event and prevent it from recurring.

IV. NEW BUSINESS UNITS OR LOCATIONS

In the event that LifePoint: (1) purchases or establishes a new hospital, freestanding ambulatory surgery center, home health agency, or another line of business that provides services that are billed to Federal health care programs; or (2) sells or divests an existing hospital, freestanding ambulatory surgery center, or home health agency, LifePoint shall notify OIG of this fact within 30 days of the date of purchase, establishment, sale, or divestiture. This notification shall include the location of the operation(s), telephone number, fax number, Federal health care program provider number(s) (if any), and the corresponding payor(s) (contractor specific) that has issued each provider number. All Covered Persons at new locations shall be subject to the requirements in this CIA that apply to new Covered Persons (e.g., completing certifications and undergoing training). If LifePoint sells all of the assets related to a location, then that location shall no longer be considered part of LifePoint for the purposes of this CIA. If the location is still owned or operated in whole or in part by LifePoint or any of its subsidiaries, affiliates, or their successors, then the location shall continue to be considered part of LifePoint for the purposes of this CIA.

V. IMPLEMENTATION AND ANNUAL REPORTS

- A. <u>Implementation Report</u>. Within 120 days after the effective date of this CIA, LifePoint shall submit a written report to OIG summarizing the status of its implementation of the requirements of this CIA. This Implementation Report shall include:
 - 1. the name, title, address, facility name (if applicable), and telephone number of all of the individuals who are in positions, or on committees, described in section III.A (except that with respect to section III.A.6 only, the Compliance Officer shall certify that the Hospital Committees are in

place as required and the information otherwise required by this section shall be available to the OIG upon request);

- 2. a copy of all Policies and Procedures required by section III.B.2 that have not been previously provided to the OIG;
- 3. a description of the training required by section III.C, including a description of the targeted audiences and a schedule of when the training sessions were held;
- 4. a certification by the Compliance Officer that, except as set forth in the Implementation Report:
 - a. the Policies and Procedures required by section III.B have been developed and implemented, and have been distributed to all pertinent Covered Persons;
 - b. all Covered Persons have completed the Code of Conduct certification required by section III.B.1; and
 - all Covered Persons required to have received training have completed the training and executed the certification required by section III.C;
- 5. the identity of the Independent Review Organization(s) and the proposed start and completion date of the first set of reviews;
- 6. a summary of personnel actions taken pursuant to section III.F.
- 7. a list of all of LifePoint's locations (including physical 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 identification number(s), and the contractor's name and address that issued each provider identification number; and;
- 8. To the extent not already furnished to OIG, or if modified, a description of LifePoint's corporate structure, including identification of any parent, sister, and other related companies, subsidiaries and their respective lines of business.

- 9. the certification required by section V.C.
- B. <u>Annual Reports</u>. LifePoint shall submit to OIG Annual Reports with respect to the status of and findings regarding of LifePoint's compliance activities for each of the calendar years from 2001 through and including 2005. The first Annual Report shall cover the time period from the effective date of the CIA through December 31, 2001. (The one-year period covered by each Annual Report shall be referred to as "the Reporting Period").

Each Annual Report shall include:

- 1. any change in the identity, title, address, facility name (if applicable), telephone number, and position description of all of the individuals who are in positions, or on committees, described in section III.A (except that with respect to section III.A.6 only, the Compliance Officer shall certify that the Hospital Committees are in place as required and the information otherwise required by this section shall be available to the OIG upon request);
- 2. a certification by the Compliance Officer that, except as set forth in the Annual Report:
 - a. all Covered Persons have completed the annual Code of Conduct certification required by section III.B.1; and
 - b. all Covered Persons have completed the training and executed the certification required by section III.C;

(the documentation supporting this certification shall be available to OIG, upon request);

- 3. 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);
- 4. a description of the training required by section III.C conducted during the Reporting Period, including a description of the targeted audiences, length of sessions, which sessions were mandatory and for whom, percentage of completion of requirement by those required to attend, and a schedule of when the training sessions were held;

- 5. a complete copy of all reports prepared pursuant to the Review Procedures referenced in III.D, including a copy of the methodology used, along with a copy of the IRO's engagement letter;
- 6. LifePoint's response and corrective action plan(s) related to any issues raised by the IRO or LifePoint's Internal Audit and Compliance Department;
- 7. a summary of Reportable Events (as defined in III.H) identified during the Reporting Period and the status of any corrective and preventative action relating to all such Reportable Events;
- 8. a report of the aggregate overpayments that have been returned to the Federal health care programs. Overpayment amounts should be broken down into the following categories: inpatient Medicare, outpatient Medicare, Medicaid (report each applicable state separately), and other Federal health care programs;
- 9. a summary of the disclosures in the confidential disclosure log required by section III.E that: (a) relate to Federal health care programs; or (b) allege abuse or neglect of patients;
- 10. a description of any personnel actions (other than hiring) taken by LifePoint as a result of the obligations in section III.F, and the name, title, and responsibilities of any person that falls within the ambit of section III.F.4, and the actions taken in response to the obligations set forth in that section;
- 11. 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;
- 12. a description of all changes to the most recently provided list (as updated) of LifePoint'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 phone numbers and fax numbers, each location's Federal health care program provider

identification number(s), and the contractor name and address that issued each provider identification number; and

13. the certification required by section V.C.

The first Annual Report shall be received by the OIG no later than May 1, 2002. Subsequent Annual Reports shall be received by OIG no later than May 1 of the calendar year following the year covered by the Annual Report.

- C. <u>Certifications</u>. The Implementation Report and Annual Reports shall include a certification by the Compliance Officer that: (1) except as otherwise described in the applicable report, LifePoint 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. <u>Designation of Information</u>: LifePoint 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 exempt from disclosure under the Freedom of Information Act ("FOIA"), 5 U.S.C. § 552. LifePoint 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 of this CIA, all notifications and reports required under this CIA shall be submitted to the following entities:

OIG:

Civil Recoveries Branch - Compliance Unit
Office of Counsel to the Inspector General
Office of Inspector General
U.S. Department of Health and Human Services
Cohen Building, Room 5527
330 Independence Avenue, SW
Washington, DC 20201
Phone 202.619.2078
Fax 202.205.0604

LifePoint:

Todd J. Kerr Vice President, Audit and Compliance 103 Powell Court, Suite 200 Brentwood, TN 37027 Phone 615.372.8538 Fax 615.372.8575

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 LifePoint's books, records, and other documents and supporting materials and/or conduct on-site reviews of any of LifePoint's locations for the purpose of verifying and evaluating: (a) LifePoint's compliance with the terms of this CIA; and (b) LifePoint's compliance with the requirements of the Federal health care programs in which it participates. The documentation described above shall be made available by LifePoint 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 LifePoint'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. LifePoint agrees to assist OIG or its duly authorized representative(s) in contacting and arranging interviews with such individuals upon OIG's request. LifePoint's employees may elect to be interviewed with or without a representative of LifePoint present.

VIII. DOCUMENT AND RECORD RETENTION

In addition to any other requirements for record retention, LifePoint shall maintain for inspection all documents and records: (1) related to reimbursement from the Federal health care programs for at least five years after the submission of the request for reimbursement (or longer if otherwise required); and (2) necessary to establish LifePoint's compliance with this CIA for at least three years following the submission of the Annual Report covering the relevant year. Imaged copies of documents shall satisfy this requirement.

IX. DISCLOSURES

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

LifePoint 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, LifePoint and OIG hereby agree that failure to comply with certain obligations set forth in this CIA may lead to the imposition of the following monetary penalties (hereinafter referred to as "Stipulated Penalties") in accordance with the following provisions.
- 1. A Stipulated Penalty of \$2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day LifePoint fails to have in place any of the following:
 - a. all of the personnel and committees required in section III.A;
 - b. a written Code of Conduct as described by section III.B.1;
 - c. written Policies and Procedures as described by section III.B.2;
 - d. a requirement that Covered Persons be trained as described in section III.C; and
 - e. a Confidential Disclosure Program as described in section III.E.
- 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 LifePoint fails to retain an IRO, as required in 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 LifePoint fails to meet any of the deadlines for the submission of 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 LifePoint employs, contracts with, or grants staff privileges to an Ineligible Person and that person: (i) has responsibility for, or involvement with, LifePoint'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 LifePoint 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 for each day LifePoint fails to grant access to the information or documentation as required in section VII of this CIA. (This Stipulated Penalty shall begin to accrue on the date LifePoint fails to grant access.)
- 6. A Stipulated Penalty of \$1,000 (which shall begin to accrue 10 days after the date that OIG provides notice to LifePoint of the failure to comply) for each day LifePoint fails to comply fully and adequately with any obligation of this CIA, where the failure to comply does not form the basis for Stipulated Penalties under the provisions of section X.A.1 through X.A.5. In its notice to LifePoint, OIG shall state the specific grounds for its determination that the LifePoint has failed to comply fully and adequately with the CIA obligation(s) at issue. With respect to the Stipulated Penalty provision described in this section X.A.6 only, the OIG shall not seek a Stipulated Penalty if LifePoint demonstrates to the OIG's satisfaction that the alleged failure to comply could not be cured within the 10-day period, but that: (i) LifePoint has begun to take action to cure the failure to comply, (ii) LifePoint is pursuing such action with due diligence, and (iii) LifePoint has provided to OIG a reasonable timetable for curing the failure to comply.
- B. <u>Timely Written Requests for Extensions</u>. LifePoint 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 LifePoint 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 two business days after LifePoint 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 LifePoint 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 LifePoint of: (a) LifePoint'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 10 days of the receipt of the Demand Letter, LifePoint 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 LifePoint elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until LifePoint 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.
- 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 LifePoint 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. Monetary Penalty for Material Breach of this CIA.
 - 1. Definition of Material Breach. A material breach of this CIA means:
 - a. a failure by LifePoint to report a Reportable Event, take corrective action and make the appropriate refunds, as required in section III.H.2;
 - 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 retain and use an Independent Review Organization in accordance with section III.D.
- 2. Notice of Material Breach and Intent to Impose Material Breach Penalty. The parties agree that a material breach of this CIA by LifePoint constitutes grounds for OIG to impose an enhanced stipulated penalty that is separate and apart from the Stipulated Penalties described in Sections X.A-B, above. This monetary penalty (hereinafter referred to as the "Material Breach Penalty") shall be \$25,000 per day. Upon a determination by OIG that LifePoint has materially breached this CIA and that a Monetary Penalty should be imposed, OIG shall notify LifePoint of: (a) LifePoint's material breach; and (b) OIG's intent to exercise its contractual right to impose the Material Breach Penalty (this notification is hereinafter referred to as the "Notice of Material Breach").
- 3. Opportunity to Cure. LifePoint shall have 30 days from the date of receipt of the Notice of Material Breach to demonstrate to OIG's satisfaction that:
 - a. LifePoint is in full compliance with this CIA;
 - b. the alleged material breach has been cured; or
 - c. the alleged material breach cannot be cured within the 30-day period, but that: (i) LifePoint has begun to take action to cure the material breach; (ii) LifePoint is pursuing such action with due

diligence; and (iii) LifePoint has provided to OIG a reasonable timetable for curing the material breach.

4. Penalty Letter. If at the conclusion of the 30-day period, LifePoint fails to satisfy the requirements of section X.D.3, OIG may impose the Material Breach Penalty on LifePoint, and the Material Breach Penalty shall begin to accrue on that day. OIG will notify LifePoint in writing of its determination to impose the Material Breach Penalty (this letter shall be referred to hereinafter as the "Material Breach Penalty Letter"). Within 15 days of receipt of the Material Breach Penalty Letter, LifePoint shall either: (a) cure the material breach to OIG's satisfaction and pay the applicable Material Breach Penalty; or (b) request a hearing before an HHS administrative law judge ("ALJ") to dispute OIG's determination of material breach, pursuant to the agreed upon provisions set forth below in Section X.E.

E. Dispute Resolution

- 1. Review Rights. Upon OIG's delivery to LifePoint of its Demand Letter or of its Material Breach Penalty Letter, and as an agreed-upon contractual remedy for the resolution of disputes arising under this CIA, LifePoint 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 Material Breach Penalty sought pursuant to this CIA. Specifically, OIG's determination to demand payment of Stipulated Penalties or Material Breach Penalty shall be subject to review by an ALJ and, in the event of an appeal, the Departmental Appeals Board ("DAB"), in a manner consistent with the provisions in 42 C.F.R. §§ 1005.2-1005.21. Notwithstanding the language in 42 C.F.R. § 1005.2(c), the request for a hearing involving Stipulated Penalties shall be made within fifteen (15) days of the date of the Demand Letter or the Material Breach Penalty 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 LifePoint was in full and timely compliance with the obligations of this CIA for which the OIG demands payment; and (b) the period of noncompliance. LifePoint shall have the burden of proving its full and timely compliance and the steps taken to cure the noncompliance, if any. If the ALJ agrees with OIG with regard to a finding of a breach of this CIA and orders LifePoint to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable 20 days after the ALJ issues such a decision unless LifePoint 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. Material Breach Penalty 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 a Material Breach Penalty shall be:
 - a. whether LifePoint was in material breach of this CIA;
 - b. whether such breach was continuing on the date of the Material Breach Penalty Letter; and
 - c. whether the alleged material breach could not have been cured within the 30 day period, but that:
 - (i) LifePoint had begun to take action to cure the material breach within that period;
 - (ii) LifePoint has pursued and is pursuing such action with due diligence; and
 - (iii) LifePoint provided to OIG within that period a reasonable timetable for curing the material breach and LifePoint has followed the timetable.

If the ALJ finds for OIG with regard to a finding of a material breach of this CIA and orders LifePoint to pay a Material Breach Penalty, such Material Breach Penalty shall become due and payable 20 days after the ALJ issues such a decision notwithstanding that LifePoint may request review of the ALJ decision by the DAB.

4. Finality of Decision. The review by an ALJ or DAB provided for above shall not be considered to be an appeal right arising under any statutes or regulations. Consequently, the parties to this CIA agree that the DAB's decision (or the ALJ's decision if not appealed) shall be considered final for all purposes under this CIA.

XI. UNALLOWABLE COSTS

LifePoint agrees that all costs (as defined in the Federal Acquisition Regulations ("FAR") § 31.205-47 and in Titles XVIII and XIX of the Social Security Act, 42 U.S.C. §§ 1395-1395ggg (1997) and 1396-1396v (1997)), and the regulations promulgated

thereunder) incurred by or on behalf of LifePoint in connection with: (1) LifePoint's investigation, defense, and corrective actions undertaken in response to the Government's audit(s) and civil and criminal investigation(s) in connection with the matters covered by the Settlement Agreement with HCA (including attorney's fees); (2) the negotiation of this CIA; and (3) the obligations under this CIA to: (i) perform Review Procedures as described in section III.D (except to the extent that such Review Procedures are performed by LifePoint); and (ii) prepare and submit reports to the OIG-HHS, are unallowable costs on Government contracts and under the Medicare Program, Medicaid Program, TRICARE Program, Veterans Affairs Program (VA) and Federal Employee Health Benefits Program (FEHBP) (hereafter, "unallowable costs"). These unallowable costs will be separately estimated and accounted for by LifePoint, and LifePoint will not charge such unallowable costs directly or indirectly to any contracts with the United States or any state Medicaid program, or seek payment for such unallowable costs through any cost report, cost statement, information statement or payment request submitted by LifePoint or any of its subsidiaries to the Medicare, Medicaid, TRICARE. VA or FEHBP programs. LifePoint further agrees that within 60 days of the effective date of this CIA it will identify to applicable Medicare and TRICARE fiscal intermediaries, carriers and/or contractors, and Medicaid, VA and FEHBP fiscal agents. any unallowable costs (as defined in this section) included in payments previously sought from the United States, or any State Medicaid Program, including, but not limited to. payments sought in any cost reports, cost statements, information reports, or payment requests already submitted by LifePoint or any of its subsidiaries, and will request, and agree, that such cost reports, cost statements, information reports or payment requests, even if already settled, be adjusted to account for the effect of the inclusion of the unallowable costs. LifePoint agrees that the United States will be entitled to recoup from LifePoint any overpayment as a result of the inclusion of such unallowable costs on previously-submitted cost reports, information reports, cost statements or requests for payment. Any payments due after the adjustments have been made shall be paid pursuant to the direction of the OIG and/or the affected agencies. The OIG and/or the affected agencies reserve their rights to disagree with any calculations submitted by LifePoint or any of its subsidiaries on the effect of inclusion of unallowable costs on LifePoint or any of its subsidiaries' cost reports, cost statements or information reports. Nothing in this CIA shall constitute a waiver of the rights of the OIG to examine or reexamine the unallowable costs described in this Paragraph.

XII. EFFECTIVE AND BINDING AGREEMENT

LifePoint and OIG agree as follows:

- A. This CIA shall be binding on the successors, assigns, and transferees of LifePoint, consistent with the provisions of section IV of this CIA;
- 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. This CIA is being entered into by LifePoint in contemplation of the settlement between HCA and the United States. Through the settlement agreement and this CIA, LifePoint hospitals will be entitled to the same release that shall be provided to HCA facilities through the HCA settlement. In the event that HCA and United States have not been able to reach a the above-contemplated settlement on or before December 31, 2001, then this Agreement may be terminated by LifePoint upon notice to OIG, and thereafter, this Agreement shall be of no further force and effect; and
- E. The undersigned LifePoint 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 LIFEPOINT

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Chairman and Chief Executive Officer LifePoint Hospitals, Inc.

Vice President, Audit and Compliance

LifePoint Hospitals, Inc.

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

LEWIS MORRIS

Assistant Inspector General for Legal Affairs

Office of Inspector General

U. S. Department of Health and Human Services

APPENDIX A

A. Claims Review.

- 1. *Definitions*. For the purposes of the DRG and Laboratory Claims Reviews, the following definitions shall be used:
 - a. <u>Claims Review Sample</u>: A statistically valid, randomly selected, sample of items selected for appraisal in the DRG or Laboratory Claims Review.
 - b. <u>Item</u>: (i) for the purposes of a DRG review, an "Item" is a hospital inpatient discharge for which LifePoint has been reimbursed by Medicare on the basis of one of the focused DRGs set forth in Appendix D; and (ii) for the purposes of a Laboratory Review, an "Item" is an outpatient laboratory test. The OIG shall have the right to change the DRGs included in Appendix D at any time during the term of the CIA.
 - c. Overpayment: Consistent with the definition of Overpayment as articulated in section III.H.1.a of the CIA, the amount of money LifePoint has received in excess of the amount due and payable under any Federal health care program requirements. For the purposes of the DRG and Laboratory Claims Reviews (including all Probe Sample Reviews) and all reporting to the OIG under this CIA, LifePoint shall not subtract or "net out" underpayments when determining the amount of relevant Overpayments.
 - d. <u>Paid Claim</u>: A code or line item submitted by LifePoint and for which LifePoint has received reimbursement from the Medicare program.
 - e. <u>Population</u>: All Items for which LifePoint has submitted a code or line item and for which LifePoint has received reimbursement from the Medicare program (<u>i.e.</u>, a Paid Claim) during the six-month period covered by the DRG or Laboratory Claims Review. To be included in the Population, an Item must have resulted in at least one Paid Claim.
 - f. <u>Probe Sample</u>: A sample of Items selected through simple random sampling from the Population for the purpose of estimating the mean and standard deviation of the Population. The estimated mean and standard deviation of the Population are to be used to calculate the minimum number

Appendix A: LifePoint Hospitals, Inc. of Items to be included in the Claims Review Sample. In addition, the incidence of errors in the Probe Sample may be used to determine whether further review is required.

- g. <u>RAT-STATS</u>: OIG's Office of Audit Services Statistical Sampling Software. RAT-STATS is publicly available to download through the Internet at "www.hhs.gov/oig/oas/ratstat.html."
- 2. **Description of Claims Review**. Each DRG and Laboratory Claims Review shall consist of an appraisal of a statistically valid sample of Items (the Claims Review Sample) that can be projected to the total Population.
 - a. <u>DRG Claims Review Confidence and Precision Requirements</u>. The DRG Claims Review Sample must contain a sufficient number of Items so that if the Overpayments identified in the Claims Review Sample were projected to the Population, the projection would provide a 90% confidence level and a maximum relative precision (<u>i.e.</u>, semi-width of the confidence interval) of plus or minus 25% of the point estimate. In other words, if the DRG Claims Review Overpayment results were projected to the Population at a 90% confidence level, the confidence interval (expressed in dollars) must be sufficiently narrow that the upper bound of the confidence interval would not exceed 125% of the midpoint of the confidence interval (the point estimate), and the lower bound of the confidence interval would not be less than 75% of the midpoint of the confidence interval.
 - b. Use of a Probe Sample to Determine Whether to Conduct a Full DRG Claims Review and to Determine the Sample Size for Such a Full DRG Claims Review. To determine how many Items must be included in the DRG Claims Review Sample to meet the 90% confidence level and 25% precision requirements, the mean and the standard deviation of the Population must be estimated. These estimates shall be developed through the use of a single Probe Sample. The Probe Sample shall be used to determine the minimum DRG Claims Review Sample size through the following methodology. The Probe Sample shall include at least 100 Items, and shall be selected through the use of RAT-STATS "Random Numbers" function. Once all Paid Claims associated with the Items included in the Probe Sample have been reviewed, the estimated mean and standard deviation of the Population shall be determined. This determination is based on the Overpayment amount received by LifePoint for each Item in the sample. The "Variable Appraisals" function of RAT-STATS shall be

used to calculate the estimated mean and standard deviation of the Population. For purposes of estimating the mean and standard deviation of the Population, and entering this information into the "Variable Appraisals" function of RAT-STATS, any underpayment identified for a Paid Claim in the Probe Sample shall be treated as a zero overpayment. If the gross dollar overpayment rate is not greater than 5% in this 100 Item Probe Sample, then LifePoint shall not be required to conduct a Full Sample as part of the applicable DRG Claims Review. In such a case, the results of the Probe Sample shall be reported in lieu of the results of the Claims Review when preparing and submitting the Claims Review Report (see section B, below).

- c. Calculation of DRG Claims Review Sample Size and Selection of the DRG Claims Review Sample. The estimates of the mean and the standard deviation of the Population obtained through the review of the Probe Sample shall be used to calculate the minimum size of the Claims Review Sample. In order to determine the minimum number of Items that must be included in the Claims Review Sample to meet the 90% confidence level and 25% precision requirements, RAT-STATS' "Sample Size Estimators" (located under the "Utility Programs" file) shall be used. The Claims Review Sample shall be selected by using RAT-STATS' "Random Numbers" function, and shall be selected from the entire Population, with the Population including those Items reviewed as part of the Probe Sample, so that all Items in the Population have an equal chance of inclusion in the Claims Review Sample.
- c. <u>Laboratory Claims Review Sample</u>. Each Laboratory Claims Review Sample shall consist of an appraisal of a random sample of 200 Items for each hospital for each period under review.
- d. <u>Item Appraisal</u>. For each Item appraised (either as part of the Claims Review Sample or of the Probe Sample), only Paid Claims shall be evaluated. Every Paid Claim in the Claims Review Sample shall be evaluated by LifePoint. Ten percent of all Paid Claims in the DRG or Laboratory Probe Sample Review or the DRG or Laboratory Claims Review shall be evaluated by the IRO to determine whether the claim submitted was correctly coded, submitted, and reimbursed. Each appraisal must be sufficient to provide all information required under the Claims Review Report.

- e. <u>Paid Claims without Supporting Documentation</u>. For the purpose of appraising Items included in the Claims Review and/or the Probe Sample, any Paid Claim for which LifePoint cannot produce documentation sufficient to support the Paid Claim shall be considered an error and the total reimbursement received by LifePoint for such Paid Claim shall be deemed an Overpayment. Replacement sampling for Paid Claims with missing documentation is not permitted.
- f. <u>Use of First Samples Drawn</u>. For the purposes of all samples (Probe Sample(s) and Claims Review Sample(s)) discussed in this Appendix, the Paid Claims associated with the Items selected in the first sample (or first sample for each strata, if applicable) shall be used. In other words, it is not permissible to generate a number of random samples and then select one for use as the Probe Sample or Claims Review Sample.
- **B.** <u>Claims Review Report</u>. The following information shall be included in each Claims Review Report:

1. Claims Review Methodology

- a. <u>Claims Review Objective</u>: A clear statement of the objective intended to be achieved by the DRG or Laboratory Claims Review.
- b. <u>Sampling Unit</u>: A description of the Item as that term is utilized for the DRG or Laboratory Claims Review. As noted in section A.1.b above, (i) for the purposes of a DRG review, an "Item" is a hospital inpatient discharge for which LifePoint has been reimbursed by Medicare on the basis of one of the "high-risk" DRGs set forth in Appendix D; and (ii) for the purposes of a Laboratory Review, an "Item" is an outpatient laboratory test.
- c. <u>Claims Review Population</u>: A description of the Population subject to the DRG or Laboratory Claims Review.
- d. <u>Sampling Frame</u>: A description of the sampling frame, which is the totality of Items from which the Probe Sample and Claims Review Sample have 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. <u>Sources of Data</u>: A description of the documentation relied upon by the IRO when performing the DRG or Laboratory Claims Review (<u>e.g.</u>, medical records, physician orders, certificates of medical necessity, requisition forms, local medical review policies, HCFA program memoranda, Medicare carrier or intermediary manual or bulletins, other policies, regulations, or directives).
- f. <u>Review Protocol</u>: A narrative description of how the Claims Review was conducted and what was evaluated. This shall include a description of the analysis used to determine which hospitals were chosen for review under the Billing Engagement and the statistics relevant to the selection of the hospitals.

2. Statistical Sampling Documentation

- a. The number of Items appraised in the Probe Sample and in the Claims Review Sample.
- b. A copy of the RAT-STATS printout of the random numbers generated by the "Random Numbers" function.
- c. A copy of the RAT-STATS printout of the "Sample Size Estimators" results used to calculate the minimum number of Items for inclusion in the Claims Review Sample.
- d. A copy of the RAT-STATS printout of the "Variable Appraisals" function results for the Probe Sample.
- e. The Sampling Frame used in the Probe Sample(s) and the Claims Review Sample will be available to the OIG upon request.

3. Claims Review Results

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

- b. 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 LifePoint.
- c. The total dollar amount of all Paid Claims in the Claims Review Sample and the total dollar amount of Overpayments associated with the Paid Claims identified by the DRG or Laboratory Claims Review. (This is the total dollar amount of the Overpayments identified in section B.3.b above.) LifePoint may, in its internal report, identify underpayments, but any underpayments identified during the DRG or Laboratory Claims Review shall not be offset or "netted out" of the total dollar amount of Paid Claims or of the Overpayments when reporting these amounts in the Claims Review Report to the OIG.
- d. A spreadsheet of the DRG or Laboratory 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 LifePoint), correct allowed amount (as determined by LifePoint), dollar difference between allowed amount reimbursed by payor and the correct allowed amount. (See Attachment 1 to this Appendix.)
- 4. *Credentials*. The names and credentials of the individuals who: (1) designed the statistical sampling procedures and the review methodology utilized for the DRG or Laboratory Claims Review; and (2) performed the DRG or Laboratory Claims Review.

Claim Review Results

	 T	Т	 1	· · · · · · · · ·	 	1.	_		
Dollar Difference between Amt Reimbursed and Correct Allowed Amt									
Correct Allowed Amt (IRO determined)						T.			
Correct Procedure Code (IRO determined)									
Allowed Amount Reimbursed						·			
Procedure Code Reimbursed		-				·			
Procedure Code Submitted			,						
Date of Service									
Bene HIC #					 				
Federal Health Care Program Billed								-	

Appendix A: LifePoint Hospitals, Inc.

APPENDIX B

<u>Systems Reviews</u>. The following two reviews shall be conducted annually at a random sample of at least four LifePoint hospitals.

I. Billing System Review

Billing System Review Objective: To review the internal controls in place over the Registration process and Billing system to ensure that the policies and procedures are designed to provide reasonable assurance that the hospitals meet the requirements of applicable Federal health care program rules and regulations.

Internal Audit will perform the following steps for the sample of hospitals, noting any material weaknesses and appropriate recommendations:

Registration Process Review

- 1. Document the registration process through interviews with Registration department employees.
- 2. Select a sample of 30 Medicare admissions (15 Inpatient & 15 Outpatient) and trace to the coding and billings systems, testing for accuracy and completeness.
- 3. Obtain and review the hospital's Registration policies and procedures. Ensure these policies address the relevant risk areas.
- 4. Interview Registration employees to make sure they are aware of the current registration policies and procedures and are educated on registration and billing updates.
- 5. Review the Bill Alert Edits by Patient, Bill Alert Edits by Responsible Department, & Final Bill Alert Exception Reports to ensure issues are being followed up and resolved timely.

Billing Process Review

- 1. Document the billing process through interviews with Billing Department employees. Obtain and read the hospital's Billing policies and procedures. Ensure these policies address the relevant risk areas.
- 2. Using the 30 Medicare admissions selected under the Registration Review, trace the paid claims to the applicable UB92 & Medicare Remittances for accuracy and completeness.
- 3. Test the accuracy of the 30 Medicare paid claims to the applicable patient accounts, ensuring that the patients are billed in accordance with Medicare rules and regulations.
- 4. Verify all employees involved in the billing process, including the laboratory and business office directors, have received the required 8 hours of required training. This

Appendix B: LifePoint Hospitals, Inc.

- training should include information on the essential rules for billing the Federal Health Care Programs.
- 5. Review the most recent SSI edits to determine that the hospital is staying current on all edits required by Medicare.
- 6. Obtain and review policies regarding updating of chargemaster and billing software.

II. Coding System Review

Coding System Review Objective: To review the internal controls in place over the Coding system to ensure that the policies, procedures, and practices are designed to provide reasonable assurance that the hospitals meet the requirements of applicable Federal health care program rules and regulations.

Internal Audit will perform the following steps for the sample of hospitals, noting any material weaknesses and appropriate recommendations.

Coding System Review

- 1. Document the coding process through interviews with the Coding department employees.
- 2. Obtain and review the hospital's coding policies and procedures. Ensure these policies address the relevant risk areas.
- 3. Using the 30 Medicare paid claims selected under the Billing & Registration reviews, test the interface of the coding system to the billing system for accuracy and completeness.
- 4. Verify all employees involved in the coding process, including coding directors and coders, have received the required 10 hours of training. This training should include information on the essential rules of the Federal Health Care Program.
- 5. Verify the coders are using current CCI and 3M edits available to ensure accuracy.
- 6. Inquire of management as to the incorporation of policy and procedure implementation, training implementation, audit results or other objective compliance considerations in the management review and evaluation process.

APPENDIX C

LifePoint Hospitals, Inc. DRG Inpatient Coding Operational Audit Program

1 A

In-Office		W/P Referenc
-	1. Contact the facility CFO and HIM Director and schedule a field week for the audit.	1A
2.	Contact the HIM director to discuss the audit protocol (dates, information needed, etc.).	1A
3.	Send (email) Engagement Memo and Internal Control Questionnaire (ICQ) to the facility CFO and HIM Director at least two weeks in advance. Copy the Division CFO, Hospital CEO, and Hospital ECO on the engagement letter.	1B
4.	Include a copy of the engagement memo in the audit workpapers.	1B
5.	Request a Clear Access Query for all inpatients/all payors billed within the last six months. The query should come from the case mix database.	1E
6.	Select 25 random records for review using RATSTATS.	1E
7.	Select 25 focus records for review from identified high risk DRG's. If 25 identified high-risk records are not available, the auditor will supplement with records at their discretion.	1E
8. In Field	For the 50 records selected, request that the facility pull the medical record and corresponding UB-92.	1E
<u> </u>		
9.	Conduct an informal entrance conference with the HIM Director. Review and discuss the ICQ, audit protocol, and inquire about any other potential coding/documentation issues.	1D
10.	Review all pertinent PRO/PEPP correspondence.	
11.	Review each medical record to ensure documentation is present to support all	1G, 1F

Appendix C: LifePoint Hospitals, Inc.

20.	Prepare a Draft Report summarizing audit results. The Draft Report should include a narrative summary and the log of audit results.	1C
21.	Conduct a technical/training exit (minimum two hours) with the coding staff and	1C, 1G

HIM director. The technical exit should consist of reviewing the results of the audit in detail. Explain the reasons for each proposed DRG change and ensure the coding staff understands and complies with all Federal Healthcare coding regulations.

In-Office		W/P Referenc
22.	Conduct an executive exit with the CFO, CEO, ECO, HIM Director and others as appropriate. Review the audit results. This exit is not intended to be in as much detail as the technical exit.	1C
In Office		
23.	Forward the Draft Report to the Director of Coding Compliance for Review. The Director will forward the report to the VP of Compliance prior to distribution.	1C
24.	Distribute the Draft Report and allow approximately 3 weeks for the facility to submit an action plan. The action plan should consist of a brief statement of the issue, a description of the proposed resolution to the issue, the person responsible for the resolution, and the proposed date for completion of the resolution. NOTE: The action plan for overpayments to federal programs must meet the LifePoint 30 day refund policy.	1C
25.	Once the action plan is received and approved, Director will issue the Final Report.	N/A

Appendix D

LifePoint DRG Workplan Focused DRGs

(Subject to change by OIG during term of CIA)

Medicare DRG Under Review	Paired Medicare DRG(s)	Ratio	Medicare CC DRG
76	82	76/(76+82)	No
79	89	79/(79+89)	Yes
· 87	88, 127	87/(87+88+127)	No
89	90	, 89/(89+90)	Yes
121	122	121/(121+122)	Ŷes
124	125	124/(124+125)	Yes
132	140, 143	132/(132+140+143)	No
138	139	138/(138+139)	Yes
148	149	148/(148+149)	Yes
174	175	174/(174+175)	Yes
182	183	182/(182+183)	Yes
197	198	197/(197+198)	Yes
210	211	210/(210+211)	Yes
296	297	296/(296+297)	Yes
316	127	316/(316+127)	No
416	320, 277	416/(416+320+277)	No
475	(Total # cases for all Medicare	475/Total Medicare Discharges	No

AMENDMENT TO THE CORPORATE INTEGRITY AGREEMENT BETWEEN THE

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

LIFEPOINT HOSPITALS, INC.

The Office of Inspector General ("OIG") of the Department of Health and Human Services and LifePoint Hospitals, Inc. ("LifePoint") entered into a Corporate Integrity Agreement ("CIA") on December 21, 2000.

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

Section III.D., Review Procedures, of the CIA is hereby superseded by the attached new section III.D., Review Procedures.

Appendix A of LifePoint's CIA is hereby superseded by the attached new Appendix A.

- B. The OIG and LifePoint agree that all other sections of LifePoint's CIA will remain unchanged and in effect, unless specifically amended upon the prior written consent of the OIG and LifePoint.
- C. The undersigned LifePoint signatories represent and warrant that they are authorized to execute this Amendment. The undersigned OIG signatory represents that he is signing the Amendment in his official capacity and that he is authorized to execute this Amendment.
- D. This effective date of this Amendment will be the date on which the final signatory of this Amendment signs this Amendment.

ON BEHALF OF LIFEPOINT

Kenneth C. Donahey

Chairman and Chief Executive Officer

LifePoint Hospitals, Inc.

4-25-2000

DATE

Todd Kerr

Senior Vice President of Audit and Compliance LifePoint Hospitals, Inc.

DATE

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

Lewis Morris

Assistant Inspector General for Legal Affairs

Office of Inspector General

U.S. Department of Health and Human Services

D. Review Procedures.

- 1. General Description.
 - a. Retention of Independent Review Organization. Within 90 days of the effective date of this CIA, LifePoint shall retain an entity (or entities), such as an accounting, auditing or consulting firm (hereinafter "Independent Review Organization" or "IRO"), to perform a review engagement to assist LifePoint in evaluating its billing and coding practices. The Independent Review Organization retained by LifePoint shall have expertise in the billing, coding, reporting and other requirements of the particular sector of the health care industry pertaining to matters that the IRO is reviewing and in the general requirements of the Federal health care program(s) from which LifePoint seeks reimbursement. The IRO shall assess, along with LifePoint, whether it can perform the IRO review in a professionally independent fashion taking into account any other business relationships or other engagements that may exist.
 - b. Types of Engagement. LifePoint's Internal Audit and Compliance Department (references to "LifePoint" in the review procedures described in this CIA and the incorporated appendices refer to this department) and the Independent Review Organization(s) shall conduct an engagement that shall address LifePoint's billing and coding to the Federal health care programs ("Billing Engagement") and shall include a review of DRG and laboratory claims.
 - c. Frequency of Billing Engagement. The Billing Engagement shall be performed annually and shall cover each of the calendar years 2001 through 2005.
 - d. Retention of records. The IRO and LifePoint shall retain and make available to the OIG upon request all work papers related to the engagement (including, but not limited to, all substantive correspondence exchanged regarding the reports) and all draft and final reports delivered to LifePoint.
- 2. Billing Engagement. The Billing Engagement shall be composed of the following types of reviews: a "DRG Claims Review," a "Laboratory Claims Review," a "Systems Review," and an Operations DRG Review." The Claims Reviews and corresponding Reports are discussed in detail in

Appendices A, B, and C to this CIA, which are incorporated by reference.

- a. DRG Claims Review.
 - i. DRG Claims Review. LifePoint shall perform a Claims Review to identify any overpayments through an appraisal of inpatient discharges paid by Medicare DRG to LifePoint. The Claims Reviews shall be performed in accordance with the procedures set forth in Appendix A to this CIA. The Claims Reviews shall cover the two six-month periods during each year covered by the Billing Engagement. LifePoint will perform Claims Reviews at a minimum of two hospitals during each six-month period (for a minimum of four hospitals each year.) The hospitals, and the DRGs to be reviewed at each hospital, will be chosen as set forth in section III.D.2.c.
 - ii. DRG Claims Review Report. LifePoint shall prepare a report based upon each Claims Review performed ("Claims Review Report"). The Claims Review Report shall be created in accordance with the procedures set forth in Appendix A to this CIA.
 - iii. IRO Review. With respect to LifePoint's Claims Reviews, the IRO will prepare a report documenting the IRO's findings with respect to the following procedures:
 - A. The IRO will obtain LifePoint's workpapers and perform procedures to test concurrence with the criteria included in section III.D.2.c.
 - B. The IRO will select a random sample of a minimum of 10% of the Items reviewed by LifePoint
 - pursuant to the DRG Claims Review and reperform LifePoint's workplan steps.
- b. Laboratory Claims Review.
 - i. Claims Review. LifePoint shall perform a Claims Review to identify any overpayments through an appraisal of outpatient laboratory claims submitted by LifePoint to the

Medicare program and paid by Medicare. The Claims Reviews shall be performed in accordance with the procedures set forth in Appendix A to this CIA. The Claims Reviews shall cover the two six-month periods during each year covered by the Billing Engagement. LifePoint will perform Claims Reviews at a minimum of two hospitals during each six-month period (for a minimum of four hospitals each year.) The hospitals, and the tests to be reviewed at each hospital, will be chosen as set forth in section III.D.2.c.

- ii. Laboratory Claims Review Report. LifePoint shall prepare a report based upon each Laboratory Claims Review performed ("Claims Review Report"). The Claims Review Report shall be created in accordance with the procedures set forth in Appendix A to this CIA.
- iii. IRO Review. With respect to LifePoint's Laboratory Claims Review, the IRO will prepare a report documenting the IRO's findings with respect to the following procedures:
 - A. The IRO will obtain LifePoint's workpapers and perform procedures to test concurrence with the criteria set forth in section III.D.2.c.
 - B. The IRO will select a random sample of a minimum of 10% of the Items reviewed pursuant to the Laboratory Review and re-perform LifePoint's workplan steps.
- c. Selection of Hospitals for Claims Reviews.
 - i. DRG Claims Review Hospital Selection. LifePoint shall select the two hospitals subject to review during each sixmonth period as follows:
 - A. The hospital that has the highest percentage of Medicare focused DRGs, as compared to total Medicare DRGs, during the relevant six month period under review, will be chosen. (However, if a hospital has already been selected under this process during any of the immediately preceding two reviews then the hospital with the next highest percentage shall be

chosen instead).

- B. One hospital will be randomly selected using RAT-STATS. A replacement hospitals should be generated in case the hospital randomly selected has already been identified under section III.D.2.c.i.A.
- ii. Laboratory Claims Review Hospital Selection. LifePoint shall select the two hospitals subject to review during each six-month period as follows:
 - A. The hospital that has the highest percentage of Medicare outpatient laboratory services revenue, as compared to total Medicare outpatient services revenue, during the relevant six month period, will be chosen. (However, if a hospital has already been selected under this process during any of the immediately preceding two reviews then the hospital with the next highest percentage shall be chosen instead).
 - B. One hospital will be randomly selected using RATSTATS. A replacement hospital should be generated in case the hospital randomly selected has already been identified under section III.D.2.c.ii.A.
- d. Systems Review. LifePoint shall review LifePoint's billing and coding systems and/or operations (the "Systems Review"). The Systems Review shall include the reviews described in Appendix B for at least four hospitals. The Systems Review shall consist of a thorough review of the following as more specifically described in Appendix B:
 - i. LifePoint's billing systems and/or operations relating to claims submitted to all Federal health care programs (including, but not limited to, the operation of the billing system, safeguards to ensure proper claim submission and billing, and procedures to correct inaccurate billing); and
 - ii. LifePoint's coding systems and/or operations relating to claims submitted to all Federal health care programs (including, but not limited to, the process by which claims are coded, safeguards to ensure proper coding, and procedures to correct inaccurate coding).

- e. Systems Review Report. LifePoint shall prepare a report based upon each Systems Review performed ("Systems Review Report"). The Systems Review Report shall include LifePoint's findings and supporting rationale regarding:
 - i. all findings and recommendations regarding LifePoint's billing systems and/or operations;
 - ii. all findings and recommendations regarding LifePoint's coding systems and/or operations; and
 - iii. any recommendations LifePoint may have to improve any of these systems, operations, and processes.
- f. Operational DRG Review. LifePoint shall review LifePoint's DRG coding for hospital inpatients (the "Operational DRG Review"). The Operational DRG Review shall include the reviews described in Appendix C for at least eight hospitals. The Operational DRG Review shall consist of a thorough review of the DRG coding operations (including a review of at least 50 DRG claims at each hospital) as more specifically described in Appendix C. Except for the fact that the review of claims need not meet the statistical confidence and precision parameters set forth in Appendix A, the Operational DRG Review shall be conducted in a manner consistent with Appendix A, e.g., paid claims without supporting documentation shall be considered an error and the total reimbursement received by LifePoint for such Paid Claim shall be deemed an Overpayment.
- g. Operational DRG Review Report. LifePoint shall provide to the OIG in its Annual Reports the Executive Summaries related to the Operational DRG Reviews. The Executive Summaries shall include a summary of the Medicare and other Federal health care program overpayments (including number of overpayments, dollar amount of overpayments, and percentage of paid dollars attributable to overpayments) identified in each Operational DRG Review. All other documents related to the Operational DRG Reviews shall be available to the OIG upon request.
- 3. Validation Review. In the event the OIG has reason to believe that: (a) LifePoint's Billing Engagement fails to conform to the requirements of this

CIA; or (b) LifePoint's or the IRO's findings or Billing Engagement results are inaccurate, the OIG may, at its sole discretion, conduct its own review to determine whether the Billing Engagement complied with the requirements of the CIA and/or the findings or Billing Engagement results are inaccurate ("Validation Review"). LifePoint 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 LifePoint's final Annual Report and any additional information requested by the OIG is received by the OIG.

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

4. *Independence Certification*. The IRO shall include in its report(s) to LifePoint a certification or sworn affidavit that it has evaluated its professional independence with regard to the Billing Engagement and that it has concluded that it is, in fact, independent.

APPENDIX A

A. Claims Review.

- 1. *Definitions*. For the purposes of the DRG and Laboratory Claims Reviews, the following definitions shall be used:
 - a. <u>Claims Review Sample</u>: A statistically valid, randomly selected, sample of items selected for appraisal in the DRG or Laboratory Claims Review.
 - b. <u>Item</u>: (i) for the purposes of a DRG review, an "Item" is a hospital inpatient discharge for which LifePoint has been reimbursed by Medicare on the basis of one of the focused DRGs set forth in Appendix D; and (ii) for the purposes of a Laboratory Review, an "Item" is an outpatient laboratory test. The OIG shall have the right to change the DRGs included in Appendix D at any time during the term of the CIA.
 - c. <u>Overpayment</u>: The amount of money LifePoint has received in excess of the amount due and payable under any Federal health care program requirements.
 - d. <u>Paid Claim</u>: A code or line item submitted by LifePoint and for which LifePoint has received reimbursement from the Medicare program.
 - e. <u>Population</u>: All Items for which LifePoint has submitted a code or line item and for which LifePoint has received reimbursement from the Medicare program (<u>i.e.</u>, a Paid Claim) during the six-month period covered by the DRG or Laboratory Claims Review. To be included in the Population, an Item must have resulted in at least one Paid Claim.
 - f. 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.

- g. <u>RAT-STATS</u>: OIG's Office of Audit Services Statistical Sampling Software. RAT-STATS is publicly available to download through the Internet at "www.hhs.gov/oig/oas/ratstat.html."
- 2. *Description of Claims Review*. Each DRG and Laboratory Claims Review shall consist of an appraisal of a statistically valid sample of Items (the Claims Review Sample) that can be projected to the total Population.
 - a. <u>DRG Claims Review</u>. The DRG Claims Review shall include a Discovery Sample and, if necessary, a Full Sample. The applicable definitions, procedures, and reporting requirements are outlined in this Appendix A.
 - b. <u>Discovery Sample</u>. LifePoint shall randomly select and review a sample of 50 Medicare Paid Claims submitted by or on behalf of LifePoint. The Paid Claims shall be reviewed based on the supporting documentation available at LifePoint or under LifePoint's control and applicable billing and coding regulations and guidance to determine whether the claim submitted was correctly coded, submitted, and reimbursed.
 - i. If the Error Rate for the Discovery Sample is less than 5%, no additional sampling is required, nor is the Systems Review required. (Note: The threshold listed above does not imply that this is an acceptable error rate. Accordingly, LifePoint should, as appropriate, further analyze any errors identified in the Discovery Sample. LifePoint recognizes that the OIG or other HHS component, in its discretion and as authorized by statute, regulation, or other appropriate authority may also analyze or review Paid Claims included, or errors identified, in the Discovery Sample.)
 - ii. If the Discovery Sample indicates that the Error Rate is 5% or greater, LifePoint shall perform a Full Sample and a Systems Review, as described below.
 - c. Full Sample. If necessary, as determined by procedures set forth above, LifePoint shall perform an additional sample of Paid Claims using commonly accepted sampling methods and in accordance with this Appendix A. The Full Sample should be designed to (1) estimate the actual Overpayment in the population with a 90% confidence level and with a maximum relative precision of 25% of the point estimate and (2) conform with the Centers for Medicare and Medicaid Services' statistical sampling

for overpayment estimation guidelines. The Paid Claims shall be reviewed based on supporting documentation available at LifePoint or under LifePoint'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, LifePoint 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 LifePoint 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.

- d. <u>Claims Systems Review</u>. If LifePoint's Discovery Sample identifies an Error Rate of 5% or greater, LifePoint shall also conduct a Systems Review. Specifically, for each claim in the Discovery Sample and Full Sample that resulted in an Overpayment, LifePoint should perform a "walk through" of the system(s) and process(es) that generated the claim to identify any problems or weaknesses that may have resulted in the identified Overpayments. LifePoint shall prepare a report containing the observations and recommendations on suggested improvements to the system(s) and the process(es) that generated the claim.
- e. Repayment of Identified Overpayments. In accordance with section III.H.1 of the CIA, LifePoint agrees to repay within 30 days any Overpayment(s) identified in the Discovery Sample or the Full Sample (if applicable), regardless of the Error Rate, to the appropriate payor and in accordance with payor refund policies. LifePoint agrees to make available to the OIG any and all documentation that reflects the refund of the Overpayment(s) to the payor.
- f. <u>Laboratory Claims Review Sample</u>. Each Laboratory Claims Review Sample shall consist of an appraisal of a random sample of 200 Items for each hospital for each period under review.
- g. <u>Item Appraisal</u>. For each Item appraised (either as part of the Claims Review Sample or of the Probe Sample), only Paid Claims shall be evaluated. Every Paid Claim in the Claims Review Sample shall be evaluated by LifePoint. Ten percent of all Paid Claims in the DRG or Laboratory Probe Sample Review or the DRG or Laboratory Claims Review shall be evaluated by the IRO to determine whether the claim submitted was correctly coded, submitted, and reimbursed. Each appraisal

must be sufficient to provide all information required under the Claims Review Report.

- h. <u>Paid Claims without Supporting Documentation</u>. For the purpose of appraising Items included in the Claims Review and/or the Probe Sample, any Paid Claim for which LifePoint cannot produce documentation sufficient to support the Paid Claim shall be considered an error and the total reimbursement received by LifePoint for such Paid Claim shall be deemed an Overpayment. Replacement sampling for Paid Claims with missing documentation is not permitted.
- i. <u>Use of First Samples Drawn</u>. For the purposes of all samples (Probe Sample(s) and Claims Review Sample(s)) discussed in this Appendix, the Paid Claims associated with the Items selected in the first sample (or first sample for each strata, if applicable) shall be used. In other words, it is not permissible to generate a number of random samples and then select one for use as the Probe Sample or Claims Review Sample.
- **B.** <u>Claims Review Report</u>. The following information shall be included in each Claims Review Report:

1. Claims Review Methodology

- a. <u>Claims Review Objective</u>: A clear statement of the objective intended to be achieved by the DRG or Laboratory Claims Review.
- b. <u>Sampling Unit</u>: A description of the Item as that term is utilized for the DRG or Laboratory Claims Review. As noted in section A.1.b above, (i) for the purposes of a DRG review, an "Item" is a hospital inpatient discharge for which LifePoint has been reimbursed by Medicare on the basis of one of the "high-risk" DRGs set forth in Appendix D; and (ii) for the purposes of a Laboratory Review, an "Item" is an outpatient laboratory test.
- c. <u>Claims Review Population</u>: A description of the Population subject to the DRG or Laboratory Claims Review.
- d. <u>Sampling Frame</u>: A description of the sampling frame, which is the totality of Items from which the Probe Sample and Claims Review Sample have 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. <u>Sources of Data</u>: A description of the documentation relied upon by the IRO when performing the DRG or Laboratory Claims Review (<u>e.g.</u>, medical records, physician orders, certificates of medical necessity, requisition forms, local medical review policies, HCFA program memoranda, Medicare carrier or intermediary manual or bulletins, other policies, regulations, or directives).
- f. <u>Review Protocol</u>: A narrative description of how the Claims Review was conducted and what was evaluated. This shall include a description of the analysis used to determine which hospitals were chosen for review under the Billing Engagement and the statistics relevant to the selection of the hospitals.

2. Statistical Sampling Documentation

- a. The number of Items appraised in the Probe Sample and in the Claims Review Sample.
- b. A copy of the RAT-STATS printout of the random numbers generated by the "Random Numbers" function.
- c. A copy of the RAT-STATS printout of the "Sample Size Estimators" results used to calculate the minimum number of Items for inclusion in the Claims Review Sample.
- d. A copy of the RAT-STATS printout of the "Variable Appraisals" function results for the Probe Sample.
- e. The Sampling Frame used in the Probe Sample(s) and the Claims Review Sample will be available to the OIG upon request.

3. Claims Review Results

a. Narrative Results.

- i. A narrative description of how the Claims Review was conducted and what was evaluated. This shall include a description of the analysis used to determine which hospitals were chosen for review under the Billing Engagement and the statistics relevant to the selection of the hospitals.
- ii. A narrative explanation of LifePoint'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 LifePoint determined that the Paid Claim submitted by the LifePoint hospital ("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 LifePoint.
- iii. The total dollar amount of all Paid Claims in the Claims Review Sample and the total dollar amount of Overpayments associated with the Paid Claims identified by the DRG or Laboratory Claims Review. (This is the total dollar amount of the Overpayments identified in section B.3.b above.)
- iv. Error Rate in the sample.
- v. A spreadsheet of the DRG or Laboratory 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 LifePoint), correct allowed amount (as determined by LifePoint), dollar difference between allowed amount reimbursed by payor and the correct allowed amount. (See Attachment 1 to this Appendix.)
- 4. *Claims Systems Review.* Observations, findings and recommendations on possible improvements to the system(s) and process(es) that generated the Overpayment(s).
- 5. *Credentials.* The names and credentials of the individuals who: (1) designed the statistical sampling procedures and the review methodology utilized for the DRG or Laboratory Claims Review; and (2) performed the DRG or Laboratory

Claims Review.