CORPORATE INTEGRITY AGREEMENT
BETWEEN THE
OFFICE OF INSPECTOR GENERAL
OF THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND
MID HUDSON MEDICAL GROUP, P.C.

I. PREAMBLE

Mid Hudson Medical Group, P.C. (Mid Hudson) hereby enters into this Corporate Integrity Agreement (CIA) with the Office of Inspector General (OIG) of the United States Department of Health and Human Services (HHS) to promote compliance with the statutes, regulations, and written directives of Medicare, Medicaid, and all other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)) (Federal health care program requirements). Contemporaneously with this CIA, Mid Hudson is entering into a Settlement Agreement with the OIG.

Prior to the execution of this CIA, Mid Hudson established a corporate compliance program (Compliance Program). The Compliance Program includes, among other things, a Compliance Officer and a Compliance Committee responsible for compliance oversight. The Compliance Program also includes a Code of Conduct, written Policies and Procedures, educational and training initiatives, a Disclosure Program that allows for the confidential disclosure and investigation of potential compliance violations, and screening measures for Ineligible Persons. Mid Hudson shall continue the Compliance Program throughout the term of this CIA and shall do so in accordance with the terms set forth below. Mid Hudson may modify the Compliance Program as appropriate, but, at a minimum, Mid Hudson shall ensure that the Compliance Program satisfies the obligations set forth herein during the term of this CIA.

II. TERM AND SCOPE OF THE CIA

A. The period of the compliance obligations assumed by Mid Hudson under this CIA shall be five years from the effective date of this CIA. The "Effective Date" shall be the date on which the final signatory of this CIA executes this CIA. Each one-year period, beginning with the one-year period following the Effective Date, shall be referred to as a "Reporting Period."

B. Sections VII, X, and XI shall expire no later than 120 days after OIG's receipt of: (1) Mid Hudson's final annual report; or (2) any additional materials submitted by Mid Hudson pursuant to OIG's request, whichever is later.

C. The scope of this CIA shall be governed by the following definitions:

1. "Covered Persons" includes:

a. all owners, officers, directors, and employees of Mid Hudson; and

b. all contractors, subcontractors, agents, and other persons who provide patient care items or services to Mid Hudson patients at a Mid Hudson Location, as defined in Section II.C.2, or who perform billing or coding functions on behalf of Mid Hudson, excluding: (i) vendors whose sole connection with Mid Hudson is selling or otherwise providing medical supplies or equipment to Mid Hudson and who do not bill the Federal health care programs for such medical supplies or equipment; and (ii) physicians or other health care providers whose sole connection to Mid Hudson consists of renting space at a Mid Hudson Location to furnish services to their own patients and who bill independently for such services.

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

2. "Mid Hudson Locations" means the following 15 office locations:

Carmel Office 664 Stoneleigh Avenue Carmel, NY 10512	Fishkill Office 600 Westage Business Center Drive Fishkill, NY 12524	Highland Office 550 Route 299 Highland, NY 12528

Hopewell Junction Office 10 Cranberry Drive Hopewell Junction, NY 12533	Kingston – Family/Internal Medicine Office 35 Barbarossa Lane Kingston, NY 12401	Kingston – OB/GYN Office 340 Washington Avenue Kingston, NY 12401
Kingston – Ophthalmology Office 500 Aaron Court Kingston, NY 12401	Kingston – Orthopedics Office 90 Prince Street Kingston, NY 12401	Kingston – Pediatrics Office 140 Pine Street Kingston, NY 12401
Livingston Office 2400 Route 9 Livingston, NY 12534	Millerton Office 37 Century Boulevard Millerton, NY 12456	Poughkeepsie Office 30 Columbia Street Poughkeepsie, NY 12601
Poughkeepsie Ophthalmology Office 22 Green Street Poughkeepsie, NY 12601	Rhinebeck Office 6734 Route 9 Rhinebeck, NY 12572	Sharon Office 101 Gay Street Sharon, CT 06069

3. "Relevant Covered Persons" includes Covered Persons involved in: (1) the delivery of patient care items or services; or (2) the preparation or submission of claims for reimbursement from any Federal health care program. Notwithstanding the foregoing, the term "Relevant Covered Persons" does not include Covered Persons who bill for their own services independently of Mid Hudson.

III. CORPORATE INTEGRITY OBLIGATIONS

During the term of this CIA, Mid Hudson shall maintain a Compliance Program that includes the following elements:

A. Compliance Responsibilities of Certain Mid Hudson Employees and the Board of Directors

1. *Compliance Officer*. Mid Hudson has appointed a Covered Person to serve as its Compliance Officer and shall maintain a Compliance Officer for the term of the

CIA. The Compliance Officer shall be responsible for developing and implementing policies, procedures, and practices designed to ensure compliance with the requirements set forth in this CIA and with Federal health care program requirements. The Compliance Officer shall be a member of senior management of Mid Hudson, shall report directly to the Chief Executive Officer of Mid Hudson, shall make periodic (at least quarterly) reports regarding compliance matters directly to the Board of Directors of Mid Hudson, and shall be authorized to report on such matters to the Board of Directors at any time. Written documentation of the Compliance Officer's reports to the Board of Directors shall be made available to OIG upon request. The Compliance Officer shall not be or be subordinate to the General Counsel or Chief Financial Officer. The Compliance Officer shall be responsible for monitoring the day-to-day compliance activities engaged in by Mid Hudson as well as for any reporting obligations created under this CIA. Any noncompliance job responsibilities of the Compliance Officer shall be limited and must not interfere with the Compliance Officer's ability to perform the duties outlined in this CIA.

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

2. *Compliance Committee*. Mid Hudson has appointed a Compliance Committee. The Compliance Committee shall, at a minimum, include the Compliance Officer and other members of senior management necessary to meet the requirements of this CIA (*e.g.*, senior executives of relevant departments, such as billing, clinical, human resources, audit, and operations). The Compliance Officer shall chair the Compliance Committee and the Committee shall support the Compliance Officer in fulfilling his/her responsibilities (*e.g.*, shall assist in the analysis of Mid Hudson's risk areas and shall oversee monitoring of internal and external audits and investigations). The Compliance Committee shall meet at least quarterly. The minutes of the Compliance Committee meetings shall be made available to OIG upon request.

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

3. *Board of Directors Compliance Obligations*. The Board of Directors (or a committee of the Board) of Mid Hudson (Board) shall be responsible for

the review and oversight of matters related to compliance with Federal health care program requirements and the obligations of this CIA. The Board must include independent (*i.e.*, non-executive) members.

The Board shall, at a minimum, be responsible for the following:

a. meeting at least quarterly to review and oversee Mid Hudson's Compliance Program, including but not limited to the performance of the Compliance Officer and Compliance Committee; and

b. for each Reporting Period of the CIA, adopting a resolution, signed by each member of the Board summarizing its review and oversight of Mid Hudson's compliance with Federal health care program requirements and the obligations of this CIA.

At minimum, the resolution shall include the following language:

"The Board of Directors has made a reasonable inquiry into the operations of Mid Hudson's Compliance Program, including the performance of the Compliance Officer and the Compliance Committee. Based on its inquiry and review, the Board has concluded that, to the best of its knowledge, Mid Hudson has implemented an effective Compliance Program to meet Federal health care program requirements and the obligations of the CIA."

If the Board is unable to provide such a conclusion in the resolution, the Board shall include in the resolution a written explanation of the reasons why it is unable to provide the conclusion and the steps it is taking to implement an effective Compliance Program at Mid Hudson.

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

4. *Management Accountability and Certifications*. In addition to the responsibilities set forth in this CIA for all Covered Persons, certain Mid Hudson officers or employees (Certifying Employees) are specifically expected to monitor and oversee activities within the group practice and shall certify annually that the areas under their

authority are compliant with applicable Federal health care program requirements and with the obligations of this CIA. These Certifying Employees shall include, at a minimum, the following: the President, the Chief Executive Officer (if different), the Chief Operating Officer, the Chief Financial Officer, and the Chief Medical Officer.

For each Reporting Period, each Certifying Employee shall sign a certification that states as follows:

"I have been trained on and understand the compliance requirements and responsibilities as they relate to [functional area], an area under my supervision. My job responsibilities include ensuring that the [functional area] remains compliant with all applicable Federal health care program requirements, obligations of the Corporate Integrity Agreement, and Mid Hudson Policies and Procedures, and I have taken steps to promote such compliance. To the best of my knowledge, except as otherwise described herein, the [functional area] of Mid Hudson is in compliance with all applicable Federal health care program requirements and the obligations of the CIA. I understand that this certification is being provided to and relied upon by the United States."

If any Certifying Employee is unable to provide such a conclusion in the certification, he or she shall provide a written explanation of the reasons why he or she is unable to provide the certification outlined above and the steps being taken to address the issues identified.

B. Written Standards

1. *Code of Conduct*. Mid Hudson has developed and implemented a written Code of Conduct. To the extent not already accomplished, Mid Hudson shall distribute its Code of Conduct to all Covered Persons within 90 days after the Effective Date. Mid Hudson shall make the promotion of, and adherence to, the Code of Conduct an element in evaluating the performance of all employees. The Code of Conduct shall, at a minimum, set forth:

a. Mid Hudson's commitment to full compliance with all Federal health care program requirements, including its commitment to prepare and submit accurate claims consistent with such requirements;

b. Mid Hudson's requirement that all of its Covered Persons shall be expected to comply with all Federal health care

program requirements and with Mid Hudson's own Policies and Procedures;

c. the requirement that all of Mid Hudson's Covered Persons shall be expected to report to the Compliance Officer, or other appropriate individual designated by Mid Hudson, suspected violations of any Federal health care program requirements or of Mid Hudson's own Policies and Procedures; and

d. the right of all individuals to use the Disclosure Program described in Section III.E, and Mid Hudson's commitment to nonretaliation and to maintain, as appropriate, confidentiality and anonymity with respect to such disclosures.

Within 90 days after the Effective Date, each Covered Person shall certify, in writing or in electronic form, that he or she has received, read, understood, and shall abide by Mid Hudson's Code of Conduct. New Covered Persons shall receive the Code of Conduct and shall complete the required certification within 30 days after becoming a Covered Person or within 90 days after the Effective Date, whichever is later.

Mid Hudson shall periodically review the Code of Conduct to determine if revisions are appropriate and shall make any necessary revisions based on such review. The Code of Conduct shall be distributed at least annually to all Covered Persons.

2. *Policies and Procedures*. Mid Hudson has implemented written Policies and Procedures regarding the operation of its compliance program. Within 90 days after the Effective Date, Mid Hudson shall review its written Policies and Procedures and revise them as necessary to comply with the requirements of this CIA. At a minimum, the Policies and Procedures shall address:

a. the compliance program requirements outlined in this CIA;

b. the Code of Conduct requirements identified in Section III.B.1;

c. Mid Hudson's compliance with Federal health care program requirements regarding accurate coding and submission of claims;

d. Mid Hudson's compliance with Federal health care program requirements regarding medical necessity;

e. Mid Hudson's compliance with Federal health care program requirements regarding proper and accurate documentation of medical records;

f. the expectation that physicians are aware of relevant Federal health care program requirements and the personal obligation of each individual involved in the medical documentation process to ensure that such documentation is accurate; and

g. the expectation that all Covered Persons shall comply with the Code of Conduct, the Policies and Procedures under this Section III.B.2, and the terms of this CIA.

Within 90 days after the Effective Date, the Policies and Procedures listed in Section III.B.2.a–g, above, shall be distributed to all Covered Persons whose job functions and responsibilities relate to those Policies and Procedures. All Policies and Procedures shall otherwise be made available to all Covered Persons. Appropriate and knowledgeable staff shall be available to explain the Policies and Procedures.

At least annually (and more frequently, if appropriate), Mid Hudson shall assess and update, as necessary, the Policies and Procedures. Within 30 days after the effective date of any revisions, a description of the revisions shall be communicated to all affected Covered Persons, and any revised Policies and Procedures shall be made available to all Covered Persons.

C. Training and Education

1. *General Training*. Within 90 days after the Effective Date, Mid Hudson shall provide at least two hours of General Training to each Covered Person. This training, at a minimum, shall explain Mid Hudson's:

a. CIA requirements; and

b. Compliance Program, including the Code of Conduct.

For any Covered Persons who received training on Mid Hudson's Compliance Program, including its Code of Conduct, after October 1, 2013, Mid Hudson may credit such training toward fulfillment of the General Training requirements during the first Reporting Period. Within 90 days after the Effective Date, however, Mid Hudson shall supplement such General Training to ensure that all Covered Persons are trained on the requirements of this CIA.

New Covered Persons shall receive the General Training described above within 30 days after becoming a Covered Person or within 90 days after the Effective Date, whichever is later. After receiving the initial General Training described above, each Covered Person shall receive at least one hour of General Training in each subsequent Reporting Period.

2. *Specific Training*. Within 90 days after the Effective Date, each Relevant Covered Person shall receive at least two hours of Specific Training in addition to the General Training required above. This Specific Training shall include a discussion of:

a. the Federal health care program requirements regarding the accurate coding and submission of claims;

b. the personal obligation of each individual involved in the claims submission process to ensure that such claims are accurate;

c. examples of proper and improper claims submission practices;

d. the importance of accurate medical documentation in the billing, coding, and reimbursement process;

e. policies, procedures, and other requirements applicable to the documentation of medical records;

f. the personal obligation of each individual involved in the medical documentation process to ensure that such records are complete and accurate;

g. examples of proper and improper medical documentation practices;

h. the Federal health care program requirements regarding medical necessity;

i. applicable reimbursement statutes, regulations, and program requirements and directives; and

j. the legal sanctions for violations of the Federal health care program requirements.

For any Relevant Covered Persons who received training on the topics identified in Section III.C.2.a–j, above, after October 1, 2013, Mid Hudson may credit such training toward fulfillment of the Specific Training requirements during the first Reporting Period. Within 90 days after the Effective Date, however, Mid Hudson shall supplement such Specific Training as necessary to ensure that all Relevant Covered Persons are trained on each of the above-described topics.

New Relevant Covered Persons shall receive this training within 30 days after the beginning of their employment or becoming Relevant Covered Persons, or within 90 days after the Effective Date, whichever is later.

After receiving the initial Specific Training described in this section, each Relevant Covered Person shall receive at least one hour of Specific Training, in addition to the General Training, in each subsequent Reporting Period.

3. *Board Member Training*. Within 90 days after the Effective Date, Mid Hudson shall provide at least one hour of training to each member of the Board of Directors, in addition to the General Training. This training shall address the responsibilities of board members and corporate governance.

New members of the Board of Directors shall receive two hours of the Board Member Training described above within 30 days after becoming a member or within 90 days after the Effective Date, whichever is later.

4. *Certification*. Each individual who is required to attend training shall certify, in writing or in electronic form, that he or she has received the required training. The certification shall specify the type of training received and the date

received. The Compliance Officer (or designee) shall retain the certifications, along with all course materials.

5. *Qualifications of Trainer*. Persons providing or preparing the training shall be knowledgeable about the subject area.

6. *Update of Training*. Mid Hudson shall review the training annually, and, where appropriate, update the training to reflect changes in Federal health care program requirements; any issues discovered during internal audits, the Claims Review, or the Surgical Procedures Quality Review; and any other relevant information.

7. *Computer- or Video-Based Training*. Mid Hudson may provide the training required under this CIA through appropriate computer-based or video-based training approaches. If Mid Hudson chooses to provide computer-based or video-based training, it shall make available appropriately qualified and knowledgeable staff or trainers to answer questions or provide additional information to the individuals receiving such training.

D. Review Procedures

1. *General Description*

a. *Engagement of Independent Review Organization*. Within 90 days after the Effective Date, Mid Hudson shall engage an entity (or entities), such as an accounting, auditing, or consulting firm (hereinafter Independent Review Organization or IRO), to perform the reviews listed in this Section III.D. The applicable requirements relating to the IRO are outlined in Appendix A to this CIA, which is incorporated by reference.

b. *Retention of Records*. The IRO and Mid Hudson shall retain and make available to OIG, upon request, all work papers, supporting documentation, correspondence, and draft reports (those exchanged between the IRO and Mid Hudson) related to the reviews.

2. *Claims Review*. The IRO shall review Mid Hudson's coding, billing, and claims submission to the Medicare program and the reimbursement received for

certain surgical procedures (Claims Review) and shall prepare a Claims Review Report, as outlined in Appendix B to this CIA, which is incorporated by reference.

3. *Surgical Procedures Quality Review*. The IRO shall evaluate and analyze the medical necessity and appropriateness of certain surgical procedures performed by Mid Hudson physicians (Surgical Procedures Quality Review). The IRO shall prepare a Surgical Procedures Quality Review Report, as outlined in Appendix C to this CIA, which is incorporated by reference.

4. *Validation Review*. In the event OIG has reason to believe that: (a) Mid Hudson's Claims Review or Surgical Procedures Quality Review fails to conform to the requirements of this CIA; or (b) the IRO's findings or the Claims Review or Surgical Procedures Quality Review results are inaccurate, OIG may, at its sole discretion, conduct its own review to determine whether the Claims Review or Surgical Procedures Quality Review complied with the requirements of the CIA and/or the IRO's findings or Claims Review or Surgical Procedures Quality Review results are inaccurate (Validation Review). Mid Hudson shall pay for the reasonable cost of any such review performed by OIG or any of its designated agents. Any Validation Review of Reports submitted as part of Mid Hudson's final Annual Report shall be initiated no later than one year after Mid Hudson's final submission (as described in Section II) is received by OIG.

Prior to initiating a Validation Review, OIG shall notify Mid Hudson of its intent to do so and provide a written explanation of why OIG believes such a review is necessary. To resolve any concerns raised by OIG, Mid Hudson may request a meeting with OIG to: (a) discuss the results of any Claims Review or Surgical Procedures Quality Review submissions or findings; (b) present any additional information to clarify the results of the Claims Review or Surgical Procedures Quality Review, or to correct the inaccuracy of the Claims Review or Surgical Procedures Quality Review; and/or (c) propose alternatives to the proposed Validation Review. Mid Hudson agrees to provide any additional information as may be requested by OIG under this Section III.D.4 in an expedited manner. OIG will attempt in good faith to resolve any Claims Review or Surgical Procedures Quality Review issues with Mid Hudson prior to conducting a Validation Review. However, the final determination as to whether or not to proceed with a Validation Review shall be made at the sole discretion of OIG.

5. *Independence and Objectivity Certification*. The IRO shall include in its report(s) to Mid Hudson a certification that the IRO has: (a) evaluated its professional independence and objectivity with respect to the reviews conducted under

this Section III.D; and (b) concluded that it is, in fact, independent and objective, in accordance with the requirements specified in Appendix A to this CIA.

E. Disclosure Program

Mid Hudson has established a Disclosure Program that includes a mechanism (*e.g.*, a toll-free compliance telephone line) to enable individuals to disclose, to the Compliance Officer or some other person who is not in the disclosing individual's chain of command, any identified issues or questions associated with Mid Hudson's policies, conduct, practices, or procedures with respect to a Federal health care program believed by the individual to be a potential violation of criminal, civil, or administrative law. Mid Hudson shall continue to appropriately publicize the existence of the disclosure mechanism (*e.g.*, via periodic e-mails to employees or by posting the information in prominent common areas).

The Disclosure Program shall emphasize a nonretribution, nonretaliation policy, and shall include a reporting mechanism for anonymous communications for which appropriate confidentiality shall be maintained. Upon receipt of a disclosure, the Compliance Officer (or designee) shall gather all relevant information from the disclosing individual. The Compliance Officer (or designee) shall make a preliminary, good faith inquiry into the allegations set forth in every disclosure to ensure that he or she has obtained all of the information necessary to determine whether a further review should be conducted. For any disclosure that is sufficiently specific so that it reasonably: (1) permits a determination of the appropriateness of the alleged improper practice; and (2) provides an opportunity for taking corrective action, Mid Hudson shall conduct an internal review of the allegations set forth in the disclosure and ensure that proper follow-up is conducted.

The Compliance Officer (or designee) shall maintain a disclosure log, which shall include a record and summary of each disclosure received (whether anonymous or not), the status of the respective internal reviews, and any corrective action taken in response to the internal reviews.

F. Ineligible Persons

1. *Definitions*. For purposes of this CIA:

a. an "Ineligible Person" shall include an individual or entity who:

i. is currently excluded, debarred, suspended, or otherwise ineligible to participate in the Federal health care programs or in Federal procurement or nonprocurement programs; or

ii. has been convicted of a criminal offense that falls within the scope of 42 U.S.C. § 1320a-7(a), but has not yet been excluded, debarred, suspended, or otherwise declared ineligible.

b. "Exclusion Lists" include:

i. the HHS/OIG List of Excluded Individuals/Entities (available through the Internet at http://www.oig.hhs.gov); and

ii. the General Services Administration's System for Award Management (available through the Internet at http://www.sam.gov).

2. *Screening Requirements*. Mid Hudson shall ensure that all prospective and current Covered Persons are not Ineligible Persons, by implementing the following screening requirements.

a. Mid Hudson shall screen all prospective Covered Persons against the Exclusion Lists prior to engaging their services and, as part of the hiring or contracting process, shall require such Covered Persons to disclose whether they are Ineligible Persons.

b. Mid Hudson shall screen all Covered Persons against the Exclusion Lists within 90 days after the Effective Date and on a monthly basis thereafter.

c. Mid Hudson shall implement a policy requiring all Covered Persons to disclose immediately any debarment, exclusion, suspension, or other event that makes that person an Ineligible Person.

Nothing in Section III.F affects Mid Hudson's responsibility to refrain from (and liability for) billing Federal health care programs for items or services furnished, ordered, or prescribed by excluded persons. Mid Hudson understands that items or services furnished, ordered, or prescribed by excluded persons are not payable by Federal health care programs and that Mid Hudson may be liable for overpayments and/or criminal, civil, and administrative sanctions for employing or contracting with an excluded person regardless of whether Mid Hudson meets the requirements of Section III.F.

3. *Removal Requirement*. If Mid Hudson has actual notice that a Covered Person has become an Ineligible Person, Mid Hudson shall remove such Covered Person from responsibility for, or involvement with, Mid Hudson's business operations related to the Federal health care programs and shall remove such Covered Person from any position for which the Covered Person's compensation or the items or services furnished, ordered, or prescribed by the Covered 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 Covered Person is reinstated into participation in the Federal health care programs.

4. *Pending Charges and Proposed Exclusions*. If Mid Hudson has actual notice that a Covered Person is charged with a criminal offense that falls within the scope of 42 U.S.C. §§ 1320a-7(a), 1320a-7(b)(1)–(3), or is proposed for exclusion during the Covered Person's employment or contract term, Mid Hudson shall take all appropriate actions to ensure that the responsibilities of that Covered Person have not and shall not adversely affect the quality of care rendered to any beneficiary, patient, or resident, or any claims submitted to any Federal health care program.

G. Notification of Government Investigation or Legal Proceedings

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

H. Repayment of Overpayments

1. *Definition of Overpayments*. For purposes of this CIA, an "Overpayment" shall mean the amount of money Mid Hudson has received in excess of the amount due and payable under any Federal health care program requirements.

2. *Repayment of Overpayments*

a. If, at any time, Mid Hudson identifies or learns of any Overpayment, Mid Hudson shall repay the Overpayment to the appropriate payor (*e.g.*, Medicare contractor) within 60 days after identification of the Overpayment and take remedial steps within 90 days after identification (or such additional time as may be agreed to by the payor) to correct the problem, including preventing the underlying problem and the Overpayment from recurring. If not yet quantified, within 60 days after identification, Mid Hudson shall notify the payor of its efforts to quantify the Overpayment amount along with a schedule of when such work is expected to be completed. Notification and repayment to the payor shall be done in accordance with the payor's policies.

b. Notwithstanding the above, notification and repayment of any Overpayment amount that routinely is reconciled or adjusted pursuant to policies and procedures established by the payor should be handled in accordance with such policies and procedures.

I. Reportable Events

1. *Definition of Reportable Event*. For purposes of this CIA, a "Reportable Event" means anything that involves:

a. a substantial Overpayment;

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

c. the employment of or contracting with a Covered Person who is an Ineligible Person as defined by Section III.F.1.a; or

d. the filing of a bankruptcy petition by Mid Hudson.

A Reportable Event may be the result of an isolated event or a series of occurrences.

2. *Reporting of Reportable Events*. If Mid Hudson determines (after a reasonable opportunity to conduct an appropriate review or investigation of the allegations) through any means that there is a Reportable Event, Mid Hudson shall notify OIG, in writing, within 30 days after making the determination that the Reportable Event exists.

3. *Reportable Events under Section III.I.1.a*. For Reportable Events under Section III.I.1.a, the report to OIG shall be made within 30 days of the identification of the Overpayment, and shall include:

a. a description of the steps taken by Mid Hudson to identify and quantify the Overpayment;

b. a complete description of the Reportable Event, including the relevant facts, persons involved, and legal and Federal health care program authorities implicated;

c. a description of Mid Hudson's actions taken to correct the Reportable Event; and

d. any further steps Mid Hudson plans to take to address the Reportable Event and prevent it from recurring.

Within 60 days of identification of the Overpayment, Mid Hudson shall provide OIG with a copy of the notification and repayment to the payor required by Section III.H.2.

4. *Reportable Events under Section III.I.1.b and c*. For Reportable Events under Section III.I.1.b and III.I.1.c, the report to OIG shall include:

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

b. a description of Mid Hudson's actions taken to correct the Reportable Event;

c. any further steps Mid Hudson plans to take to address the Reportable Event and prevent it from recurring; and

d. if the Reportable Event has resulted in an Overpayment, a description of the steps taken by Mid Hudson to identify and quantify the Overpayment.

5. *Reportable Events under Section III.I.1.d*. For Reportable Events under Section III.I.1.d, the report to OIG shall include documentation of the bankruptcy filing and a description of any Federal health care program authorities implicated.

6. *Reportable Events Involving the Stark Law*. Notwithstanding the reporting requirements outlined above, any Reportable Event that involves only a probable violation of section 1877 of the Social Security Act, 42 U.S.C. § 1395nn (the Stark Law) should be submitted by Mid Hudson to the Centers for Medicare & Medicaid Services (CMS) through the self-referral disclosure protocol (SRDP), with a copy to OIG. The requirements of Section III.H.2 that require repayment to the payor of any identified Overpayment within 60 days shall not apply to any Overpayment that may result from a probable violation of only the Stark Law that is disclosed to CMS pursuant to the SRDP. If Mid Hudson identifies a probable violation of the Stark Law and repays the applicable Overpayment directly to the CMS contractor, then Mid Hudson is not required by this Section III.I to submit the Reportable Event to CMS through the SRDP.

IV. SUCCESSOR LIABILITY; CHANGES TO BUSINESS UNITS OR LOCATIONS

A. Sale of Business, Business Unit, or Location

In the event that, after the Effective Date, Mid Hudson proposes to sell any or all of its business, business units, or locations (whether through a sale of assets, sale of stock, or other type of transaction) that are subject to this CIA, Mid Hudson shall notify OIG of the proposed sale at least 30 days prior to the sale of its business, business unit, or

location. This notification shall include a description of the business, business unit, or location to be sold; a brief description of the terms of the sale; and the name and contact information of the prospective purchaser. This CIA shall be binding on the purchaser of the business, business unit, or location, unless otherwise determined and agreed to in writing by the OIG.

B. Change or Closure of Business, Business Unit, or Location

In the event that, after the Effective Date, Mid Hudson changes locations or closes a business, business unit, or location related to the furnishing of items or services that may be reimbursed by Federal health care programs, Mid Hudson shall notify OIG of this fact as soon as possible, but no later than within 30 days after the date of change or closure of the business, business unit, or location.

C. Purchase or Establishment of New Business, Business Unit, or Location

In the event that, after the Effective Date, Mid Hudson purchases or establishes a new business, business unit, or location related to the furnishing of items or services that may be reimbursed by Federal health care programs, Mid Hudson shall notify OIG at least 30 days prior to such purchase or the operation of the new business, business unit, or location. This notification shall include the address of the new business, business unit or location; its phone number and fax number; the location's Medicare and state Medicaid program provider number and/or supplier number(s); and the name and address of each Medicare and state Medicaid program contractor to which Mid Hudson currently submits claims. Each new business, business unit, or location and all Covered Persons at each new business, business unit, or location shall be subject to the applicable requirements of this CIA, unless otherwise agreed to in writing by the OIG.

V. IMPLEMENTATION AND ANNUAL REPORTS

A. Implementation Report

Within 120 days after the Effective Date, Mid Hudson shall submit a written report to OIG summarizing the status of its implementation of the requirements of this CIA (Implementation Report). The Implementation Report shall, at a minimum, include:

1. the name, address, phone number, and position description of the Compliance Officer required by Section III.A.1, and a summary of other noncompliance job responsibilities the Compliance Officer may have;

2. the names and positions of the members of the Compliance Committee required by Section III.A.2;

3. the names of the Board members who are responsible for satisfying the Board of Directors compliance obligations described in Section III.A.3;

4. a copy of Mid Hudson's Code of Conduct required by Section III.B.1;

5. the number of individuals required to complete the Code of Conduct certification required by Section III.B.1, the percentage of individuals who have completed such certification, and an explanation of any exceptions (the documentation supporting this information shall be available to OIG upon request);

6. a summary of all Policies and Procedures required by Section III.B.2 (copies of the Policies and Procedures shall be made available to OIG upon request);

7. the following information regarding each type of training required by Section III.C:

   a. a description of such training, including a summary of the topics covered, the length of sessions, and a schedule of training sessions; and

   b. the number of individuals required to be trained, percentage of individuals actually trained, and an explanation of any exceptions.

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

8. a description of the Disclosure Program required by Section III.E;

9. the following information regarding the IRO(s): (a) identity, address, and phone number; (b) a copy of the engagement letter; (c) information to demonstrate that the IRO has the qualifications outlined in Appendix A to this CIA; (d) a summary and description of any and all current and prior engagements and agreements

between Mid Hudson and the IRO; and (e) a certification from the IRO regarding its professional independence and objectivity with respect to Mid Hudson;

10. a description of the process by which Mid Hudson fulfills the requirements of Section III.F regarding Ineligible Persons;

11. a list of all of Mid Hudson's locations (including locations and mailing addresses); the corresponding name under which each location is doing business; the corresponding phone numbers and fax numbers; each location's Medicare and state Medicaid program provider number and/or supplier number(s); and the name and address of each Medicare and state Medicaid program contractor to which Mid Hudson currently submits claims;

12. a description of Mid Hudson's corporate structure, including identification of any individual owners, parent and sister companies, subsidiaries, and their respective lines of business; and

13. the certifications required by Section V.C.

B. Annual Reports

Mid Hudson shall submit to OIG annually a report with respect to the status of, and findings regarding, Mid Hudson's compliance activities for each of the five Reporting Periods (Annual Report). Each Annual Report shall include, at a minimum:

1. any change in the identity, position description, or other noncompliance job responsibilities of the Compliance Officer and any change in the membership of the Compliance Committee described in Section III.A;

2. the dates of each report made by the Compliance Officer to the Board (written documentation of such reports shall be made available upon request);

3. the Board resolution required by Section III.A.3;

4. the management certifications required by Section III.A.4;

5. a summary of any changes or amendments to Mid Hudson's Code of Conduct required by Section III.B.1 and the reason for such changes, along with a copy of the revised Code of Conduct;

6. the number of individuals required to complete the Code of Conduct certification required by Section III.B.1, the percentage of individuals who have completed such certification, and an explanation of any exceptions (the documentation supporting this information shall be made available to OIG upon request);

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

8. the following information regarding each type of training required by Section III.C:

a. a description of the initial and annual training, including a summary of the topics covered, the length of sessions, and a schedule of training sessions; and

b. the number of individuals required to complete the initial and annual training, the percentage of individuals who actually completed the initial and annual training, and an explanation of any exceptions.

A copy of all training materials and the documentation to support this information shall be made available to OIG upon request;

9. a complete copy of all reports prepared pursuant to Section III.D, along with a copy of the IRO's engagement letter;

10. Mid Hudson's response to the reports prepared pursuant to Section III.D, along with corrective action plan(s) related to any issues raised by the reports;

11. a summary and description of any and all current and prior engagements and agreements between Mid Hudson and the IRO (if different from what was submitted as part of the Implementation Report);

12. a certification from the IRO regarding its professional independence and objectivity with respect to Mid Hudson;

13. a summary of Reportable Events (as defined in Section III.I) identified during the Reporting Period and the status of any corrective action relating to all such Reportable Events;

14. a report of the aggregate Overpayments that have been returned to the Federal health care programs. Overpayment amounts shall be broken down into the following categories: inpatient Medicare, outpatient Medicare, Medicaid (report each applicable state separately, if applicable), and other Federal health care programs. Overpayment amounts that are routinely reconciled or adjusted pursuant to policies and procedures established by the payor do not need to be included in this aggregate Overpayment report;

15. a summary of the disclosures in the disclosure log required by Section III.E that relate to Federal health care programs (the complete disclosure log shall be made available to OIG upon request);

16. any changes to the process by which Mid Hudson fulfills the requirements of Section III.F regarding Ineligible Persons;

17. 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;

18. a description of all changes to the most recently provided list of Mid Hudson's locations (including addresses) as required by Section V.A.11; the corresponding name under which each location is doing business; the corresponding phone numbers and fax numbers; each location's Medicare and state Medicaid program provider number(s) and/or supplier number(s); and the name and address of each Medicare and state Medicaid program contractor to which Mid Hudson currently submits claims; and

19. the certifications required by Section V.C.

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

C. Certifications

The Implementation Report and each Annual Report shall include a certification by the Compliance Officer that:

1. to the best of his or her knowledge, except as otherwise described in the report, Mid Hudson is in compliance with all of the requirements of this CIA;

2. he or she has reviewed the report and has made reasonable inquiry regarding its content and believes that the information in the report is accurate and truthful; and

3. to the best of his or her knowledge, Mid Hudson has not charged, directly or indirectly, the costs of implementing and remaining in compliance with the terms of this CIA to any contracts with the United States or any state Medicaid program, nor has Mid Hudson sought payment for such costs through any cost report, cost statement, information statement, or payment request submitted to the Federal health care programs by Mid Hudson or any of its subsidiaries or affiliates.

D. Designation of Information

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

VI. NOTIFICATIONS AND SUBMISSION OF REPORTS

Unless otherwise stated in writing after the Effective Date, all notifications and reports required under this CIA shall be submitted to the following entities:

OIG:
Administrative and Civil Remedies Branch
Office of Counsel to the Inspector General
Office of Inspector General
U.S. Department of Health and Human Services

Cohen Building, Room 5527
330 Independence Avenue, SW
Washington, DC 20201
Telephone: 202.619.2078
Facsimile: 202.205.0604

Mid Hudson:
Katherine Weir, Compliance Officer & Chief Operating Officer
600 Westage Drive
Fishkill, NY 12524
Telephone: 845.231.5502
Facsimile: 845.231.5492

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. Upon request by OIG, Mid Hudson may be required to provide OIG with an electronic copy of each notification or report required by this CIA in searchable portable document format (pdf), in addition to a paper copy.

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

VIII. DOCUMENT AND RECORD RETENTION

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

IX. DISCLOSURES

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

X. BREACH AND DEFAULT PROVISIONS

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

A. Stipulated Penalties for Failure to Comply with Certain Obligations

As a contractual remedy, Mid Hudson and OIG hereby agree that failure to comply with certain obligations as set forth in this CIA may lead to the imposition of the following monetary penalties (hereinafter referred to as "Stipulated Penalties") in accordance with the following provisions.

1. A Stipulated Penalty of $2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day Mid Hudson fails to establish and implement any of the following obligations as described in Section III:

   a. a Compliance Officer;

   b. a Compliance Committee;

   c. the Board of Directors compliance obligations;

   d. a written Code of Conduct;

e. written Policies and Procedures;

f. the training of Covered Persons, Relevant Covered Persons, and Board Members;

g. a Disclosure Program;

h. Ineligible Persons screening and removal requirements;

i. notification of government investigations or legal proceedings; and

j. reporting of Reportable Events.

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 Mid Hudson fails to engage and use an IRO, as required in Section III.D, Appendix A, Appendix B, and Appendix C.

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 Mid Hudson fails to submit the Implementation Report or any Annual Reports to OIG in accordance with the requirements of Section V by the deadlines for submission.

4. A Stipulated Penalty of $2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day Mid Hudson fails to submit any Claims Review Report or Surgical Procedures Quality Review Report in accordance with the requirements of Section III.D, Appendix A, Appendix B, and Appendix C.

5. A Stipulated Penalty of $1,500 for each day Mid Hudson fails to grant access as required in Section VII. (This Stipulated Penalty shall begin to accrue on the date Mid Hudson fails to grant access.)

6. A Stipulated Penalty of $50,000 for each false certification submitted by or on behalf of Mid Hudson as part of its Implementation Report, Annual Report, additional documentation to a report (as requested by OIG), or otherwise required by this CIA.

7. A Stipulated Penalty of $1,000 for each day Mid Hudson fails to comply fully and adequately with any obligation of this CIA. OIG shall provide notice to

Mid Hudson stating the specific grounds for its determination that Mid Hudson has failed to comply fully and adequately with the CIA obligation(s) at issue and steps Mid Hudson shall take to comply with the CIA. (This Stipulated Penalty shall begin to accrue 10 days after Mid Hudson receives this notice from OIG of the failure to comply.) A Stipulated Penalty as described in this Subsection shall not be demanded for any violation for which OIG has sought a Stipulated Penalty under Subsections 1–6 of this Section.

B. Timely Written Requests for Extensions

Mid Hudson 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 Mid Hudson fails to meet the revised deadline set by OIG. Notwithstanding any other provision in this Section, if OIG denies such a timely written request, Stipulated Penalties for failure to perform the act or file the notification or report shall not begin to accrue until three business days after Mid Hudson 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 Mid Hudson 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 Mid Hudson of: (a) Mid Hudson's failure to comply; and (b) OIG's exercise of its contractual right to demand payment of the Stipulated Penalties. (This notification shall be referred to as the "Demand Letter.")

2. *Response to Demand Letter*. Within 10 days after the receipt of the Demand Letter, Mid Hudson 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 Mid Hudson elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until Mid Hudson cures, to OIG's satisfaction, the alleged breach in dispute. Failure to respond to the Demand Letter in one of these two manners within the allowed time period

shall be considered a material breach of this CIA and shall be grounds for exclusion under Section X.D.

3. *Form of Payment*. Payment of the Stipulated Penalties shall be made by electronic funds transfer to an account specified by OIG in the Demand Letter.

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 Mid Hudson has materially breached this CIA, which decision shall be made at OIG's discretion and shall be governed by the provisions in Section X.D, below.

D. Exclusion for Material Breach of this CIA

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

a. a repeated or flagrant violation of the obligations under this CIA, including, but not limited to, the obligations addressed in Section X.A;

b. a failure by Mid Hudson to report a Reportable Event, take corrective action, and make the appropriate refunds, as required in Section III.I;

c. a failure to respond to a Demand Letter concerning the payment of Stipulated Penalties in accordance with Section X.C; or

d. a failure to engage and use an IRO in accordance with Section III.D, Appendix A, Appendix B, and Appendix C.

2. *Notice of Material Breach and Intent to Exclude*. The parties agree that a material breach of this CIA by Mid Hudson constitutes an independent basis for Mid Hudson's exclusion from participation in the Federal health care programs. Upon a determination by OIG that Mid Hudson has materially breached this CIA and that exclusion is the appropriate remedy, OIG shall notify Mid Hudson of: (a) Mid Hudson's material breach; and (b) OIG's intent to exercise its contractual right to impose exclusion.

(This notification shall be referred to as the "Notice of Material Breach and Intent to Exclude.")

3. *Opportunity to Cure*. Mid Hudson shall have 30 days from the date of receipt of the Notice of Material Breach and Intent to Exclude to demonstrate to OIG's satisfaction that:

a. Mid Hudson is in compliance with the obligations of the CIA cited by OIG as being the basis for the material breach;

b. the alleged material breach has been cured; or

c. the alleged material breach cannot be cured within the 30-day period, but that: (i) Mid Hudson has begun to take action to cure the material breach; (ii) Mid Hudson is pursuing such action with due diligence; and (iii) Mid Hudson has provided to OIG a reasonable timetable for curing the material breach.

4. *Exclusion Letter*. If, at the conclusion of the 30-day period, Mid Hudson fails to satisfy the requirements of Section X.D.3, OIG may exclude Mid Hudson from participation in the Federal health care programs. OIG shall notify Mid Hudson in writing of its determination to exclude Mid Hudson. (This letter shall be referred to as the "Exclusion Letter.") Subject to the Dispute Resolution provisions in Section X.E, below, the exclusion shall go into effect 30 days after the date of Mid Hudson's receipt of the Exclusion Letter. The exclusion shall have national effect. Reinstatement to program participation is not automatic. After the end of the period of exclusion, Mid Hudson may apply for reinstatement by submitting a written request for reinstatement in accordance with the provisions at 42 C.F.R. §§ 1001.3001–.3004.

E. Dispute Resolution

1. *Review Rights*. Upon OIG's delivery to Mid Hudson of its Demand Letter or of its Exclusion Letter, and as an agreed-upon contractual remedy for the resolution of disputes arising under this CIA, Mid Hudson shall be afforded certain review rights comparable to the ones that are provided in 42 U.S.C. § 1320a-7(f) and 42 C.F.R. Part 1005 as if they applied to the Stipulated Penalties or exclusion sought pursuant to this CIA. Specifically, OIG's determination to demand payment of Stipulated Penalties or to seek exclusion shall be subject to review by an HHS ALJ and, in the event of an appeal, the HHS Departmental Appeals Board (DAB), in a manner consistent with

the provisions in 42 C.F.R. § 1005.2–1005.21. Notwithstanding the language in 42 C.F.R. § 1005.2(c), the request for a hearing involving Stipulated Penalties shall be made within 10 days after receipt of the Demand Letter and the request for a hearing involving exclusion shall be made within 25 days after receipt of the Exclusion Letter.

2. *Stipulated Penalties Review*. Notwithstanding any provision of Title 42 of the United States Code or Title 42 of the Code of Federal Regulations, the only issues in a proceeding for Stipulated Penalties under this CIA shall be: (a) whether Mid Hudson was in full and timely compliance with the obligations of this CIA for which OIG demands payment; and (b) the period of noncompliance. Mid Hudson shall have the burden of proving its full and timely compliance and the steps taken to cure the noncompliance, if any. OIG shall not have the right to appeal to the DAB an adverse ALJ decision related to Stipulated Penalties. If the ALJ agrees with OIG with regard to a finding of a breach of this CIA and orders Mid Hudson to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable 20 days after the ALJ issues such a decision unless Mid Hudson requests review of the ALJ decision by the DAB. If the ALJ decision is properly appealed to the DAB and the DAB upholds the determination of OIG, the Stipulated Penalties shall become due and payable 20 days after the DAB issues its decision.

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

a. whether Mid Hudson was in material breach of this CIA;

b. whether such breach was continuing on the date of the Exclusion Letter; and

c. whether the alleged material breach could not have been cured within the 30-day period, but that: (i) Mid Hudson had begun to take action to cure the material breach within that period; (ii) Mid Hudson has pursued and is pursuing such action with due diligence; and (iii) Mid Hudson provided to OIG within that period a reasonable timetable for curing the material breach and Mid Hudson has followed the timetable.

For purposes of the exclusion herein, exclusion shall take effect only after an ALJ decision favorable to OIG, or, if the ALJ rules for Mid Hudson, only after a DAB

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

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

XI. EFFECTIVE AND BINDING AGREEMENT

Mid Hudson and OIG agree as follows:

A. This CIA shall become final and binding on the date the final signature is obtained on the CIA.

B. This CIA constitutes the complete agreement between the parties and may not be amended except by written consent of the parties to this CIA.

C. OIG may agree to a suspension of Mid Hudson's obligations under this CIA based on a certification by Mid Hudson that it is no longer providing health care items or services that will be billed to any Federal health care program and that it does not have any ownership or control interest, as defined in 42 U.S.C. § 1320a-3, in any entity that bills any Federal health care program. If Mid Hudson is relieved of its CIA obligations, Mid Hudson will be required to notify OIG in writing at least 30 days in advance if Mid Hudson plans to resume providing health care items or services that are billed to any Federal health care program or to obtain an ownership or control interest in any entity that bills any Federal health care program. At such time, OIG shall evaluate whether the CIA will be reactivated or modified.

D. The undersigned Mid Hudson signatories represent and warrant that they are authorized to execute this CIA. The undersigned OIG signatories represent that they

are signing this CIA in their official capacities and that they are authorized to execute this CIA.

E. This CIA may be executed in counterparts, each of which constitutes an original and all of which constitute one and the same CIA. Facsimiles of signatures shall constitute acceptable, binding signatures for purposes of this CIA.

ON BEHALF OF MID HUDSON MEDICAL GROUP, P.C.

/Joseph A. Garvey, M.D./ 4/28/2014

JOSEPH A. GARVEY, M.D. DATE
President & Chief Executive Officer
Mid Hudson Medical Group, P.C.

/Steven J. Chananie, Esq./ 4/29/14

STEVEN J. CHANANIE, ESQ. DATE
Garfunkel Wild, P.C.
Counsel for Mid Hudson Medical Group, P.C.

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

/Robert K. DeConti/ 5/9/14

ROBERT K. DECONTI
Assistant Inspector General for Legal Affairs
Office of Inspector General
U.S. Department of Health and Human Services

DATE

/Kaitlyn L. Dunn/ 5/6/14

KAITLYN L. DUNN
Associate Counsel
Office of Counsel to the Inspector General
Office of Inspector General
U.S. Department of Health and Human Services

DATE

APPENDIX A

INDEPENDENT REVIEW ORGANIZATION

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

A. IRO Engagement

1. Mid Hudson shall engage an IRO that possesses the qualifications set forth in Paragraph B, below, to perform the responsibilities in Paragraph C, below. The IRO shall conduct the review in a professionally independent and objective fashion, as set forth in Paragraph D, below. Within 30 days after OIG receives the information identified in Section V.A.9 of the CIA or any additional information submitted by Mid Hudson in response to a request by OIG, whichever is later, OIG will notify Mid Hudson if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, Mid Hudson may continue to engage the IRO.

2. If Mid Hudson engages a new IRO during the term of the CIA, this IRO shall also meet the requirements of this Appendix. If a new IRO is engaged, Mid Hudson shall submit the information identified in Section V.A.9 of the CIA to OIG within 30 days of engagement of the IRO. Within 30 days after OIG receives this information or any additional information submitted by Mid Hudson at the request of OIG, whichever is later, OIG will notify Mid Hudson if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, Mid Hudson may continue to engage the IRO.

B. IRO Qualifications

The IRO shall:

1. assign individuals to conduct the Claims Review and Surgical Procedures Quality Review who have expertise in the billing, coding, reporting, and other requirements governing the surgical procedures subject to review during the applicable Reporting Period, and in the general requirements of the Federal health care program(s) from which Mid Hudson seeks reimbursement;

2. assign individuals to design and select the Claims Review and Surgical Procedures Quality Review samples who are knowledgeable about the appropriate statistical sampling techniques;

3. assign individuals to conduct the coding review portions of the Claims Review who have a nationally recognized coding certification and who have maintained this certification (*e.g.*, completed applicable continuing education requirements);

4. for purposes of the Surgical Procedures Quality Review, engage an independent outside physician who is board-certified in the applicable medical specialty and has expertise in the Federal health care program requirements governing the category of surgical procedures subject to review during the applicable Reporting Period (Medical Consultant); and

5. have sufficient staff and resources to conduct the reviews required by the CIA on a timely basis.

C. IRO Responsibilities

The IRO shall:

1. perform each Claims Review and Surgical Procedures Quality Review in accordance with the specific requirements of the CIA;

2. follow all applicable Medicare, Medicaid, and other Federal health care program rules and reimbursement guidelines in making assessments in the Claims Review and Surgical Procedures Quality Review;

3. if in doubt of the application of a particular Federal health care program policy or regulation, request clarification from the appropriate authority (*e.g.*, Medicare contractor);

4. respond to all OIG inquires in a prompt, objective, and factual manner; and

5. prepare timely, clear, well-written reports that include all the information required by Appendix B and Appendix C to the CIA.

D. IRO Independence and Objectivity

The IRO must perform the Claims Review and Surgical Procedures Quality Review in a professionally independent and objective fashion, as defined in the most recent Government Auditing Standards issued by the United States Government Accountability Office.

E. IRO Removal/Termination

1. *Mid Hudson and IRO*. If Mid Hudson terminates its IRO or if the IRO withdraws from the engagement during the term of the CIA, Mid Hudson must submit a notice explaining its reasons for termination or the reason for withdrawal to OIG no later than 30 days after termination or withdrawal. Mid Hudson must engage a new IRO in accordance with Paragraph A of this Appendix and within 60 days of termination or withdrawal of the IRO.

2. *OIG Removal of IRO*. In the event OIG has reason to believe the IRO does not possess the qualifications described in Paragraph B, is not independent and objective as set forth in Paragraph D, or has failed to carry out its responsibilities as described in Paragraph C, OIG may, at its sole discretion, require Mid Hudson to engage a new IRO in accordance with Paragraph A of this Appendix. Mid Hudson must engage a new IRO within 60 days of termination of the IRO.

Prior to requiring Mid Hudson to engage a new IRO, OIG shall notify Mid Hudson of its intent to do so and provide a written explanation of why OIG believes such a step is necessary. To resolve any concerns raised by OIG, Mid Hudson may present additional information regarding the IRO's qualifications, independence, or performance of its responsibilities. OIG will attempt in good faith to resolve any differences regarding the IRO with Mid Hudson prior to requiring Mid Hudson to terminate the IRO. However, the final determination as to whether or not to require Mid Hudson to engage a new IRO shall be made at the sole discretion of OIG.

APPENDIX B

CLAIMS REVIEW

A. Claims Review. The IRO shall perform the Claims Review annually to cover each of the five Reporting Periods. The IRO shall perform all components of each Claims Review.

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

a. Overpayment: The amount of money Mid Hudson has received in excess of the amount due and payable under any Federal health care program requirements, as determined by the IRO in connection with the claims reviews performed under this Appendix B, and which shall include any extrapolated Overpayments determined in accordance with Section A.3 of this Appendix B.

b. Paid Claim: A claim submitted by Mid Hudson and for which Mid Hudson has received reimbursement from the Medicare program.

c. Population: The Population shall be defined as all Paid Claims during the 12-month period covered by the Claims Review.

d. 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 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 Paid Claims in the sample.

2. *Discovery Sample*. The IRO shall randomly select and review a sample of 50 Paid Claims (Discovery Sample). For the first Reporting Period, the Paid Claims subject to review shall be for orthopedic surgical procedures, including, but not limited to, open rotator cuff repairs, distal clavicle resections, chondroplasties, removal of loose or foreign bodies, and repair of superior labrum anterior and posterior (SLAP) lesions.

For the second through fifth Reporting Periods, OIG shall select the type of surgical procedures for the Claims Review. First, as part of its internal risk assessment and monitoring activities, the Compliance Committee shall identify five categories of surgical procedures that would be appropriate for the IRO to review (*e.g.*, cardiac procedures, ophthalmological procedures, dermatological procedures, etc.). Mid Hudson shall provide a written description to OIG of: (1) each category of surgical procedures that the Compliance Committee proposes for potential examination as part of the Claims Review; and (2) the Compliance Committee's basis for identifying those procedures as risk areas appropriate for the IRO's evaluation. Within 60 days of receiving Mid Hudson's suggestions, OIG shall select one category of surgical procedures to be subject to the Claims Review during the applicable Reporting Period and notify Mid Hudson and the IRO concurrently in writing of OIG's selection. OIG may, in its sole discretion, select one of the categories identified by Mid Hudson or another category of surgical procedures for the Claims Review.

In each Reporting Period, the Paid Claims shall be reviewed based on the supporting documentation available at Mid Hudson's offices or under Mid Hudson's control and applicable billing and coding regulations and guidance to determine whether the claim was correctly coded, submitted, and reimbursed. If the Error Rate (as defined above) for the Discovery Sample is less than 5%, no additional sampling is required, nor is the Systems Review required. (Note: The guidelines listed above do not imply that this is an acceptable error rate. Accordingly, Mid Hudson should, as appropriate, further analyze any errors identified in the Discovery Sample. Mid Hudson recognizes that OIG or another 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 or any other segment of the universe.)

3. *Full Sample*. If the Discovery Sample indicates that the Error Rate is 5% or greater, the IRO shall select an additional sample of Paid Claims (Full Sample) using commonly accepted sampling methods. The Paid Claims selected for the Full Sample shall be reviewed based on supporting documentation available at Mid Hudson's offices or under Mid Hudson's control and applicable billing and coding regulations and

guidance to determine whether the claim 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, the IRO may use the Paid Claims sampled as part of the Discovery Sample, and the corresponding findings for those Paid Claims, as part of its Full Sample, if: (1) statistically appropriate, and (2) the IRO selects the Full Sample Paid Claims using the seed number generated by the Discovery Sample. The findings of the Full Sample shall be used by the IRO to estimate the actual Overpayment in the Population with a 90% confidence level and with a maximum relative precision of 25% of the point estimate. OIG, in its sole discretion, may refer the findings of the Full Sample (and any related workpapers) received from Mid Hudson to the appropriate Federal health care program payor (*e.g.*, Medicare contractor) for appropriate follow-up by that payor.

4. *Systems Review*. If Mid Hudson's Discovery Sample identifies an Error Rate of 5% or greater, Mid Hudson's IRO shall also conduct a Systems Review. The Systems Review shall consist of the following:

a. a review of Mid Hudson's billing and coding systems and processes relating to claims submitted to Federal health care programs (including, but not limited to, the operation of the billing system; the process by which claims are coded; safeguards to ensure proper coding, claims submission, and billing; and procedures to identify and correct inaccurate coding and billing); and

b. for each claim in the Discovery Sample and Full Sample that resulted in an Overpayment, the IRO shall review the system(s) and process(es) that generated the claim and identify any problems or weaknesses that may have resulted in the identified Overpayments. The IRO shall provide its observations and recommendations on suggested improvements to the system(s) and the process(es) that generated the claim.

5. *Other Requirements*

a. Supplemental Materials. The IRO shall request all documentation and materials required for its review of the Paid Claims selected as part of the Discovery Sample or Full Sample (if applicable), and Mid Hudson shall furnish such

documentation and materials to the IRO prior to the IRO initiating its review of the Discovery Sample or Full Sample (if applicable). If the IRO accepts any supplemental documentation or materials from Mid Hudson after the IRO has completed its initial review of the Discovery Sample or Full Sample (if applicable) (Supplemental Materials), the IRO shall identify in the Claims Review Report the Supplemental Materials, the date the Supplemental Materials were accepted, and the relative weight the IRO gave to the Supplemental Materials in its review. In addition, the IRO shall include a narrative in the Claims Review Report describing the process by which the Supplemental Materials were accepted and the IRO's reasons for accepting the Supplemental Materials.

b. Paid Claims without Supporting Documentation. Any Paid Claim for which Mid Hudson cannot produce documentation sufficient to support the Paid Claim shall be considered an error and the total reimbursement received by Mid Hudson for such Paid Claim shall be deemed an Overpayment. Replacement sampling for Paid Claims with missing documentation is not permitted.

c. Use of First Samples Drawn. For the purposes of all samples (Discovery Sample(s) and Full Sample(s)) discussed in this Appendix B, the Paid Claims selected in each first sample shall be used (*i.e.*, it is not permissible to generate more than one list of random samples and then select one for use with the Discovery Sample or Full Sample).

6. *Repayment of Identified Overpayments*. Mid Hudson shall repay within 30 days any Overpayment(s) identified in the Discovery Sample, regardless of the Error Rate, and (if applicable) the Full Sample, including the IRO's estimate of the actual Overpayment in the Population as determined in accordance with Section A.3 above, in accordance with payor refund policies. Mid Hudson shall make available to OIG all documentation that reflects the refund of the Overpayment(s) to the payor.

B. Claims Review Report. The IRO shall prepare a Claims Review Report as described in this Appendix B for each Claims Review performed. The following information shall be included in the Claims Review Report for each Discovery Sample and Full Sample (if applicable).

1. *Claims Review Methodology*

   a. Claims Review Population. A description of the Population subject to the Claims Review.

   b. Claims Review Objective. A clear statement of the objective intended to be achieved by the Claims Review.

   c. Source of Data. A description of the specific documentation relied upon by the IRO when performing the Claims Review (*e.g.*, medical records; physician orders; certificates of medical necessity; requisition forms; local medical review policies (including title and policy number); CMS program memoranda (including title and issuance number); Medicare carrier or intermediary manual or bulletins (including issue and date); other policies, regulations, or directives).

   d. Review Protocol. A narrative description of how the Claims Review was conducted and what was evaluated.

   e. Supplemental Materials. A description of any Supplemental Materials as required by Section A.5.a, above.

2. *Statistical Sampling Documentation*

   a. A copy of the printout of the random numbers generated by the "Random Numbers" function of the statistical sampling software used by the IRO.

   b. A copy of the statistical software printout(s) estimating how many Paid Claims are to be included in the Full Sample, if applicable.

   c. A description or identification of the statistical sampling software package used to select the sample and determine the Full Sample size, if applicable.

3. *Claims Review Findings*

a. Narrative Results

i. A description of Mid Hudson's billing and coding system(s), including the identification, by position description, of the personnel involved in coding and billing.

ii. A narrative explanation of the IRO's findings and supporting rationale (including reasons for errors, patterns noted, etc.) regarding the Claims Review, including the results of the Discovery Sample, and the results of the Full Sample (if any).

b. Quantitative Results

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

iii. Total dollar amount of all Overpayments in the Discovery Sample and the Full Sample (if applicable).

iv. Total dollar amount of Paid Claims included in the Discovery Sample and the Full Sample and the net Overpayment associated with the Discovery Sample and the Full Sample.

v. Error Rate in the Discovery Sample and the Full Sample.

vi. A spreadsheet of the Claims Review results that includes the following information for each Paid Claim: Federal health care program billed, beneficiary health insurance claim number, date of service, code submitted (*e.g.*, DRG, CPT code, etc.), code reimbursed, allowed amount reimbursed by payor, correct code (as determined by the IRO), correct allowed amount (as determined by the IRO), dollar difference between allowed amount reimbursed by payor and the correct allowed amount.

vii. If a Full Sample is performed, the methodology used by the IRO to estimate the actual Overpayment in the Population and the amount of such Overpayment.

c. Recommendations. The IRO's report shall include any recommendations for improvements to Mid Hudson's billing and coding system based on the findings of the Claims Review.

4. *Systems Review Findings*. The IRO shall prepare a Systems Review Report based on the Systems Review performed (if applicable) that shall include the IRO's observations, findings, and recommendations regarding:

a. the strengths and weaknesses in Mid Hudson's billing systems and processes;

b. the strengths and weaknesses in Mid Hudson's coding systems and processes; and

c. possible improvements to Mid Hudson's billing and coding systems and processes to address the specific problems or weaknesses that resulted in the identified Overpayments.

5. *Credentials*. The names and credentials of the individuals who: (1) designed the statistical sampling procedures and the review methodology utilized for the Claims Review, and (2) performed the Claims Review.

APPENDIX C

SURGICAL PROCEDURES QUALITY REVIEW

A. Surgical Procedures Quality Review. The IRO shall perform a review of Surgical Procedures, as defined in Section A.1.b of this Appendix C, annually to cover each of the five Reporting Periods (Surgical Procedures Quality Review). The IRO shall perform all components of each Surgical Procedures Quality Review, with the assistance of the Medical Consultant required by Section B.4 of Appendix A to the CIA.

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

a. Population: The Population shall be defined as all Surgical Procedures performed by a Mid Hudson physician for which Mid Hudson has received reimbursement from Medicare, Medicaid, or any other Federal health care program during the 12-month period covered by the Surgical Procedures Quality Review.

b. Surgical Procedures: For the first Reporting Period, orthopedic surgical procedures performed by a Mid Hudson physician, including, but not limited to, open rotator cuff repairs, distal clavicle resections, chondroplasties, removal of loose or foreign bodies, and SLAP lesion repairs.

For each of the second through fifth Reporting Periods, the category of procedures to be subject to the Surgical Procedures Quality Review shall be selected in accordance with the provisions of Section A.2 of Appendix B to the CIA. The Surgical Procedures subject to review under this Appendix C may, but need not, be the same category of procedures selected for the Claims Review.

2. *Surgical Procedures Sample*. The IRO shall randomly select and review a sample of 50 Surgical Procedures (Surgical Procedures Sample). The IRO shall review the Surgical Procedures for medical necessity. In conducting this review and making its determinations, the IRO shall evaluate the appropriateness of case selection, quality of procedure, execution, proper response to intraprocedural problems, accurate assessment of procedure outcome, and appropriateness of procedure management. The Surgical Procedures shall be reviewed based on the supporting documentation available at Mid Hudson's offices or under Mid Hudson's control and applicable regulations and

guidance, including but not limited to established practice guidelines and generally accepted standards of medical practice within the applicable specialty, to determine whether the procedure was medically necessary and appropriate.

3. *Other Requirements*

a. Supplemental Materials. The IRO shall request all documentation and materials required for its review of the Surgical Procedures, and Mid Hudson shall furnish such documentation and materials to the IRO prior to the IRO initiating its review of the Surgical Procedures. If the IRO accepts any supplemental documentation or materials from Mid Hudson after the IRO has completed its initial review of the Surgical Procedures (Supplemental Materials), the IRO shall identify in the Surgical Procedures Quality Review Report the Supplemental Materials, the date the Supplemental Materials were accepted, and the relative weight the IRO gave to the Supplemental Materials in its review. In addition, the IRO shall include a narrative in the Surgical Procedures Quality Review Report describing the process by which the Supplemental Materials were accepted and the IRO's reasons for accepting the Supplemental Materials.

b. Use of First Samples Drawn. For the purposes of all samples discussed in this Appendix C, the Surgical Procedures selected in each first sample shall be used (*i.e.*, it is not permissible to generate more than one list of random samples and then select one for use with the sample).

B. Surgical Procedures Quality Review Report. The IRO shall prepare a Surgical Procedures Quality Review Report for each Surgical Procedures Quality Review performed. The following information shall be included for each Surgical Procedures sample:

1. *Surgical Procedures Quality Review Methodology*

a. Sampling Unit. A description of the Surgical Procedures as that term is defined in Section A.1.b, above.

b. Surgical Procedures Quality Review Population. A description of the Population subject to the Surgical Procedures Quality Review.

c. Quality Review Objective. A clear statement of the objective intended to be achieved by the Surgical Procedures Quality Review.

d. Sampling Frame. A description of the sampling frame, which is the totality of Surgical Procedures from which the sample has been selected, and an explanation of the methodology used to identify the Sampling Frame. In most circumstances, the Sampling Frame will be identical to the Population.

e. Source of Data. A description of the specific documentation relied upon by the IRO when performing the Surgical Procedures Quality Review (*e.g.*, medical records; physician orders; certificates of medical necessity; requisition forms; local medical review policies (including title and policy number); CMS program memoranda (including title and issuance number); Medicare contractor manual or bulletins (including issue and date); or other policies, regulations, directives, or standards of medical practice).

f. Review Protocol. A narrative description of how the Surgical Procedures Quality Review was conducted and what was evaluated.

g. Supplemental Materials. A description of any Supplemental Materials as required by Section A.3.a, above.

2. *Statistical Sampling Documentation*

a. The number of Surgical Procedures appraised in the sample.

b. A copy of the printout of the random numbers generated by the "Random Numbers" function of the statistical sampling software used by the IRO.

c. A description or identification of the statistical sampling software package used to select the sample.

3. *Surgical Procedures Quality Review Findings*

a. A narrative explanation of the IRO's findings and supporting rationale (including reasons for errors, patterns noted, etc.) regarding the Surgical Procedures Quality Review, including the results of the sample.

b. The total number of instances in which the IRO determined that the Surgical Procedures were not medically necessary or appropriate.

c. A spreadsheet of the Surgical Procedures Quality Review results that includes the following information for each Surgical Procedure appraised: (1) type of Surgical Procedure performed; (2) whether the procedure was medically necessary and appropriate; (3) beneficiary name; (4) beneficiary health insurance claim number; (5) date of service; (6) procedure code submitted; (7) Federal health care program billed; and (8) amount reimbursed.

4. *Systems Review*. The IRO's observations, findings, and recommendations on possible improvements to Mid Hudson's policies, procedures, and processes based on the results of the Surgical Procedures Quality Review.

5. *Credentials*. The names and credentials of the individuals who: (1) designed the statistical sampling procedures and the review methodology utilized for the Surgical Procedures Quality Review, and (2) performed the Surgical Procedures Quality Review.