

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

I. PREAMBLE

Catskill Regional Medical Center (Catskill) 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: (1) promote compliance by its officers, directors, employees, 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); and (2) promote compliance with the “Anti-Kickback Statute” (42 U.S.C. § 1320a-7b(b)), and the regulations and other guidance documents related to this statute (collectively, (1) - (2) shall be referred to as “Applicable Guidance and Requirements”). Contemporaneously with this CIA, Catskill is entering into a Settlement Agreement with the United States, and this CIA is incorporated by reference into the Settlement Agreement.

Prior to the execution of this CIA, Catskill established a Corporate Compliance Program (the “Compliance Plan”). This Compliance Plan provides for policies and procedures and, as represented by Catskill in this CIA, is aimed at ensuring that its participation in the Federal health care programs is in conformity with the statutes, regulations and other directives applicable to those programs. Therefore, pursuant to this CIA, Catskill hereby agrees to maintain in full operation the Compliance Plan for the term of this CIA. The Compliance Plan may be modified by Catskill as appropriate but, at a minimum, shall comply with the integrity obligations enumerated in this CIA.

II. TERM AND SCOPE OF THE CIA

A. The period of the compliance obligations assumed by Catskill under this CIA shall be five (5) years from the effective date of this CIA (Effective Date) (unless otherwise specified). 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, VIII, IX, X, and XI shall expire no later than 120 days after OIG’s receipt of: (1) Catskill’s final annual report; or (2) any additional materials submitted by Catskill 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 all officers, directors, and employees of Catskill.
2. “Relevant Covered Persons” includes all Covered Persons that have the authority to enter into contracts on behalf of Catskill or to negotiate or directly influence the terms of contracts on behalf of Catskill.

III. CORPORATE INTEGRITY OBLIGATIONS

Catskill shall maintain its Compliance Plan that shall continue to include the following elements:

A. Compliance Officer and Committee.

1. *Compliance Officer.* Catskill represents to OIG that, pursuant to its Compliance Plan, it has created a Compliance Officer position and appointed an individual to serve in that capacity. The Compliance Officer shall continue to be responsible for developing and implementing policies, procedures, and practices designed to ensure compliance with the requirements set forth in this CIA, with Federal health care program requirements, and with Applicable Guidance and Requirements. While the Compliance Officer retains the ultimate responsibility to ensure that Catskill complies with the preceding requirements, he may use a designee, as necessary, to carry out these duties. The Compliance Officer shall be a member of senior management of Catskill, shall make periodic (at least quarterly) formal or informal reports regarding compliance matters directly to the Board of Directors of Catskill or appropriate sub-committee, and shall be authorized to report on such matters to the Board of Directors at any time. The Compliance Officer shall continue to be responsible for monitoring the day-to-day compliance activities engaged in by Catskill as well as for any reporting obligations created under this CIA.

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

2. *Compliance Committee.* Catskill represents to OIG that, pursuant to its Compliance Plan, it has created a Compliance Committee to monitor the implementation of the Compliance Plan and to provide advice and recommendations to Catskill's Compliance Officer and Board of Directors on compliance issues, policies, and procedures, and changes to the Compliance Plan. 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 the organization's risk areas and shall oversee monitoring of internal and external audits and investigations).

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

B. Written Standards.

1. *Code of Conduct.* Catskill has established a written Code of Conduct (hereafter the "Code of Conduct"), which the OIG has reviewed. The Code of Conduct shall be distributed to all Covered Persons within 90 days after the Effective Date of this CIA. Catskill 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. Catskill's commitment to full compliance with all Applicable Guidance and Requirements;
- b. Catskill's requirement that all of its Covered Persons shall be expected to comply with all Applicable Guidance and Requirements

and with Catskill's own Policies and Procedures as implemented pursuant to Section III.B (including the requirements of this CIA);

c. the requirement that all of Catskill's Covered Persons shall be expected to report to the Compliance Officer or other appropriate individual designated by Catskill suspected violations of any Applicable Guidance and Requirements or of Catskill's own Policies and Procedures;

d. the possible consequences to both Catskill and Covered Persons of failure to comply with Applicable Guidance and Requirements and with Catskill's own Policies and Procedures and the failure to report such noncompliance; and

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

Within 90 days after the Effective Date, and to the extent this has not already occurred, each Covered Person shall certify, in writing, that he or she has received, read, and understands Catskill's commitment to compliance, and shall abide by Catskill's Code of Conduct. New Covered Persons shall receive the Code of Conduct (or summary) 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.

Catskill shall periodically review the Code of Conduct to determine if revisions are appropriate and shall make any necessary revisions based on such a review. Any such revised Code of Conduct shall be distributed within 30 days after finalizing such changes. Each Covered Person shall certify that he or she has received, read, understands Catskill's commitment to compliance, and shall abide by the revised Code of Conduct within 30 days after the distribution of such revisions.

2. *Policies and Procedures.* Within 120 days after the Effective Date, Catskill shall implement (to the extent it has not already done so) written Policies and Procedures regarding the operation of Catskill's Compliance Plan and its compliance with Applicable Guidance and Requirements. At a minimum, the Policies and Procedures shall address:

- a. the subjects relating to the Code of Conduct identified in Section III.B.1;
- b. the obligations of Catskill under this CIA;
- c. compliance with 42 U.S.C. § 1320a-7b(b) (the “Anti-Kickback Statute”) and the regulations and other guidance documents related to this statute, and business or financial arrangements or contracts that may induce the unlawful referral of Federal health care program beneficiaries in violation of the Anti-Kickback Statute; and
- d. the requirements set forth in Section III.D.

To the extent Catskill has not already done so, within 120 days after the Effective Date, the relevant portions of the Policies and Procedures shall be distributed to all individuals whose job functions relate to those Policies and Procedures. Appropriate and knowledgeable staff shall be available to explain the Policies and Procedures.

At least annually (and more frequently, if appropriate), Catskill shall assess and update as necessary the Policies and Procedures. Within 30 days after the effective date of any revisions, the relevant portions of any such revised Policies and Procedures shall be distributed to all individuals whose job functions relate to those Policies and Procedures.

C. Training and Education.

1. *General Training.* Within 120 days after the Effective Date, Catskill shall provide at least one hour of general training to each Covered Person. This training, at a minimum, shall explain Catskill’s:

- a. CIA requirements; and
- b. Catskill’s Compliance Plan (including the Code of Conduct and the Policies and Procedures as they pertain to general compliance issues).

New Covered Persons shall receive the general training described above within 30 days after becoming a Covered Person or within 120 days after the Effective Date,

whichever is later. After receiving the initial training described above, each Covered Person shall receive at least one hour of general training annually.

2. *Specific Training.* Within 120 days after the Effective Date, each Relevant Covered Person shall receive at least two (2) hours of specific training in addition to the general training required above. This specific training shall include a discussion of:

- a. the Policies and Procedures set forth in Section III.B;
- b. the legal sanctions and consequences for improper contracting or financial arrangements;
- c. examples of violations of the Anti-Kickback Statute;
- d. the personal obligation of each individual involved in the development or maintenance of Catskill's Arrangements (as defined below in Section III.D) to know the Applicable Guidance and Requirements and Catskill's Policies and Procedures; and
- e. a review of Catskill's Policies and Procedures related to Arrangements, as defined in Section III.D below, as developed pursuant to Sections III.B.2 and III.D and the personal obligation of each individual involved in the development or maintenance of Arrangements to know applicable legal requirements and Catskill's Policies and Procedures.

Persons providing the training shall be knowledgeable about the subject area.

Relevant Covered Persons shall receive this training within 30 days after the beginning of their employment or becoming Relevant Covered Persons, or within 120 days after the Effective Date, whichever is later. A Catskill employee who has completed the specific training shall review a new Relevant Covered Person's work until such time as the new Relevant Covered Person completes his or her applicable training.

After receiving the initial training described in this Section, each Relevant Covered Person shall receive at least two (2) hours of specific training annually. Catskill shall annually review the training, and, where appropriate, update the training to reflect

changes in Applicable Guidance and Requirements, any issues discovered during internal audits, and any other relevant information.

3. *Certification.* Each individual who is required to attend training shall certify, in writing, that he or she has received the required training. The certification shall specify the type of training received and the date received. The Compliance Officer (or designee) shall retain the certifications, along with all course materials. These shall be made available to OIG, upon request.

4. *Credit for Prior Training.* For the purposes of this Section III.C, Catskill shall receive credit for any General Training or Specific Training provided to Covered Persons and/or Relevant Covered Persons since April 1, 2003.

D. Contractual Compliance with the Anti-Kickback Statute.

This Section shall apply to every arrangement or transaction that: (a) involves, directly or indirectly, the offer, payment, solicitation, or receipt of anything of value; and (b) is between Catskill and any actual or potential source of health care business or referrals to Catskill or any actual or potential recipient of health care business or referrals from Catskill. The term “source” shall mean any contractor, vendor, or agent and the term “health care business or referrals” shall be read to include referring, recommending, arranging for, ordering, leasing, or purchasing of any good, facility, item, or service for which payment may be made in whole or in part by a Federal health care program. The arrangements and transactions described above, and the written versions thereof, are collectively referred to as “Arrangements.” The party(ies) to an Arrangement other than Catskill shall be referred to as “contractor(s).”

Within 120 days after the Effective Date, Catskill shall create procedures reasonably designed to ensure that each Arrangement does not violate the Anti-Kickback Statute, and shall implement procedures to evaluate all existing Arrangements, to the extent not already so evaluated, to determine whether such Arrangements violate the Anti-Kickback Statute. Catskill shall summarize all Arrangements in the form provided at Appendix B. Catskill shall update the summary at Appendix B annually and shall submit the summary with each Annual Report.

Prior to entering into new Arrangements or renewing existing Arrangements, Catskill shall ensure that all Arrangements are in compliance with the Anti-Kickback

Statute, and the regulations, directives, and guidance related to this statute, and comply with the following requirements:

1. The Arrangement shall be set forth in writing and signed by Catskill and the contractor(s);
2. The Arrangement shall include a provision that all individuals who meet the definition of Covered Persons or qualify as contractors shall comply with Catskill's Compliance Plan, including the training related to the Anti-Kickback Statute. Additionally, Catskill shall provide each contractor with a summary of its Code of Conduct and Anti-Kickback Policies and Procedures; and
3. Catskill shall certify and shall require the contractor(s) to certify, at the time of signing the Arrangement and upon contract renewal, that the Arrangement is not intended to generate referrals which violate the Anti-Kickback Statute.

Catskill shall retain and make available to OIG, upon request, copies of all Arrangements subject to this Section and, to the extent available, all nonprivileged communications related to the Arrangements and the actual performance of the duties under the Arrangements. Nothing in this CIA, or any other communication or report made pursuant to this CIA, shall constitute a waiver by Catskill of its attorney-client, attorney-work-product, or other applicable privileges. Notwithstanding that fact, the existence of any such privilege shall not be used by Catskill to avoid its obligations to comply with the provisions of this CIA.

E. Disclosure Program.

Catskill represents to OIG that it has established a Disclosure Program that includes a mechanism (e.g., a dedicated 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 Catskill'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. Catskill shall appropriately publicize the existence of the disclosure mechanism (e.g., via periodic e-mails to employees or by posting the information in prominent common areas).

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

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

F. Ineligible Persons.

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

2. *Screening Requirements.* Catskill shall ensure that all owners, officers, directors, employees, contractors, and agents of Catskill, as well as Catskill’s physicians with staff privileges, are not Ineligible Persons. To ensure that such persons are not Ineligible Persons, Catskill shall screen such persons prior to engaging their services by: (a) requiring such persons to disclose whether they are Ineligible Persons; and (b) appropriately querying the General Services Administration’s List of Parties Excluded from Federal Programs (available through the Internet at <http://epls.arnet.gov>) and the HHS/OIG List of Excluded Individuals/Entities (available through the Internet at <http://oig.hhs.gov>) (these lists shall hereinafter be referred to as the “Exclusion Lists”).

Nothing in this Section affects the responsibility of (or liability for) Catskill to refrain from billing Federal health care programs for services of the Ineligible Person.

3. *Review and Removal Requirement.* Within 120 days after the Effective Date, Catskill shall review its list of the persons identified in Section III.F.2 against the Exclusion Lists. Thereafter, Catskill shall review its list of such persons against the Exclusion Lists annually. In addition, Catskill shall require such persons to disclose immediately any debarment, exclusion, suspension, or other event that makes such person an Ineligible Person.

If Catskill has actual notice that such person has become an Ineligible Person, Catskill shall remove such person from responsibility for, or involvement with, Catskill's business operations related to the Federal health care programs and shall remove such person from any position for which the person's compensation or the items or services 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 Catskill has actual notice that a person identified in Section III.F.2 is charged with a criminal offense related to any Federal health care program, or is proposed for exclusion during his or her employment, involvement, or contract term, or in the case of physician, during the term of the physician's medical staff privileges, Catskill shall take all appropriate actions to ensure that the responsibilities of that person have not and shall not adversely affect the quality of care rendered to any beneficiary, patient, or resident, or the accuracy of any claims submitted to any Federal health care program.

G. Notification of Government Investigation or Legal Proceedings.

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

H. Reporting.

1. *Overpayments*

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

b. Reporting of Overpayments. If, at any time, Catskill identifies or learns of any Overpayment, Catskill shall notify the payor (e.g., Medicare fiscal intermediary or carrier) within 30 days after identification of the Overpayment and take remedial steps within 60 days after identification (or such additional time as may be agreed to by the payor) to correct the problem, including preventing the underlying problem and the Overpayment from recurring. Also, within 30 days after identification of the Overpayment, Catskill shall repay the Overpayment to the appropriate payor to the extent such Overpayment has been quantified. If not yet quantified, within 30 days after identification, Catskill shall notify the payor of its efforts to quantify the Overpayment amount along with a schedule of when such work is expected to be completed. Notification and repayment to the payor shall be done in accordance with the payor’s policies, and for Medicare contractors, shall include the information contained on the Overpayment Refund Form, provided as Appendix A to this CIA. Notwithstanding the above, notification and repayment of any Overpayment amount that routinely is reconciled or adjusted pursuant to policies and procedures established by the payor should be handled in accordance with such policies and procedures.

2. *Reportable Events.*

a. 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 probable violation of criminal, civil, or administrative laws applicable to any Federal health care program for which penalties or exclusion may be authorized.

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

b. Reporting of Reportable Events. If Catskill determines through any means that there is a Reportable Event, Catskill shall notify OIG, in writing, within 30 days after making the determination that the Reportable Event exists. The report to OIG shall include the following information:

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

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

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

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

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

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

IV. NEW BUSINESS UNITS OR LOCATIONS

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

V. ANNUAL REPORTS

A. Annual Reports. Catskill shall submit to OIG Annual Reports with respect to the status of, and findings regarding, Catskill's compliance activities for each of the five Reporting Periods.

Each Annual Report shall include:

1. any change in the identity, position description, or other noncompliance job responsibilities of the Compliance Officer and any change in the membership of the Compliance Committee described in Section III.A;
2. a copy of Catskill's Code of Conduct required by Section III.B.1, to the extent not already provided;
3. a certification by the Compliance Officer that:
 - a. all Covered Persons have completed any Code of Conduct certifications required by Section III.B.1;
 - b. all Covered Persons have completed the applicable training and executed the certification(s) required by Section III.C;
 - c. Catskill has complied with its obligations under the Settlement Agreement: (i) not to resubmit to any Federal health care program

payors any previously denied claims related to the Covered Conduct addressed in the Settlement Agreement, and not to appeal any such denials of claims; (ii) not to charge to or otherwise seek payment from Federal or State payors for unallowable costs (as defined in the Settlement Agreement); and (iii) to identify and adjust any past charges or claims for unallowable costs; and

d. the Policies and Procedures required by Section III.B have been developed, are being implemented, and have been distributed to all appropriate Covered Persons.

The documentation supporting this certification shall be available to OIG, upon request during the term of this CIA.

4. a copy of all Policies and Procedures required by Section III.B.2, to the extent not already provided. Subsequent Annual Reports shall include a summary of any significant changes or amendments to the Policies and Procedures required by Section III.B and the reasons for such changes (e.g., change in contractor policy) and copies of any compliance-related Policies and Procedures;

5. a copy of all training materials used for the training required by Section III.C, a description of such training conducted during the Reporting Period, including a description of the targeted audiences, length of sessions, which sessions were mandatory and for whom, percentage of attendance, and a schedule of when the training sessions were held;

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

7. 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;

8. a summary of the disclosures in the disclosure log required by Section III.E that: (a) relate to the provision of items or services that are reimbursable under the Federal health care programs, regardless of the identity of the individual or entity that may seek such reimbursement; or (b) allege violations of Applicable Guidance and Requirements;
9. a description of any personnel actions (other than hiring) taken by Catskill as a result of the obligations in Section III.F, and the name, title, and responsibilities of any person who is determined to be an Ineligible Person under Section III.F., and the actions taken in response to the obligations set forth in that Section;
10. 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;
11. the information required by Section III.D, in the form provided at Appendix B;
12. a list of all of Catskill's locations (including locations and mailing addresses), the corresponding name under which each location is doing business, the corresponding phone numbers and fax numbers, each location's Medicare provider identification number(s), and the name and address of the Medicare contractor to which Catskill currently submits claims. Subsequent Annual Reports shall include any changes to this list; and
13. the certification required by Section V.B.

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.

B. Certifications. The Annual Reports shall include a certification by the Compliance Officer that: (1) to the best of his or her knowledge, except as otherwise described in the applicable report, Catskill is in compliance with all of the requirements

of this CIA; 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.

C. Designation of Information. Catskill 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 (and related regulations). Catskill shall refrain from identifying any information as exempt from disclosure if that information does not meet the criteria for exemption from disclosure under FOIA (and related regulations).

VI. NOTIFICATIONS AND SUBMISSION OF REPORTS

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

OIG:

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

Catskill:

Marc Mendelsohn
Compliance Officer
P.O. Box 800
68 Harris Bushville Road
Harris, NY 12742-0800
Telephone: 845-794-3300 x 2074
Facsimile: 845-794-6973

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 Catskill's books, records, and other documents and supporting materials and/or conduct on-site reviews of any of Catskill's locations for the purpose of verifying and evaluating: (a) Catskill's compliance with the terms of this CIA; and (b) Catskill's compliance with the requirements of the Federal health care programs in which it participates. The documentation described above shall be made available by Catskill to OIG or its duly authorized representative(s) at all reasonable times for inspection, audit, or reproduction consistent with all of Catskill's rights. Furthermore, for purposes of this provision and during the term of this CIA, OIG or its duly authorized representative(s) may interview any of Catskill's employees, contractors, or agents who consent to be interviewed (and consistent with such individual's or entity's legal rights, including the right to counsel) 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. Catskill shall assist OIG or its duly authorized representative(s) in contacting and arranging interviews with such individuals upon OIG's request. Catskill's employees may elect to be interviewed with or without a representative of Catskill present.

VIII. DOCUMENT AND RECORD RETENTION

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

IX. DISCLOSURES

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

shall have the rights set forth at 45 C.F.R. § 5.65(d) or in other applicable laws and regulations.

X. BREACH AND DEFAULT PROVISIONS

Catskill 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, Catskill 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 Catskill fails to have in place any of the obligations described in Section III:

- a. a Compliance Officer;
- b. a Compliance Committee;
- c. a written Code of Conduct;
- d. written Policies and Procedures;
- e. a requirement that Covered Persons be trained; and
- f. a Disclosure Program.

2. A Stipulated Penalty of \$2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day Catskill fails to meet any of the deadlines (including any revised deadlines) for the submission of the Annual Reports to OIG unless a request for an extension has been timely submitted and granted pursuant to Section X.B, below.

3. A Stipulated Penalty of \$2,000 (which shall begin to accrue on the date the failure to comply began) for each day Catskill employs or contracts with or grants staff privileges to an Ineligible Person and that person: (a) has responsibility for, or

involvement with, Catskill's business operations related to the Federal health care programs; or (b) 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 (if the Ineligible Person is a physician with staff privileges at Catskill, then the Stipulated Penalty shall accrue for each day that the Ineligible Person provided, ordered, or prescribed any items or services at Catskill that were payable in whole or in part by any Federal health care program) (the Stipulated Penalty described in this Subsection shall not be demanded for any time period during which Catskill 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).

4. A Stipulated Penalty of \$1,500 for each day Catskill fails to grant access to the information or documentation as required in Section VII. (This Stipulated Penalty shall begin to accrue on the date Catskill fails to grant access.)

5. A Stipulated Penalty of \$5,000 for each false certification submitted by or on behalf of Catskill as part of any Annual Report, additional documentation to a report (as requested by the OIG), or otherwise required by this CIA.

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

B. Timely Written Requests for Extensions. Catskill 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 Catskill 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 Catskill

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 Catskill 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 Catskill of: (a) Catskill's failure to comply; and (b) 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 after the receipt of the Demand Letter, Catskill 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 Catskill elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until Catskill cures, to OIG's satisfaction, the alleged breach in dispute. Failure to respond to the Demand Letter in one of these two manners within the allowed time period shall be considered a material breach of this CIA and shall be grounds for exclusion under Section X.D.

3. *Form of Payment.* Payment of the Stipulated Penalties shall be made by certified or cashier's check, payable to: "Secretary of the Department of Health and Human Services," and submitted to OIG at the address set forth in Section VI.

4. *Independence from Material Breach Determination.* Except as set forth in Section X.D.1.c, these provisions for payment of Stipulated Penalties shall not affect or otherwise set a standard for OIG's decision that Catskill has materially breached this CIA, which decision shall be made at OIG's discretion and shall be governed by the provisions in Section X.D, below.

D. Exclusion for Material Breach of this CIA.

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

- a. a failure by Catskill to report a Material Deficiency, take corrective action, and make the appropriate refunds, as required in Section III.H;
- b. a repeated or flagrant violation of the obligations under this CIA, including, but not limited to, the obligations addressed in Section X.A; or
- c. a failure to respond to a Demand Letter concerning the payment of Stipulated Penalties in accordance with Section X.C.

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

3. *Opportunity to Cure.* Catskill 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. Catskill 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) Catskill has begun to take action to cure the material breach; (ii) Catskill is pursuing such action with due diligence; and (iii) Catskill has provided to OIG a reasonable timetable for curing the material breach.

4. *Exclusion Letter.* If, at the conclusion of the 30-day period, Catskill fails to satisfy the requirements of Section X.D.3, OIG may exclude Catskill from participation in the Federal health care programs. OIG shall notify Catskill in writing of its determination to exclude Catskill (this letter shall be referred to hereinafter as the

“Exclusion Letter”). Subject to the Dispute Resolution provisions in Section X.E, below, the exclusion shall go into effect 30 days after the date of the Exclusion Letter. The exclusion shall have national effect and shall also apply to all other Federal procurement and nonprocurement programs. Reinstatement to program participation is not automatic. After the end of the period of exclusion, Catskill 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 Catskill 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, Catskill 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 Chapter 42 of the Code of Federal Regulations, the only issues in a proceeding for Stipulated Penalties under this CIA shall be: (a) whether Catskill was in full and timely compliance with the obligations of this CIA for which OIG demands payment; and (b) the period of noncompliance. Catskill 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 Catskill to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable 20 days after the ALJ issues such a decision unless Catskill requests review of the ALJ decision by the DAB. If the ALJ decision is properly appealed to the DAB and the DAB upholds the determination of OIG, the Stipulated Penalties shall become due and payable 20 days after the DAB issues its decision.

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

- a. whether Catskill 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) Catskill had begun to take action to cure the material breach within that period; (ii) Catskill has pursued and is pursuing such action with due diligence; and (iii) Catskill provided to OIG within that period a reasonable timetable for curing the material breach and Catskill 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 Catskill, only after a DAB decision in favor of OIG. Catskill's election of its contractual right to appeal to the DAB shall not abrogate OIG's authority to exclude Catskill 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 Catskill 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. Catskill 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 Catskill, Catskill shall be reinstated effective on the date of the original exclusion.

XI. EFFECTIVE AND BINDING AGREEMENT

Consistent with the provisions in the Settlement Agreement pursuant to which this CIA is entered, and into which this CIA is incorporated, Catskill and OIG agree as follows:

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

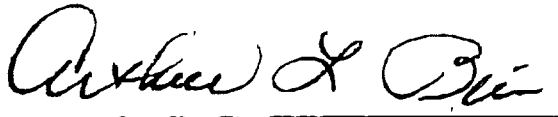
B. This CIA shall become final and binding on the date the final signature is obtained on the CIA;

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

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

E. The undersigned Catskill 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.

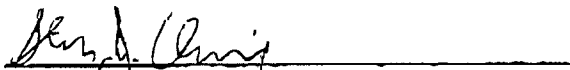
ON BEHALF OF CATSKILL REGIONAL MEDICAL CENTER



ARTHUR L. BRIEN
President and CEO

5/11/04

DATE

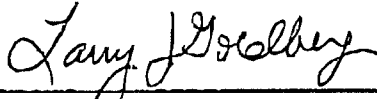


STEVEN J. CHANANIE
Counsel for Catskill Regional Medical Center

5/7/04

DATE

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



LARRY J. GOLDBERG
Assistant Inspector General for Legal Affairs
Office of Counsel to the Inspector General

10 May 2007
DATE

OVERPAYMENT REFUND

TO BE COMPLETED BY MEDICARE CONTRACTOR

Date: _____
 Contractor Deposit Control # _____ Date of Deposit: _____
 Contractor Contact Name: _____ Phone # _____
 Contractor Address: _____
 Contractor Fax: _____

TO BE COMPLETED BY PROVIDER/PHYSICIAN/SUPPLIER

Please complete and forward to Medicare Contractor. This form, or a similar document containing the following information, should accompany every voluntary refund so that receipt of check is properly recorded and applied.

PROVIDER/PHYSICIAN/SUPPLIER NAME _____
 ADDRESS _____
 PROVIDER/PHYSICIAN/SUPPLIER # _____ CHECK NUMBER# _____
 CONTACT PERSON: _____ PHONE # _____
 AMOUNT OF CHECK \$ _____ CHECK DATE _____

REFUND INFORMATION

For each Claim, provide the following:

Patient Name _____ HIC # _____
 Medicare Claim Number _____ Claim Amount Refunded \$ _____
 Reason Code for Claim Adjustment: _____ (Select reason code from list below. Use one reason per claim)

(Please list all claim numbers involved. Attach separate sheet, if necessary)

Note: If Specific Patient/HIC/Claim #/Claim Amount data not available for all claims due to Statistical Sampling, please indicate methodology and formula used to determine amount and reason for overpayment: _____

For Institutional Facilities Only:

Cost Report Year(s) _____
 (If multiple cost report years are involved, provide a breakdown by amount and corresponding cost report year.)

For OIG Reporting Requirements:

Do you have a Corporate Integrity Agreement with OIG? Yes No

Reason Codes:

<u>Billing/Clerical Error</u>	<u>MSP/Other Payer Involvement</u>	<u>Miscellaneous</u>
01 - Corrected Date of Service	08 - MSP Group Health Plan Insurance	13 - Insufficient Documentation
02 - Duplicate	09 - MSP No Fault Insurance	14 - Patient Enrolled in an HMO
03 - Corrected CPT Code	10 - MSP Liability Insurance	15 - Services Not Rendered
04 - Not Our Patient(s)	11 - MSP, Workers Comp.(Including Black Lung	16 - Medical Necessity
05 - Modifier Added/Removed	12 - Veterans Administration	17 - Other (Please Specify)
06 - Billed in Error		
07 - Corrected CPT Code		

