

UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF NEW YORK

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UNITED STATES OF AMERICA, ex rel.  
JOHN F. REILLY,

Plaintiff,

00 Civ. 7906 (KMW)

-against -

CATSKILL REGIONAL MEDICAL CENTER  
f/k/a COMMUNITY GENERAL HOSPITAL  
OF SULLIVAN COUNTY, et al.,

SETTLEMENT AGREEMENT  
BETWEEN THE UNITED STATES,  
THE MOUNT VERNON HOSPITAL,  
AND RELATOR

Defendants.

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I. PARTIES

This Settlement Agreement ("Agreement") is entered into among the United States of America, acting through the United States Department of Justice and on behalf of the Office of Inspector General ("OIG-HHS") of the Department of Health and Human Services ("HHS") (collectively the "United States"), The Mount Vernon Hospital ("MVH"), and John F. Reilly (the "Relator") (hereafter referred to collectively as "the Parties"), through their authorized representatives.

II. PREAMBLE

As a preamble to this Agreement, the Parties agree to the following:

A. MVH is a New York not-for-profit corporation with facilities located at 12 North Seventh Avenue, Mt. Vernon, New York 10550, which is within the Southern District of New York. MVH is licensed to operate a hospital by the New York State Department of

Health ("DOH") and is approved to participate in the Medicaid program, 42 U.S.C. §§ 1396-1396v ("Medicaid").

B. John F. Reilly, the Relator, was at all relevant times an individual resident of the State of New York. On October 17, 2000, the Relator filed a complaint (the "Relator's Complaint") under the qui tam provisions of the False Claims Act, 31 U.S.C. §§ 3729-3733 (the "False Claims Act") in the United States District Court for the Southern District of New York under docket number 00 Civ. 7906 (KMW) (hereinafter "the Civil Action"). At the time, the Relator was an employee of A.R.E.B.A.-Casriel, Inc. ("ACI"), an entity affiliated with Applied CaseManagement, Inc. ("Applied"), with which MVH had entered into an "administrative services agreement" for the provision of services related to MVH's medical detoxification unit. The United States is simultaneously intervening in part in the Civil Action and filing a complaint (the "United States' Complaint") against MVH and Applied under the qui tam provisions of the False Claims Act.

C. The United States contends that it has certain civil claims, as specified in Paragraph 2 below, against MVH for engaging in the following alleged conduct, which MVH denies: (1) during the period from January 1, 1997 to December 31, 2004, MVH knowingly submitted or caused to be submitted to the United States false or fraudulent claims for payment to the Medicaid Program for alcohol and substance abuse services it provided to patients it had

obtained by paying kickbacks or other illegal remuneration to Applied to induce patient referrals; and (2) during the period from January 1, 1997 to December 31, 2004, MVH knowingly submitted or caused to be submitted to the United States false or fraudulent claims for payment to the Medicaid Program for alcohol and substance abuse detoxification services it provided to patients in a facility that was not certified by the New York State Office of Alcoholism and Substance Abuse Services ("OASAS") to provide such services, as more specifically described in the United States' Complaint (hereinafter referred to as the "Covered Conduct").

D. The United States contends also that it has certain administrative claims, as specified in Paragraph 3 below, against MVH for engaging in the Covered Conduct.

E. This Agreement is neither an admission of liability, wrongdoing, or improper conduct by MVH nor a concession by the United States that its claims are not well founded.

F. To avoid the delay, uncertainty, inconvenience, and expense of protracted litigation of the above claims, the Parties reach a full and final settlement pursuant to the Terms and Conditions below.

### III. TERMS AND CONDITIONS

1. MVH agrees to pay to the United States \$2,650,000.00 (the "Settlement Amount"), which amount shall be due and owing and payable as described below, and in the attached Amortization

Schedule (Appendix A), and agrees to entry of a judgment (in the form attached hereto as Exhibit A) against it and in favor of the United States, in full compromise and satisfaction of the allegations against it set forth in the United States' Complaint. The United States agrees to pay twenty percent (20%) of the Settlement Amount (\$530,000) to the Relator, plus interest, as provided herein. MVH further agrees to pay Relator his expenses and attorney's fees and costs, and the amount thereof has been agreed upon between Relator and MVH in a separate written agreement. The foregoing payments shall be made as follows:

a. MVH shall pay to the United States the first settlement payment on August 1, 2005 in the amount provided in the attached Amortization Schedule (Appendix A). MVH shall thereafter make quarterly payments to the United States for a period of five years in accordance with the attached Amortization Schedule (Appendix A) (which includes interest at a rate of 4.5 percent per annum, compounded daily, which interest is to begin accruing on August 1, 2005). Any such interest shall be added to and deemed to be part of the Settlement Amount as defined and used herein. MVH agrees to make each quarterly payment to the United States by electronic funds transfer pursuant to written instructions to be provided by the United States Attorney's Office for the Southern District of New York.

b. If MVH fails to comply with the payment obligations set forth in Paragraph 1.a., the United States will send written notice to MVH giving it ten (10) business days to cure the nonpayment. If after the ten (10) days, MVH fails to cure, it shall pay interest at the rate of 10% per annum, compounded daily beginning on the date the payment was due, on any balance of the Settlement Amount that remains unpaid. Once MVH becomes current with the payment schedule as described in Appendix A, the interest will revert back to 4.5 percent as set forth in this Settlement Agreement. Any such interest shall be added to and deemed to be part of the Settlement Amount as defined and used herein. If MVH still fails to comply with the payment obligations set forth in Paragraph 1.a. before the end of the month in which the payment was due, the remaining unpaid balance of the Settlement Amount shall become immediately due and payable, and the United States may exercise all statutory, common law, or equitable rights to collect such outstanding balance of the Settlement Amount, including offsetting funds owed to MVH by the United States. MVH agrees not to contest any offset imposed and not to contest any collection action undertaken by the United States in accordance with this Paragraph, either administratively or in any state or federal court, except that MVH shall retain the right to challenge only the amount of the offset or collection action undertaken by the United States. Any such amounts collected shall be deemed to be part of

the Settlement Amount as defined and used herein. The United States shall be entitled to an award of reasonable costs and attorney's fees in connection with its collection efforts. MVH may at any time pay the outstanding balance of the Settlement Amount without further payment of interest.

c. Contingent upon the United States receiving each quarterly payment from MVH and as soon as feasible after receipt, the United States agrees to pay twenty percent (20%) of each payment to relator by electronic funds transfer to the trust account of Timothy J. McInnis, Esq, f/b/o John F. Reilly, pursuant to written instructions to be provided to the United States Attorney's Office for the Southern District of New York.

2. Subject to the exceptions in Paragraph 4 below, in consideration of the obligations of MVH in this Agreement, conditioned upon MVH's full payment of the Settlement Amount, plus interest as set forth above, and subject to Paragraph 18 below (concerning bankruptcy proceedings commenced within 91 days of any payment under this Agreement), the United States (on behalf of itself, its officers, agents, agencies, and departments), fully and finally releases MVH, together with its current and former parent corporations, including Sound Shore Health Systems, Inc., each of its direct and indirect subsidiaries and brother or sister corporations, including Sound Shore Medical Center of Westchester, and together with its current and former officers, agents,

servants, and employees from any civil or administrative monetary claim the United States has or may have under the False Claims Act, 31 U.S.C. §§ 3729-3733; the Civil Monetary Penalties Law, 42 U.S.C. § 1320a-7a; the Program Fraud Civil Remedies Act, 31 U.S.C. §§ 3801-3812; and the Stark Law, 42 U.S.C. § 1395nn, the Federal Health Care Program Antikickback Statute, 42 U.S.C. § 1320a-7b(b), New York State Social Services Law § 366-d and applicable regulations, and other state statutes and regulations cited in the Complaint of the United States, as they may be enforced under the False Claims Act; and the common law theories of payment by mistake, unjust enrichment, and fraud.

3. In consideration of the obligations of MVH in this Agreement and the Corporate Integrity Agreement ("CIA"), incorporated by reference and attached as Exhibit B, and conditioned upon MVH's full payment of the Settlement Amount, plus interest as set forth above, and subject to Paragraph 18 below (concerning bankruptcy proceedings commenced within 91 days of any payment under this Agreement), the OIG-HHS agrees to release and refrain from instituting, directing, or maintaining any administrative action seeking exclusion from the Medicare, Medicaid, and other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)) against MVH under 42 U.S.C. § 1320a-7a (Civil Monetary Penalties Law) or 42 U.S.C. § 1320a-7(b)(7) (permissive exclusion for fraud, kickbacks, and other prohibited activities)

for the Covered Conduct, except as reserved in Paragraph 4 below, and as reserved in this Paragraph. The OIG-HHS expressly reserves all rights to comply with any statutory obligations to exclude MVH from the Medicare, Medicaid, and other Federal health care programs under 42 U.S.C. § 1320a-7(a) (mandatory exclusion) based upon the Covered Conduct. Nothing in this Paragraph precludes the OIG-HHS from taking action against entities or persons, or for conduct and practices, for which claims have been reserved in Paragraph 4 below.

4. Notwithstanding any term of this Agreement, specifically reserved and excluded from the scope and terms of this Agreement as to any entity or person (including MVH and Relator) are the following claims of the United States:

a. Any civil, criminal, or administrative liability arising under Title 26, U.S. Code (Internal Revenue Code);

b. Any criminal liability;

c. Except as explicitly stated in this Agreement, any administrative liability, including mandatory exclusion from Federal health care programs;

d. Any liability to the United States (or its agencies) for any conduct other than the Covered Conduct;

e. Any liability based upon such obligations as are created by this Agreement;



f. Any liability for express or implied warranty claims or other claims for defective or deficient products or services, including quality of goods and services; and

g. Any liability for failure to deliver goods or services due.

5. Conditioned upon receipt of the payments described in Paragraph 1.c., the Relator, for himself and for his heirs, successors, attorneys, agents, and assigns, agrees to release the United States, its officers, agents, and employees, from any claims arising from or relating to 31 U.S.C. § 3730 in connection with this Civil Action, or arising from the filing of the Civil Action, including 31 U.S.C. §§ 3730(b), (c), (c)(5), (d), and (d)(1) in connection with this Civil Action. The Relator agrees and confirms that this Agreement is fair, adequate, and reasonable under all the circumstances, pursuant to 31 U.S.C. § 3730(c)(2)(B).

6. Conditioned upon receipt of the payment described in Paragraph 1, the Relator, for himself, and for his heirs, successors, attorneys, agents, and assigns, hereby forever waives, and fully and finally releases and discharges MVH, together with its current and former parent corporations, each of its direct and indirect subsidiaries and brother or sister corporations, and its current and former officers, agents, servants, and employees from any and all claims, liabilities, causes of actions, and/or suits of any kind arising out of any actions, events, or conduct that

predate this Agreement, except for any claims under 31 U.S.C. § 3730(d) for expenses or attorney's fees and costs, which costs are referenced above in Paragraph 1.

7. In consideration of the Relator's execution of this Agreement and Relator's release of MVH provided hereunder, MVH, on behalf of itself, together with its current and former parent corporations, each of its direct and indirect subsidiaries and brother or sister corporations, hereby forever waives, and fully and finally releases the Relator, his heirs, attorneys, agents, successors, and assigns, from any claims, liabilities, causes of action, and/or suits of any kind arising out of any actions, events or conduct that predate this Agreement, including without limitation any claims arising under 31 U.S.C. § 3730(d)(4).

8. MVH has entered into a CIA with OIG-HHS, attached as Exhibit B, which is incorporated into this Agreement by reference. MVH shall immediately upon execution of the CIA implement its obligations under that CIA, subject to the timelines set forth in the CIA.

9. MVH has provided sworn financial disclosure statements to the United States and the United States has relied on the accuracy and completeness of those Financial Statements in reaching this Agreement. Specifically, MVH has provided the United States with its audited financial statements for years 1999 through 2004, its IRS Form 990 (Return of Organization Exempt from Income

Tax) for those years, as well as various cash flow statements and projections, cash receipts reports, operating budgets with explanations, accounts payable aging reports, accounts receivable reports, and other financial documents (the "Financial Statements"). If the United States learns of asset(s) in which MVH had an interest at the time of this Agreement that were not disclosed in the Financial Statements, or if the United States learns of any material misrepresentation by MVH on, or in connection with, the Financial Statements, and if such nondisclosure or misrepresentation changes the estimated net worth set forth in the Financial Statements by \$265,000 or more, the United States may at its option (a) rescind this Agreement and reinstate its suit based on the Covered Conduct, or (b) let the Agreement stand and collect the full Settlement Amount plus one hundred percent (100%) of the value of the net worth of MVH previously undisclosed. Any such payment pursuant to this provision shall be deemed to be part of the Settlement Amount as defined and used herein. Further, any amounts paid by MVH to the date of the United States' rescision shall be credited toward any recovery in a future suit for the Covered Conduct. MVH agrees not to contest any collection action undertaken by the United States pursuant to this provision.

10. In the event that the United States, pursuant to Paragraph 9 above, opts to rescind this Agreement, MVH agrees not

to plead, argue, or otherwise raise any defenses under the theories of statute of limitations, laches, estoppel, or similar theories, to any civil or administrative claims which (a) are filed by the United States within ninety (90) calendar days of written notification to MVH that this Agreement has been rescinded, and (b) relate to the Covered Conduct, except to the extent these defenses were available prior to October 17, 2000.

11. MVH waives and shall not assert any defenses MVH may have to any criminal prosecution or administrative action relating to the Covered Conduct, which defenses may be based in whole or in part on a contention that, under the Double Jeopardy Clause in the Fifth Amendment of the Constitution, or under the Excessive Fines Clause in the Eighth Amendment of the Constitution, this Agreement bars a remedy sought in such criminal prosecution or administrative action. Nothing in this Paragraph or any other provision of this Agreement constitutes an agreement by the United States concerning the characterization of the Settlement Amount for purposes of the Internal Revenue laws, Title 26 of the United States Code.

12. MVH fully and finally releases the United States, its agencies, employees, servants, and agents from any claims (including attorney's fees, costs, and expenses of every kind and however denominated) which MVH has asserted, could have asserted, or may assert in the future against the United States, its

agencies, employees, servants, and agents, related to the Covered Conduct and the United States' investigation and prosecution thereof.

13. The Settlement Amount shall not be decreased as a result of the denial of claims for payment now being withheld from payment by any Medicare carrier or intermediary, or any State payer, related to the Covered Conduct; and MVH shall not resubmit to any Medicare carrier or intermediary, or any State payer any previously denied claims related to the Covered Conduct, and shall not appeal any such denials of claims.

14. MVH agrees to the following:

a. Unallowable Costs Defined: that all costs (as defined in the Federal Acquisition Regulation, 48 C.F.R. § 31.205-47 and in Titles XVIII and XIX of the Social Security Act, 42 U.S.C. §§ 1395-1395ggg and 1396-1396v, and the regulations and official program directives promulgated thereunder) incurred by or on behalf of MVH, its present or former officers, directors, employees, shareholders, and agents in connection with the following shall be "unallowable costs" on government contracts and under the Medicare Program, Medicaid program, TRICARE Program, and Federal Employees Health Benefits Program ("FEHBP"):

(1) the matters covered by this Agreement,

(2) the United States' audit(s) and civil and any criminal investigation(s) of the matters covered by this Agreement,

(3) MVH's investigation, defense, and corrective actions undertaken in response to the United States' audit(s) and civil and any criminal investigation(s) in connection with the matters covered by this Agreement (including attorney's fees),

(4) the negotiation and performance of this Agreement,

(5) the payments MVH makes to the United States pursuant to this Agreement and any payments that MVH may make to Relator, including expenses, costs and attorneys fees, and

(6) the negotiation of, and obligations undertaken pursuant to the CIA to:

(i) Retain an independent review organization to perform annual reviews as described in Section III of the CIA; and

(ii) prepare and submit reports to the OIG-HHS.

However, nothing in this Paragraph 14.a.(6) that may apply to the obligations undertaken pursuant to the CIA affects the status of costs that are not allowable based on any other authority

applicable to MVH. (All costs described or set forth in this Paragraph 14.a. are hereafter, "unallowable costs").

b. Future Treatment of Unallowable Costs: If applicable, these unallowable costs shall be separately determined and accounted for in nonreimbursable cost centers by MVH, and MVH shall not charge such unallowable costs directly or indirectly to any contracts with the United States or any state Medicaid program, or seek payment for such unallowable costs through any cost report, cost statement, information statement, or payment request submitted by MVH or any of its subsidiaries or affiliates to the Medicare, Medicaid, TRICARE, or FEHBP Programs.

c. Treatment of Unallowable Costs Previously Submitted for Payment: If applicable, MVH further agrees that within 90 days of the Effective Date of this Agreement it shall identify to applicable Medicare and TRICARE fiscal intermediaries, carriers, and/or contractors, and Medicaid and FEHBP fiscal agents, any unallowable costs (as defined in this Paragraph) included in payments previously sought from the United States, or any state Medicaid program, including, but not limited to, payments sought in any cost reports, cost statements, information reports, or payment requests already submitted by MVH or any of its subsidiaries or affiliates, and will request, and agree, that such cost reports, cost statements, information reports, or payment requests, even if already settled, be adjusted to account for the effect of the

inclusion of the unallowable costs. MVH agrees that the United States, at a minimum, shall be entitled to recoup from MVH any overpayment plus applicable interest and penalties as a result of the inclusion of such unallowable costs on previously-submitted cost reports, information reports, cost statements, or requests for payment.

Any payments due after the adjustments have been made shall be paid to the United States pursuant to the direction of the Department of Justice, and/or the affected agencies. The United States reserves its rights to disagree with any calculations submitted by MVH or any of its subsidiaries or affiliates on the effect of inclusion of unallowable costs (as defined in this Paragraph) on MVH or any of its subsidiaries' or affiliates' cost reports, cost statements, information reports, or requests for payment.

d. Nothing in this Agreement shall constitute a waiver of the rights of the United States to audit, if any, examine or re-examine MVH's books and records to determine that no unallowable costs have been claimed in accordance with the provisions of this Paragraph.

15. MVH agrees to cooperate fully and truthfully with the United States' investigation of individuals and entities not released in this Agreement. Upon reasonable notice, MVH shall make reasonable efforts to facilitate access to, and encourage the



cooperation of, its directors, officers, and employees for interviews and testimony, consistent with the rights and privileges of such individuals, and shall furnish to the United States, upon reasonable request, and as otherwise permitted by applicable law or regulation, all nonprivileged documents and records in its possession, custody, or control relating to the Covered Conduct.

16. MVH waives and shall not seek payment for any of the health care billings covered by this Agreement from any health care beneficiaries or their parents, sponsors, legally responsible individuals, or third party payors based upon the claims defined as Covered Conduct.

17. MVH has reviewed its financial statements and projections and warrants that it has no present intention of commencing, and has no reason to believe that any third party intends to commence, any case, proceeding, or other action under any law relating to bankruptcy, insolvency, reorganization, or relief of debtors (a) seeking to have any order for relief of MVH's debts, or seeking to adjudicate MVH as bankrupt or insolvent; or (b) seeking appointment of a receiver, trustee, custodian, or other similar official for MVH or for all or any substantial part of MVH's assets; MVH intends to remain in operation at least through the term of this Agreement. Further, the Parties warrant that, in evaluating whether to execute this Agreement, they (a) have intended that the mutual promises, covenants, and obligations set

forth constitute a contemporaneous exchange for new value given to MVH, within the meaning of 11 U.S.C. § 547(c)(1); and (b) conclude that these mutual promises, covenants, and obligations do, in fact, constitute such a contemporaneous exchange. Further, the Parties warrant that the mutual promises, covenants, and obligations set forth herein are intended and do, in fact, represent a reasonably equivalent exchange of value that is not intended to hinder, delay, or defraud any entity to which MVH was or became indebted to on or after the date of this transfer, all within the meaning of 11 U.S.C. § 548(a)(1).

18. If within 91 days of the Effective Date of this Agreement or of any payment made hereunder, MVH commences, or a third party commences, any case, proceeding, or other action under any law relating to bankruptcy, insolvency, reorganization, or relief of debtors, (a) seeking to have any order for relief of MVH's debts, or seeking to adjudicate MVH as bankrupt or insolvent; or (b) seeking appointment of a receiver, trustee, custodian, or other similar official for MVH or for all or any substantial part of MVH's assets, MVH agrees as follows:

a. MVH's obligations under this Agreement may not be avoided pursuant to 11 U.S.C. §§ 547 and 548, and MVH shall not argue or otherwise take the position in any such case, proceeding, or action that: (1) MVH's obligations under this Agreement may be avoided under 11 U.S.C. §§ 547 and 548; (2) MVH was insolvent at

the time this Agreement was entered into, or became insolvent as a result of any payment made to the United States; or (3) the mutual promises, covenants, and obligations set forth in this Agreement do not constitute a contemporaneous exchange for new value given to MVH.

b. If MVH's obligations under this Agreement are avoided for any reason, including, but not limited to, the exercise of a trustee's avoidance powers under the Bankruptcy Code, the United States, at its sole option, may rescind the releases in this Agreement, and bring any civil and/or administrative claim, action, or proceeding against MVH for the claims that would otherwise be covered by the releases provided in Paragraphs 2 and 3 above. MVH agrees that (1) any such claims, actions, or proceedings brought by the United States (including any proceedings to exclude MVH from participation in Medicare, Medicaid, or other Federal health care programs) are not subject to an "automatic stay" pursuant to 11 U.S.C. § 362(a) as a result of the action, case, or proceeding described in the first clause of this Paragraph, and that MVH shall not argue or otherwise contend that the United States' claims, actions, or proceedings are subject to an automatic stay; (2) MVH shall not plead, argue, or otherwise raise any defenses under the theories of statute of limitations, laches, estoppel, or similar theories, to any such civil or administrative claims, actions, or proceeding which are brought by the United States within ninety

(90) calendar days of written notification to MVH that the releases have been rescinded pursuant to this Paragraph, except to the extent such defenses were available on October 17, 2000; and (3) the United States shall have a valid claim against MVH in the amount of \$4,500,000.00 (reduced by any payments made under this Agreement), and the United States may pursue its claim in the case, action, or proceeding referenced in the first clause of this Paragraph, as well as in any other case, action, or proceeding.

c. MVH acknowledges that its agreements in this Paragraph are provided in exchange for valuable consideration provided in this Agreement.

19. This Agreement is intended to be for the benefit of the Parties only. The Parties do not release any claims against any other person or entity, except to the extent provided for in Paragraphs 2 and 3, and 5-7, above.

20. Except as expressly provided to the contrary in this Agreement, each Party shall bear its own legal and other costs incurred in connection with this matter, including the preparation and performance of this Agreement.

21. MVH represents that this Agreement is freely and voluntarily entered into without any degree of duress or compulsion whatsoever.

22. Relator represents that this Agreement is freely and voluntarily entered into upon the advice of counsel and without any degree of duress or compulsion whatsoever.

23. This Agreement is governed by the laws of the United States. The Parties agree that the exclusive jurisdiction and venue for any dispute arising between and among the Parties under this Agreement shall be the United States District Court for the Southern District of New York, except that disputes arising under the CIA shall be resolved exclusively under the dispute resolution provisions in the CIA.

24. This Agreement and the CIA which is incorporated herein by reference constitute the complete agreement between the Parties, provided however, that the Relator's costs and attorneys fees have been resolved separately in the agreement referenced in Paragraph 1. This Agreement may not be amended except by written consent of the Parties, except that only MVH and OIG-HHS must agree in writing to modification of the CIA.

25. The individuals signing this Agreement on behalf of MVH represent and warrant that they are authorized by MVH to execute this Agreement. The individual(s) signing this Agreement on behalf of the Relator represent and warrant that they are authorized by the Relator to execute this Agreement. The United States signatories represent that they are signing this Agreement

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

26. This Agreement may be executed in counterparts, each of which constitutes an original and all of which constitute one and the same agreement.

27. This Agreement is binding on MVH and its successors, transferees, heirs and assigns.

28. All Parties consent to the United States' disclosure of this Agreement, and information about this Agreement, to the public.

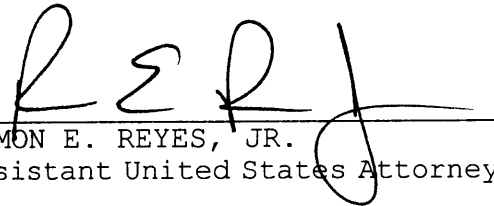
29. Upon receipt of the first payments described in Paragraph 1.a. and 1.c. above, the United States and the Relator shall promptly sign and file in the Civil Action a Joint Stipulation of Dismissal with prejudice of the Civil Action as to MVH pursuant to the terms of the Agreement. The Court shall retain jurisdiction to enforce this Agreement.

30. This Agreement is effective on the date that the Court so orders it (the "Effective Date"). Facsimiles of signatures shall constitute acceptable, binding signatures for purposes of this Agreement.


THE UNITED STATES OF AMERICA

DAVID N. KELLEY  
United States Attorney for the  
Southern District of New York

DATED: 7/26/05

BY:   
RAMON E. REYES, JR.  
Assistant United States Attorney

DATED: 7/8/05

BY:   
LEWIS MORRIS  
Chief Counsel to the Inspector  
General  
Office of Counsel to the  
Inspector General  
Office of Inspector General  
U.S. Department of Health and  
Human Services

THE MOUNT VERNON HOSPITAL

DATED: 7-8-2005

BY:   
JOHN R. SPICER  
President and Chief Executive Officer

DATED: \_\_\_\_\_

BY: \_\_\_\_\_  
BARRY J. POLLACK  
DAVID E. FRULLA  
Collier Shannon Scott, PLLC



THE MOUNT VERNON HOSPITAL

DATED: \_\_\_\_\_

BY: \_\_\_\_\_

JOHN R. SPICER  
President and Chief Executive Officer

DATED: 7-28-05

BY:  \_\_\_\_\_

BARRY J. POLLACK  
DAVID E. FRULLA  
Collier Shannon Scott, PLLC

DATED: 07-07-2005 BY: *John F. Reilly*  
JOHN F. REILLY

DATED: 7-11-05 BY: *TJ McInnis*  
TIMOTHY J. McINNIS  
Law Office of Timothy J. McInnis  
Co-Attorney for Relator

DATED: 7/13/05 BY: *David A. Koenigsberg*  
DAVID A. KOENIGSBERG  
Menz Bonner & Komar LLP  
Co-Attorney for Relator

SO ORDERED:

*Linda M. Wood*  
UNITED STATES DISTRICT JUDGE

## Exhibit A

UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF NEW YORK

-----X  
UNITED STATES OF AMERICA, ex rel.  
JOHN F. REILLY,

Plaintiff,

00 Civ. 7906 (KMW)

-against -

CONSENT JUDGMENT AGAINST  
THE MOUNT VERNON HOSPITAL

CATSKILL REGIONAL MEDICAL CENTER  
f/k/a COMMUNITY GENERAL HOSPITAL  
OF SULLIVAN COUNTY, et al.

Defendants.

-----X

This action having been commenced by the filing of a complaint-in-intervention on July \_\_, 2005, and defendants having waived service of the summons and acknowledging receipt of the complaint,

NOW, on the signed consent of the attorney for the plaintiff and the defendants, it is hereby

ORDERED, ADJUDGED and DECREED that plaintiff have judgment against defendant The Mount Vernon Hospital in the amount of \$2,650,000 and that plaintiff have execution therefor.

Agreed and Consented to:

**For the United States of America**

Dated: New York, New York  
July \_\_, 2005

DAVID N. KELLEY  
United States Attorney

By:

\_\_\_\_\_  
RAMON E. REYES, JR.  
Assistant United States Attorney  
86 Chambers Street, 3<sup>rd</sup> Floor  
New York, New York 10007  
Tel. No.: (212) 637-2740

**For Defendant The Mount Vernon Hospital**

Dated: New York, New York  
July \_\_, 2005

COLLIER SHANNON SCOTT PLLC  
Attorneys for defendant

By: \_\_\_\_\_

BARRY J. POLLACK  
DAVID E. FRULLA  
Washington Harbour, Suite 400  
3050 K Street, NW  
Washington, DC 20007  
Tel. No.: (202) 342-8400

SO ORDERED:

\_\_\_\_\_  
UNITED STATES DISTRICT JUDGE

## Exhibit B

**CORPORATE INTEGRITY AGREEMENT  
BETWEEN THE  
OFFICE OF INSPECTOR GENERAL  
OF THE  
DEPARTMENT OF HEALTH AND HUMAN SERVICES  
AND  
THE MOUNT VERNON HOSPITAL**

**I. PREAMBLE**

The Mount Vernon Hospital (MVH) 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, MVH is entering into a Settlement Agreement with the United States, and this CIA is incorporated by reference into the Settlement Agreement.

**II. TERM AND SCOPE OF THE CIA**

A. The period of the compliance obligations assumed by MVH under this CIA shall be 5 years from the effective date of this CIA, unless otherwise specified. The effective date shall be the date on which the final signatory of this CIA executes this CIA (Effective Date). 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) MVH's final Annual Report; or (2) any additional materials submitted by MVH pursuant to OIG's request, whichever is later.

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

1. "Arrangements" shall mean every arrangement or transaction that involves, directly or indirectly, the offer, payment, solicitation, or receipt of anything of value; and is between MVH and any actual or potential source of health care business or referrals to MVH or any actual or potential

recipient of health care business or referrals from MVH. The term “source” shall mean any physician, 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.

2. “Covered Persons” includes:

- a. all owners, officers, directors, and employees of MVH;
- b. all contractors, subcontractors, agents, and other persons who provide patient care items or services or who perform billing or coding functions on behalf of MVH;
- c. all members of MVH’s medical staff.

Notwithstanding the above, this term does not include part-time or per diem employees, contractors, subcontractors, agents, and other persons who are not reasonably expected to work more than 160 hours per year, except that any such individuals shall become “Covered Persons” at the point when they work more than 160 hours during the calendar year. MVH employees working in lines of business that do not provide, support, or relate to the provision of healthcare services shall not be considered “Covered Persons.”

### **III. CORPORATE INTEGRITY OBLIGATIONS**

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

#### **A. Compliance Officer and Committee.**

1. *Compliance Officer.* Within 120 days after the Effective Date, MVH shall appoint an individual to serve as its Compliance Officer and shall maintain a Compliance Officer for the term of the CIA. The Compliance Officer shall 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 MVH, shall make periodic (at least quarterly) reports regarding compliance matters directly to the Board of Directors of MVH, and shall be authorized to report on such matters to the Board of Directors at any time. The Compliance Officer shall not be or be subordinate to the General Counsel or Chief Financial Officer. The Compliance Officer shall be responsible for monitoring the day-to-day compliance activities engaged in by MVH as well as for any reporting obligations created under this CIA.

MVH 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.* Within 120 days after the Effective Date, MVH shall appoint 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 the organization's risk areas and shall oversee monitoring of internal and external audits and investigations).

MVH 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.* Within 120 days after the Effective Date, MVH shall develop, implement, and distribute a written Code of Conduct to all Covered Persons. MVH 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. MVH'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. MVH's requirement that all of its Covered Persons shall be expected to comply with all Federal health care program requirements and with MVH's own Policies and Procedures as implemented pursuant to this Section III.B (including the requirements of this CIA);
- c. the requirement that all of MVH's Covered Persons shall be expected to report to the Compliance Officer or other appropriate individual designated by MVH suspected violations of any Federal health care program requirements or of MVH's own Policies and Procedures;
- d. the possible consequences to both MVH and Covered Persons of failure to comply with Federal health care program requirements and with MVH'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.F, and MVH's commitment to nonretaliation and to maintain, as appropriate, confidentiality and anonymity with respect to such disclosures.

Within 120 days after the Effective Date, each Covered Person shall certify, in writing, that he or she has received, read, understood, and shall abide by MVH'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.

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

2. *Policies and Procedures.* Within 120 days after the Effective Date, MVH shall implement written Policies and Procedures regarding the operation of MVH's compliance program and its compliance with Federal health care program requirements. At a minimum, the Policies and Procedures shall address:

- a. the subjects relating to the Code of Conduct identified in Section III.B.1;
- b. 42 U.S.C. § 1320a-7b(b) (Anti-Kickback Statute) and 42 U.S.C. § 1395nn (Stark Law), and the regulations and other guidance documents related to these statutes, and business or financial arrangements or contracts that generate unlawful Federal health care program business in violation of the Anti-Kickback Statute or the Stark Law; and
- c. the requirements set forth in Section III.D (Compliance with the Anti-Kickback Statute and Stark Law), including but not limited to the Arrangements Database, the internal review and approval process, and the tracking of remuneration to and from sources of health care business or referrals.

Within 150 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), MVH 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 150 days after the Effective Date, MVH shall provide at least two hours of General Training to each Covered Person. This training, at a minimum, shall explain MVH's:

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

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

2. *Arrangements Training.* Within 150 days after the Effective Date, each Covered Person involved with the development, approval, management, or review of MVH's Arrangements, as such term is defined in Section II.C of the CIA (Arrangements Covered Persons) shall receive at least three hours of Arrangements Training, in addition to the General Training required above. The Arrangements Training shall include a discussion of:

- a. Arrangements that potentially implicate the Anti-Kickback Statute or the Stark Law, as well as the regulations and other guidance documents related to these statutes;
- b. MVH's policies, procedures, and other requirements relating to Arrangements, including but not limited to the Arrangements Database, the internal review and approval process, and the tracking of remuneration to and from sources of health care business or referrals required by Section III.D of the CIA;
- c. the personal obligation of each individual involved in the development, approval, management, or review of MVH's Arrangements to know the applicable legal requirements and MVH's policies and procedures;

d. the legal sanctions under the Anti-Kickback Statute and the Stark Law; and

e. examples of violations of the Anti-Kickback Statute and the Stark Law.

New Arrangements Covered Persons shall receive this training within 30 days after the beginning of their employment or becoming Arrangements Covered Persons, or within 150 days after the Effective Date, whichever is later. An MVH employee who has completed the Arrangements Training shall review a new Arrangements Covered Person's work until such time as the new Arrangements Covered Person completes his or her Arrangements Training.

After receiving the initial Arrangements Training described in this Section, each Arrangements Covered Person shall receive at least two hours of Arrangements Training annually.

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

4. *Qualifications of Trainer.* Persons providing the training shall be knowledgeable about the subject area.

5. *Update of Training.* MVH shall annually review the training, and, where appropriate, update the training to reflect changes in Federal health care program requirements, any issues discovered during internal audits or the Arrangements Review, and any other relevant information.

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

7. *Credit for Prior Training.* For the purposes of this Section III.C, MVH shall receive credit for any General Training or Arrangements Training provided to Covered Persons and/or Arrangements Covered Persons since January 1, 2005.

D. Compliance with the Anti-Kickback Statute and Stark Law.

1. *Arrangements Procedures.* Within 120 days after the Effective Date, MVH shall create procedures reasonably designed to ensure that each existing and new or renewed Arrangement does not violate the Anti-Kickback Statute and/or the Stark Law or the regulations, directives, and guidance related to these statutes (Arrangements Procedures). These procedures shall include the following:

- a. creating and maintaining a database of all existing and new or renewed Arrangements that shall contain the information specified in Appendix A (Arrangements Database);
- b. tracking remuneration to and from all parties to Arrangements;
- c. tracking service and activity logs to ensure that parties to the Arrangement are performing the services required under the applicable Arrangement(s) (if applicable);
- d. monitoring the use of leased space, medical supplies, medical devices, equipment, or other patient care items to ensure that such use is consistent with the terms of the applicable Arrangement(s) (if applicable);
- e. establishing and implementing a written review and approval process for all Arrangements, including but not limited to a legal review by counsel with expertise in the Anti-Kickback Statute and Stark Law and appropriate documentation of all internal controls, the purpose of which is to ensure that all new and existing or renewed Arrangements do not violate the Anti-Kickback Statute and Stark Law;
- f. requiring the Compliance Officer to review the Arrangements Database, internal review and approval process, and other Arrangements Procedures on at least a quarterly basis and to provide

a report on the results of such review to the Compliance Committee;  
and

g. implementing effective responses when suspected violations of the Anti-Kickback Statute and Stark Law are discovered, including disclosing Reportable Events and quantifying and repaying Overpayments pursuant to Section III.I (Reporting) when appropriate.

2. *New or Renewed Arrangements.* Prior to entering into new Arrangements or renewing existing Arrangements, in addition to complying with the Arrangements Procedures set forth above, MVH shall comply with the following requirements (Arrangements Requirements):

a. Ensure that each Arrangement is set forth in writing and signed by MVH and the other parties to the Arrangement;

b. Include in the written agreement a requirement that all individuals who meet the definition of Covered Persons shall comply with MVH's Compliance Program, including the training related to the Anti-Kickback Statute and the Stark Law. Additionally, MVH shall provide each party to the Arrangement with a copy of its Code of Conduct and Stark Law and Anti-Kickback Statute Policies and Procedures;

c. Include in the written agreement a certification by the parties to the Arrangement that the parties shall not violate the Anti-Kickback Statute and the Stark Law with respect to the performance of the Arrangement.

3. *Records Retention and Access.* MVH shall retain and make available to OIG, upon request, the Arrangements Database and all supporting documentation of the Arrangements subject to this Section and, to the extent available, all non-privileged communications related to the Arrangements and the actual performance of the duties under the Arrangements.

E. Review Procedures.

1. *General Description.*

a. *Engagement of Independent Review Organization.* Within 120 days after the Effective Date, MVH shall engage an individual or entity (or entities), such as an accounting, auditing, law, or consulting firm (hereinafter “Independent Review Organization” or “IRO”), to perform the following reviews: (i) a review to assist MVH in assessing its compliance with the obligations pursuant to Section III.D of this Agreement (Arrangements Review), and (ii) a review to analyze whether MVH sought payment for certain unallowable costs (Unallowable Cost Review). The IRO engaged by MVH to perform the Unallowable Costs Review shall have expertise in the cost reporting requirements applicable to MVH and in the general requirements of the Federal health care program(s) from which MVH seeks reimbursement.

Each IRO shall assess, along with MVH, whether it can perform the IRO review in a professionally independent and/or objective fashion, as appropriate to the nature of the engagement, taking into account any other business relationships or other engagements that may exist. The engagement of the IRO for the Arrangements Review shall not be deemed to create an attorney-client relationship between MVH and the IRO.

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

c. *Frequency of Unallowable Cost Review.* If applicable, the IRO shall perform the Unallowable Cost Review for the first Reporting Period.

d. *Retention of Records.* The IRO and MVH shall retain and make available to OIG, upon request, all work papers, supporting



documentation, correspondence, and draft reports (those exchanged between the IRO and MVH) related to the reviews.

e. *Responsibilities and Liabilities.* Nothing in this Section III.E affects MVH's responsibilities or liabilities under any criminal, civil, or administrative laws or regulations applicable to any Federal health care program including, but not limited to, the Anti-Kickback Statute and/or the Stark Law.

2. *Arrangements Review.* The IRO shall perform a review to assess whether MVH is complying with the Arrangements Procedures and Arrangements Requirements required by Sections III.D.1 and III.D.2 of this CIA. The IRO shall randomly select a sample of 25 Arrangements that were entered into or renewed during the Reporting Period. The IRO shall assess whether MVH has implemented the Arrangements Procedures and, for each selected Arrangement, the IRO shall assess whether MVH has complied with the Arrangements Procedures and Arrangements Requirements specifically with respect to that Arrangement. The IRO's assessment shall include, but is not limited to (a) verifying that the Arrangement is listed in the Arrangements Database; (b) verifying that the Arrangement was subject to the internal review and approval process (including both a legal and business review) and obtained the necessary approvals and that such review and approval is appropriately documented; (c) verifying that the remuneration related to the Arrangement is properly tracked; (d) verifying that the service and activity logs are properly completed and reviewed (if applicable); (e) verifying that leased space, medical supplies, medical devices, and equipment, and other patient care items are properly monitored (if applicable); (f) verifying that the Compliance Officer is reviewing the Arrangements Database, internal review and approval process, and other Arrangements Procedures on a quarterly basis and reporting the results of such review to the Compliance Committee; (g) verifying that effective responses are being implemented when violations of the Anti-Kickback Statute and Stark Law are discovered; and (h) verifying that the MVH has met the requirements of Section III.D.2.

3. *Arrangements Review Report.* The IRO shall prepare a report based upon the Arrangements Review performed (Arrangements Review Report). The Arrangements Review Report shall include the IRO's findings with respect to (a) whether MVH has generally implemented the Arrangements Procedures described in Section III.D.1; and (b) specific findings as to whether MVH has complied with the Arrangements Procedures and Arrangements Requirements with respect to each of the

randomly selected Arrangements reviewed by the IRO. In addition, the Arrangements Review Report shall include any observations, findings and recommendations on possible improvements to MVH's policies, procedures, and systems in place to ensure that all Arrangements do not violate the Anti-Kickback Statute and Stark Law.

4. *Unallowable Cost Review.* If applicable, the IRO shall conduct a review of MVH's compliance with the unallowable cost provisions of the Settlement Agreement. The IRO shall determine whether MVH has complied with its obligations not to charge to, or otherwise seek payment from, Federal or State payors for unallowable costs (as defined in the Settlement Agreement) and its obligation to identify to applicable Federal or State payors any unallowable costs included in payments previously sought from the United States, or any state Medicaid program. This unallowable cost analysis shall include, but not be limited to, payments sought in any cost reports, cost statements, information reports, or payment requests already submitted by MVH or any affiliates. To the extent that such cost reports, cost statements, information reports, or payment requests, even if already settled, have been adjusted to account for the effect of the inclusion of the unallowable costs, the IRO shall determine if such adjustments were proper. In making this determination, the IRO may need to review cost reports and/or financial statements from the year in which the Settlement Agreement was executed, as well as from previous years.

5. *Unallowable Cost Review Report.* The IRO shall prepare a report based upon the Unallowable Cost Review performed. The Unallowable Cost Review Report shall include the IRO's findings and supporting rationale regarding the Unallowable Cost Review and whether MVH has complied with its obligation not to charge to, or otherwise seek payment from, Federal or state payors for unallowable costs (as defined in the Settlement Agreement) and its obligation to identify to applicable Federal or state payors any unallowable costs included in payments previously sought from such payor.

6. *Validation Review.* In the event OIG has reason to believe that: (a) MVH's Arrangements Review or Unallowable Cost Review fails to conform to the requirements of this Agreement; or (b) the IRO's findings or Arrangements Review or Unallowable Cost Review results are inaccurate, OIG may, at its sole discretion, conduct its own review to determine whether the Arrangements Review or Unallowable Cost Review complied with the requirements of the Agreement and/or the findings or Arrangements Review or Unallowable Cost Review results are inaccurate (Validation Review). MVH 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

MVH's final Annual Report must be initiated no later than one year after MVH's final submission (as described in Section II) is received by OIG.

Prior to initiating a Validation Review, OIG shall notify MVH 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, MVH may request a meeting with OIG to: (a) discuss the results of any Arrangements Review or Unallowable Cost Review submissions or findings; (b) present any additional information to clarify the results of the Arrangements Review or Unallowable Cost Review or to correct the inaccuracy of the Arrangements Review or Unallowable Cost Review; and/or (c) propose alternatives to the proposed Validation Review. MVH agrees to provide any additional information as may be requested by OIG under this Section in an expedited manner. OIG will attempt in good faith to resolve any Arrangements Review or Unallowable Cost Review issues with MVH 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.

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

F. Disclosure Program.

Within 120 days after the Effective Date, MVH shall establish 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 MVH'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. MVH 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 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, MVH shall conduct an internal review of the allegations set forth in the disclosure and ensure that proper follow-up is conducted.

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

#### G. Ineligible Persons.

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

- a. an “Ineligible Person” shall include an individual or entity who:
  - i. is currently excluded, debarred, suspended, or otherwise ineligible to participate in the Federal health care programs or in Federal procurement or nonprocurement programs; or
  - ii. has been convicted of a criminal offense that falls within the ambit of 42 U.S.C. § 1320a-7(a), but has not yet been excluded, debarred, suspended, or otherwise declared ineligible.
- b. “Exclusion Lists” include:
  - i. the HHS/OIG List of Excluded Individuals/Entities (available through the Internet at <http://oig.hhs.gov>); and
  - ii. the General Services Administration’s List of Parties Excluded from Federal Programs (available through the Internet at <http://epls.arnet.gov>).

c. "Screened Persons" include prospective and current owners, officers, directors, employees, contractors, and agents of MVH.

2. *Screening Requirements.* MVH shall ensure that all Screened Persons are not Ineligible Persons, by implementing the following screening requirements.

a. MVH shall screen all Screened Persons against the Exclusion Lists prior to engaging their services and, as part of the hiring or contracting process, shall require such persons to disclose whether they are an Ineligible Person.

b. MVH shall screen all Screened Persons against the Exclusion Lists within 90 days after the Effective Date and on an annual basis thereafter.

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

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

3. *Removal Requirement.* If MVH has actual notice that a Screened Person has become an Ineligible Person, MVH shall remove such person from responsibility for, or involvement with, MVH's business operations related to the Federal health care programs and shall remove such person from any position for which the person's compensation or the items or services furnished, ordered, or prescribed by the person are paid in whole or part, directly or indirectly, by Federal health care programs or otherwise with Federal funds at least until such time as the person is reinstated into participation in the Federal health care programs.

4. *Pending Charges and Proposed Exclusions.* If MVH has actual notice that a Screened Person is charged with a criminal offense that falls within the ambit of 42 U.S.C. §§ 1320a-7(a), 1320a-7(b)(1)-(3), or is proposed for exclusion during his or her employment or contract term or, in the case of a physician, during the term of the physician's medical staff privileges, MVH 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.

#### H. Notification of Government Investigation or Legal Proceedings.

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

#### I. Reporting.

##### 1. *Overpayments.*

a. Definition of Overpayments. For purposes of this CIA, an “Overpayment” shall mean the amount of money MVH 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, MVH identifies or learns of any Overpayment, MVH 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, MVH 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, MVH shall notify the payor of its efforts to quantify the Overpayment amount along with a schedule of when such work is expected to be completed. Notification and repayment to the payor shall be done in accordance with the payor’s policies,

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

2. *Reportable Events.*

a. 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 MVH determines (after a reasonable opportunity to conduct an appropriate review or investigation of the allegations) through any means that there is a Reportable Event, MVH 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.I.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 MVH's actions taken to correct the Reportable Event; and
- iv. any further steps MVH 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, MVH 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, MVH shall notify OIG of this fact as soon as possible, but no later than within 30 days after the date of change of location, sale, closure, purchase, or establishment. This notification shall include the address of the new business unit or location, phone number, fax number, Medicare Provider number, provider identification number and/or supplier number, and the corresponding contractor's name and address that has issued each Medicare number. Each new business unit or location shall be subject to all the requirements of this CIA.

#### **V. IMPLEMENTATION AND ANNUAL REPORTS**

A. Implementation Report. Within 150 days after the Effective Date, MVH shall submit a written report to OIG summarizing the status of its implementation of the requirements of this CIA (Implementation Report). The Implementation Report shall, at a minimum, include:

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



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

3. a copy of MVH's Code of Conduct required by Section III.B.1;

4. a copy of all Policies and Procedures required by Section III.B.2;

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

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

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

b. 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 available to OIG, upon request.

7. a description of the Arrangements Database required by Section III.D.1.a;

8. a description of the internal review and approval process required by Section III.D.1.e;

9. a description of the tracking and monitoring procedures and other Arrangements Procedures required by Section III.D.1;

10. a description of the Disclosure Program required by Section III.F;

11. the following information regarding the IRO(s): (a) identity, address, and phone number; (b) a copy of the engagement letter; (c) a summary and description of any and all current and prior engagements and agreements between MVH and the IRO;

and (d) the proposed start and completion dates of the Arrangements Review and Unallowable Cost Review;

12. a certification from the IRO regarding its professional independence and/or objectivity with respect to MVH;

13. a description of the process by which MVH fulfills the requirements of Section III.G regarding Ineligible Persons;

14. the name, title, and responsibilities of any person who is determined to be an Ineligible Person under Section III.G; the actions taken in response to the screening and removal obligations set forth in Section III.G; and the actions taken to identify, quantify, and repay any overpayments to Federal health care programs relating to items or services furnished, ordered or prescribed by an Ineligible Person;

15. a list of all of MVH's locations (including locations and mailing addresses); the corresponding name under which each location is doing business; the corresponding phone numbers and fax numbers; each location's Medicare Provider number(s), provider identification number(s), and/or supplier number(s); and the name and address of each Medicare contractor to which MVH currently submits claims;

16. a description of MVH's corporate structure, including identification of any parent and sister companies, subsidiaries, and their respective lines of business; and

17. the certifications required by Section V.C.

B. Annual Reports. MVH shall submit to OIG annually a report with respect to the status of, and findings regarding, MVH'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. a summary of any significant changes or amendments to the Policies and Procedures required by Section III.B and the reasons for such changes (e.g., change in contractor policy) and copies of any compliance-related Policies and Procedures;

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

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

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

b. 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 available to OIG, upon request.

5. a description of any changes to the Arrangements Database required by Section III.D.1.a;

6. a description of any changes to the internal review and approval process required by Section III.D.1.e;

7. a description of any changes to the tracking and monitoring procedures and other Arrangements Procedures required by Section III.D.1;

8. a complete copy of all reports prepared pursuant to Section III.E, along with a copy of the IRO's engagement letter (if applicable);

9. MVH's response and corrective action plan(s) related to any issues raised by the reports prepared pursuant to Section III.E;

10. a summary and description of any and all current and prior engagements and agreements between MVH and the IRO, if different from what was submitted as part of the Implementation Report;

11. a certification from the IRO regarding its professional independence and/or objectivity with respect to MVH;

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

13. 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;

14. a summary of the disclosures in the disclosure log required by Section III.F that: (a) relate to Federal health care programs; (b) allege abuse or neglect of patients; or (c) involve allegations of conduct that may involve illegal remunerations or inappropriate referrals in violation of the Anti-Kickback Statute or Stark law;

15. any changes to the process by which MVH fulfills the requirements of Section III.G regarding Ineligible Persons;

16. the name, title, and responsibilities of any person who is determined to be an Ineligible Person under Section III.G; the actions taken by MVH in response to the screening and removal obligations set forth in Section III.G; and the actions taken to identify, quantify, and repay any overpayments to Federal health care programs relating to items or services relating to items or services furnished, ordered or prescribed by an Ineligible Person;

17. a summary describing any ongoing investigation or legal proceeding required to have been reported pursuant to Section III.H. 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 MVH's locations (including addresses) as required by Section V.A.15; the corresponding name under which each location is doing business; the corresponding phone numbers and fax numbers; each location's Medicare Provider number(s), provider identification number(s), and/or supplier number(s); and the name and address of each Medicare contractor to which MVH 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 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, MVH is in compliance with all of the requirements of this CIA;

2. to the best of his or her knowledge, MVH has implemented procedures reasonably designed to ensure that all Arrangements do not violate the Anti-Kickback Statute and Stark Law, including the Arrangements Procedures required in Section III.D of the CIA;

3. to the best of his or her knowledge, MVH has fulfilled the requirements for New and Renewed Arrangements under Section III.D.2 of the CIA;

4. 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

5. MVH has complied with its obligations under the Settlement Agreement: (a) 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; (b) not to charge to or otherwise seek payment from Federal or state payors for unallowable costs (as defined in the Settlement Agreement); and (c) to identify and adjust any past charges or claims for unallowable costs.

D. Designation of Information. MVH 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. MVH shall refrain from identifying any information as exempt from disclosure if that information does not meet the criteria for exemption from disclosure under FOIA.

**VI. NOTIFICATIONS AND SUBMISSION OF REPORTS**

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

OIG:

Administrative and Civil Remedies Branch  
Office of Counsel to the Inspector General  
Office of Inspector General  
U.S. Department of Health and Human Services  
Cohen Building, Room 5527  
330 Independence Avenue, S.W.  
Washington, DC 20201  
Telephone: 202.619.2078  
Facsimile: 202.205.0604

MVH:

The Mount Vernon Hospital  
Attn: George Haskins, Chief Operating Officer  
12 North Seventh Avenue  
Mount Vernon, NY 10550  
Telephone: 914-664-8000  
Facsimile: 914-664-2113

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

## **VIII. DOCUMENT AND RECORD RETENTION**

MVH 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 MVH prior to any release by OIG of information submitted by MVH pursuant to its obligations under this CIA and identified upon submission by MVH as trade secrets, or information that is commercial or financial and privileged or confidential, under the FOIA rules. With respect to such releases, MVH shall have the rights set forth at 45 C.F.R. § 5.65(d).

**X. BREACH AND DEFAULT PROVISIONS**

MVH 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, MVH 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 MVH fails to establish and implement any of the following obligations as described in Section III:

- a. a Compliance Officer;
- b. a Compliance Committee;
- c. a written Code of Conduct;
- d. written Policies and Procedures;
- e. the training of Covered Persons;
- f. the Arrangements Procedures and/or Arrangements Requirements described in Sections III.D.1 and III.D.2;
- g. a Disclosure Program;
- h. Ineligible Persons screening and removal requirements; and
- i. Notification of Government investigations or legal proceedings.

2. A Stipulated Penalty of \$2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day MVH fails to engage an IRO, as required in Section III.E.

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

4. A Stipulated Penalty of \$2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day MVH fails to submit the annual Arrangements Review Report and/or any other required Review Report in accordance with the requirements of Section III.E.

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

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

7. A Stipulated Penalty of \$1,000 for each day MVH fails to comply fully and adequately with any obligation of this CIA. OIG shall provide notice to MVH, stating the specific grounds for its determination that MVH has failed to comply fully and adequately with the CIA obligation(s) at issue and steps MVH shall take to comply with the CIA. (This Stipulated Penalty shall begin to accrue 10 days after MVH 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. MVH 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 MVH 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 MVH 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 MVH 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 MVH of: (a) MVH's failure to comply; and (b) OIG's exercise of its contractual right to demand payment of the Stipulated Penalties (this notification is referred to as the "Demand Letter").

2. *Response to Demand Letter.* Within 10 days after the receipt of the Demand Letter, MVH 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 MVH elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until MVH 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 MVH 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 MVH to report a Reportable Event, take corrective action, and make the appropriate refunds, as required in Section III.I;
  - b. a repeated or flagrant violation of the obligations under this CIA,

including, but not limited to, the obligations addressed in Section X.A;

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

d. a failure to engage and use an IRO in accordance with Section III.D.

2. *Notice of Material Breach and Intent to Exclude.* The parties agree that a material breach of this CIA by MVH constitutes an independent basis for MVH's exclusion from participation in the Federal health care programs. Upon a determination by OIG that MVH has materially breached this CIA and that exclusion is the appropriate remedy, OIG shall notify MVH of: (a) MVH'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.* MVH 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. MVH 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) MVH has begun to take action to cure the material breach; (ii) MVH is pursuing such action with due diligence; and (iii) MVH has provided to OIG a reasonable timetable for curing the material breach.

4. *Exclusion Letter.* If, at the conclusion of the 30-day period, MVH fails to satisfy the requirements of Section X.D.3, OIG may exclude MVH from participation in the Federal health care programs. OIG shall notify MVH in writing of its determination to exclude MVH (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 MVH's receipt of the Exclusion

Letter. The exclusion shall have national effect and shall also apply to all other Federal procurement and nonprocurement programs. Reinstatement to program participation is not automatic. After the end of the period of exclusion, MVH 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 MVH 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, MVH 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 MVH was in full and timely compliance with the obligations of this CIA for which OIG demands payment; and (b) the period of noncompliance. MVH 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 MVH to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable 20 days after the ALJ issues such a decision unless MVH 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 MVH 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) MVH had begun to take action to cure the material breach within that period; (ii) MVH has pursued and is pursuing such action with due diligence; and (iii) MVH provided to OIG within that period a reasonable timetable for curing the material breach and MVH 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 MVH, only after a DAB decision in favor of OIG. MVH's election of its contractual right to appeal to the DAB shall not abrogate OIG's authority to exclude MVH 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 MVH 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. MVH 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 MVH, MVH shall be reinstated effective on the date of the original exclusion.

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

#### **XI. EFFECTIVE AND BINDING AGREEMENT**

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

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

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

E. The undersigned MVH 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.

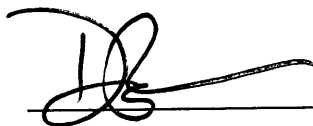
**ON BEHALF OF THE MOUNT VERNON HOSPITAL**

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JOHN R. SPICER  
President and Chief Executive Officer

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DATE



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DAVID E. FRULLA  
Counsel for The Mount Vernon Hospital  
Collier Shannon Scott, PLLC

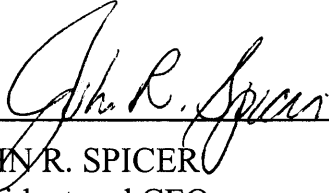
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7-28-05

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DATE

ON BEHALF OF THE MOUNT VERNON HOSPITAL



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JOHN R. SPICER  
President and CEO

7-8-2005

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DATE

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DAVID E. FRULLA  
Counsel for The Mount Vernon Hospital  
Collier Shannon & Scott, PLLC

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DATE



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



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LEWIS MORRIS  
Chief Counsel to the Inspector General  
Office of Inspector General  
U. S. Department of Health and Human Services



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DATE

## APPENDIX A

### ARRANGEMENTS DATABASE

MVH shall create and maintain an Arrangements Database to track all new and existing Arrangements in order to ensure that each Arrangement does not violate the Anti-Kickback Statute and Stark Law. The Arrangements Database shall contain certain information to assist MVH in evaluating whether each Arrangement violates the Anti-Kickback Statute and Stark Law, including but not limited to the following:

1. Each party involved in the Arrangement;
2. The type of Arrangement (e.g., physician employment contract, medical directorship, lease agreement);
3. The term of the Arrangement, including the effective and expiration dates and any automatic renewal provisions;
4. The amount of compensation to be paid pursuant to the Arrangement and the means by which compensation is paid;
5. The methodology for determining the compensation under the Arrangements, including the methodology used to determine the fair market value of such compensation;
6. Whether the amount of compensation to be paid pursuant to the Arrangement is determined based on the volume or value of referrals between the parties;
7. Whether each party has fulfilled the requirements of Section III.D.2; and
8. Whether the Arrangement satisfies the requirements of an Anti-Kickback Statute safe harbor and/or a Stark Law exception or safe harbor, as applicable.

## 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		

# Appendix A

Payment Schedule

Yearly Interest Rate= 4.50%  
 Daily Interest Rate= 0.0123%  
 Principal accrues as: 8/1/2005  
 Amount Owned \$2,650,000

Date	Principal Due (\$)	Number of Days in Quarter	Interest Due	Payment Scheduled (\$)	Amount Owned -End of Day (\$)
8/1/2005	150,000.00	0	0.00	150,000.00	2,500,000
10/1/2005	150,000.00	61	18,871.08	168,871.08	2,350,000
1/1/2006	150,000.00	92	26,804.87	176,804.87	2,200,000
4/1/2006	150,000.00	90	24,545.37	174,545.37	2,050,000
7/1/2006	150,000.00	91	23,127.38	173,127.38	1,900,000
10/1/2006	150,000.00	92	21,672.02	171,672.02	1,750,000
1/1/2007	150,000.00	92	19,961.07	169,961.07	1,600,000
4/1/2007	150,000.00	90	17,851.18	167,851.18	1,450,000
7/1/2007	150,000.00	91	16,358.39	166,358.39	1,300,000
10/1/2007	150,000.00	92	14,828.23	164,828.23	1,150,000
1/1/2008	125,000.00	92	13,117.28	138,117.28	1,025,000
4/1/2008	125,000.00	91	11,563.69	136,563.69	900,000
7/1/2008	125,000.00	91	10,153.48	135,153.48	775,000
10/1/2008	125,000.00	92	8,839.90	133,839.90	650,000
1/1/2009	112,500.00	92	7,414.11	119,914.11	537,500
4/1/2009	112,500.00	90	5,996.88	118,496.88	425,000
7/1/2009	112,500.00	91	4,794.70	117,294.70	312,500
10/1/2009	112,500.00	92	3,564.48	116,064.48	200,000
1/1/2010	100,000.00	92	2,281.27	102,281.27	100,000
4/1/2010	100,000.00	90	1,115.70	101,115.70	0
<b>Total:</b>	<b>2,650,000.00</b>		<b>252,861.09</b>	<b>2,902,861.09</b>	