

**CERTIFICATION OF COMPLIANCE AGREEMENT
BETWEEN THE
OFFICE OF INSPECTOR GENERAL OF THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND
INOVA HEALTH CARE SERVICES**

I. PREAMBLE

Inova Health Care Services, on behalf of and in connection with the operation of Inova Fair Oaks Hospital (Inova), hereby enters into this Certification of Compliance Agreement (CCA) with the Office of Inspector General (OIG) of the United States Department of Health and Human Services (HHS). Contemporaneously with this CCA, Inova is entering into a Settlement Agreement with the OIG, and this CCA is incorporated by reference into the Settlement Agreement.

The effective date of this CCA shall be the date on which the final signatory of this CCA executes this CCA (Effective Date). Each one-year period, beginning with the one-year period following the Effective Date, shall be referred to as a "Reporting Period."

II. INTEGRITY REQUIREMENTS

Inova shall, for a period of three years from the Effective Date of this CCA:

A. Continued Implementation of Compliance Program. Inova shall continue to implement its Compliance Program, as described in the attached Declaration (which is incorporated by reference as Appendix A), and continue to provide, at a minimum, the same level of resources currently provided, throughout this time period. Inova may amend its Compliance Program as it deems necessary, so long as those amendments are consistent with the overall objective of ensuring compliance with the requirements of Medicare, Medicaid, and all other Federal health care programs, as defined in 42 U.S.C. § 1320a-7b(f).

B. Reporting of Overpayments. Inova shall promptly refund to the appropriate Federal health care program payor any identified Overpayment(s). For purposes of this CCA, an "Overpayment" shall mean the amount of money Inova has received in excess of the amount due and payable under any Federal health care program requirements. If, at any time Inova identifies or learns of any Overpayment, Inova 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, Inova 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, Inova 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 CCA. Notwithstanding the above, notification and repayment of any Overpayment amount that is routinely reconciled or adjusted pursuant to policies and procedures established by the payor should be handled in accordance with such policies and procedures.

C. Reportable Events. Inova shall report to OIG in writing within 30 days after making a determination (after a reasonable opportunity to conduct an appropriate review or investigation of the allegations) that there is a Reportable Event, which shall mean anything that involves: (1) a substantial Overpayment, or (2) 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. In such report, Inova shall include the following information:

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

3. a description of Inova's actions taken to correct the Reportable Event; and

4. any further steps Inova plans to take to address the Reportable Event and prevent it from recurring.

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

E. Annual Reporting Requirements. Inova shall submit to OIG annually a report that sets forth the following information for each Reporting Period (Annual Report):

1. A description of any material amendments to its Compliance Program and the reasons for such changes;

2. Any decrease to the level of resources dedicated to its Compliance Program and the reasons for such decrease;

3. A summary of all internal or external reviews, audits, or analyses of its Compliance Program (including, at a minimum, the objective of the review, audit, or analysis; the protocol or methodology for the review, audit, or analysis; and the results of the review, audit, or analysis) and any corrective action plans developed in response to such reviews, audits, or analyses;

4. A summary of all internal or external reviews, audits, or analyses related to the compliance with Federal health care program requirements, including compliance issues related to any financial arrangements between Inova Fair Oaks Hospital and members of its medical staff (including, at a minimum, the objective of the review, audit, or analysis; the protocol or methodology for the review, audit, or analysis; and the results of the review, audit, or

analysis) and any corrective action plans developed in response to such reviews, audits, or analyses;

5. 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 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; and

6. A certification by the Compliance Officer that: (a) to the best of his or her knowledge, except as otherwise described in the Annual Report, Inova is in compliance with the requirements of this Section II; and (b) he or she has reviewed the Annual Report and has made reasonable inquiry regarding its content and believes that the information in the Annual Report is accurate and truthful.

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.

F. Notifications and Submission of Annual Reports. Unless otherwise specified in writing after the Effective Date, all notifications and Annual Reports required under this CCA shall be submitted to the following addresses:

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

Inova: Gerald L. Seager
Assistant Vice President, Chief Compliance Officer
Inova Health Care Services
8110 Gatehouse Road
Suite 200, East Tower
Falls Church, VA 22042-1210

Unless otherwise specified, all notifications and reports required by this CCA may be made by certified mail, overnight mail, hand delivery, or other means, provided that there is proof that such report or notification was received. For purposes of this requirement, internal facsimile confirmation sheets do not constitute proof of receipt.

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

H. Document and Record Retention. Inova shall maintain for inspection all documents and records relating to reimbursement from the Federal health care programs, or to compliance with this CCA, for four years (or longer if otherwise required by law).

III. BREACH AND DEFAULT PROVISIONS

Inova is expected to fully and timely comply with all of the Integrity Requirements set forth in this CCA.

A. Stipulated Penalties for Failure to Comply with Certain Obligations. As a contractual remedy, Inova and OIG hereby agree that failure to comply with the Integrity Requirements set forth in this CCA 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 Inova fails to establish and implement any of the following compliance program elements as described in Section II and the Declaration attached to this CCA as Appendix A:

- a. a Compliance Officer;
- b. a Compliance Committee;
- c. a written Code of Conduct;
- d. written Policies and Procedures;
- e. the annual training of officers, directors, and employees, including employed physicians, and the availability of annual training for medical staff;
- f. a compliance department that performs periodic reviews to monitor Inova’s compliance with Federal health care program requirements;
- g. a Disclosure Program;
- h. Ineligible Persons screening and removal requirements; and
- i. notification of government investigations and legal proceedings pursuant to Section II.D.

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 Inova fails to submit the Annual Reports to OIG in accordance with the requirements of Section II.E by the stated deadlines for submission.

3. A Stipulated Penalty of \$1,500 for each day Inova fails to grant access to the information or documentation as required in Section II.G of this CCA. (This Stipulated Penalty shall begin to accrue on the date Inova fails to grant access.)

4. A Stipulated Penalty of \$5,000 for each false certification submitted by or on behalf of Inova as part of its Annual Reports or otherwise required by this CCA.

5. A Stipulated Penalty of \$1,000 for each day Inova fails to comply fully and adequately with any Integrity Requirements of this CCA. OIG shall provide notice to Inova, stating the specific grounds for its determination that Inova has failed to comply fully and adequately with the Integrity Requirement(s) at issue and steps Inova shall take to comply with the Integrity Requirements of this CCA. (This Stipulated Penalty shall begin to accrue 10 days after Inova receives notice from OIG of the failure to comply.) A Stipulated Penalty as described in this Subsection shall not be demanded for any violation for which OIG has sought a Stipulated Penalty under Subsections 1-4 of this Section III.A.

B. Timely Written Requests for Extensions. Inova 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 CCA. 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 Inova 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 Inova 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 Inova has failed to comply with any of the obligations described in Section III.A and after determining that Stipulated Penalties are appropriate, OIG shall notify Inova of: (a) Inova'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, Inova 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 III.E. In the event Inova elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until Inova 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 CCA and shall be grounds for exclusion under Section III.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 II.F.

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

D. Exclusion for Material Breach of this CCA.

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

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

2. *Notice of Material Breach and Intent to Exclude.* The parties agree that a material breach of this CCA by Inova constitutes an independent basis for Inova's exclusion from participation in the Federal health care programs. Upon a determination by OIG that Inova has materially breached this CCA and that exclusion is the appropriate

remedy, OIG shall notify Inova of: (a) Inova's material breach; and (b) OIG's intent to exercise its contractual right to impose exclusion (this notification is referred to as the "Notice of Material Breach and Intent to Exclude").

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

4. *Exclusion Letter.* If, at the conclusion of the 30-day period, Inova fails to satisfy the requirements of Section III.D.3, OIG may exclude Inova from participation in the Federal health care programs. OIG shall notify Inova in writing of its determination to exclude Inova (this letter shall be referred to as the "Exclusion Letter"). Subject to the Dispute Resolution provisions in Section III.E, below, the exclusion shall go into effect 30 days after the date of Inova'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, Inova 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 Inova of its Demand Letter or of its Exclusion Letter, and as an agreed-upon contractual remedy for the resolution of disputes arising under this CCA, Inova 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 CCA. 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 CCA shall be: (a) whether Inova was in full and timely compliance with the requirements of this CCA for which OIG demands payment; and (b) the period of noncompliance. Inova 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 CCA and orders Inova to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable 20 days after the ALJ issues such a decision unless Inova 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 CCA shall be:

- a. whether Inova was in material breach of this CCA;
- 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) Inova had begun to take action to cure the material breach within that period; (ii) Inova has pursued and is pursuing such action with due diligence; and (iii) Inova provided to OIG within that period a reasonable timetable for curing the material breach and Inova 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 Inova, only after a DAB decision in favor of OIG. Inova's election of its contractual right to appeal to the DAB shall not abrogate OIG's authority to exclude Inova 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 Inova 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. Inova 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 Inova, Inova 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 CCA agree that the DAB's decision (or the ALJ's decision if not appealed) shall be considered final for all purposes under this CCA.

IV. EFFECTIVE AND BINDING AGREEMENT

Inova and OIG agree as follows:

- A. This CCA shall be binding on the successors, assigns, and transferees of Inova;
- B. This CCA shall become final and binding on the date the final signature is obtained on the CCA;
- C. Any modifications to this CCA shall be made with the prior written consent of the parties to this CCA;

D. OIG may agree to a suspension of Inova's obligations under this CCA in the event of Inova's cessation of participation in Federal health care programs. If Inova withdraws from participation in Federal health care programs and is relieved of its CCA obligations by OIG, Inova shall notify OIG at least 30 days in advance of Inova'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 CCA should be reactivated or modified.

E. The undersigned Inova signatories represent and warrant that they are authorized to execute this CCA. The undersigned OIG signatory represents that he is signing this CCA in his official capacity and that he is authorized to execute this CCA.


ON BEHALF OF INOVA HEALTH CARE SERVICES



SHANNON E. SINCLAIR
SENIOR VICE PRESIDENT, GENERAL COUNSEL
INOVA HEALTH CARE SERVICES

11/21/05
DATE

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



LEWIS MORRIS
Chief Counsel to the Inspector General
Office of Inspector General
United States Department of Health and Human Services

11/22/05
DATE