

**CORPORATE INTEGRITY AGREEMENT  
BETWEEN THE  
OFFICE OF INSPECTOR GENERAL  
OF THE  
DEPARTMENT OF HEALTH AND HUMAN SERVICES  
AND  
ALLINA HEALTH SYSTEM**

**I. PREAMBLE**

Allina Health System (“Allina”) hereby enters into this Corporate Integrity Agreement (“CIA”) with the Office of Inspector General (“OIG”) of the United States Department of Health and Human Services (“HHS”) to promote compliance by the following persons (hereinafter collectively “Covered Persons”):

1. Allina’s subsidiaries,<sup>1</sup> which shall include wholly-owned subsidiaries and partnerships or joint ventures over which Allina exercises operational control or for whom Allina generates bills;

2. Allina and its subsidiaries’ officers, directors, and employees, excluding maintenance employees, housekeeping employees, laundry employees, day care employees, food service employees, and employees whose cumulative service to all Allina entities is less than .1 full-time equivalent (“FTE”) during the Reporting Period;

3. Physicians with staff privileges at Allina or its subsidiaries’ hospitals and other facilities (“Covered Staff Physicians”);

4. “Covered Contractors,” which shall include Allina and its subsidiaries’ contractors, agents, and third parties engaged to bill or submit reimbursement claims, responsible for the provision, marketing or documentation of items or services reimbursable by Federal health care programs, or responsible for the preparation of

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<sup>1</sup>Effective December 31, 2001, Medica Health Plans and its affiliates, Medica Insurance Company, Medica Health Plans of Wisconsin, and Allina Self-Insured (collectively, “Medica”) will no longer be a wholly-owned subsidiary of Allina Health System, or affiliated with Allina in any way. This Corporate Integrity Agreement does not apply to Medica in any way.

claims, reports or other requests for reimbursement for such items or services with the statutes, regulations, and written directives of Medicare, Medicaid and all other Federal health care program (as defined in 42 U.S.C. Section 1320a-7b(f)) (“Federal health care program requirements”) on a regular basis (i.e. greater than or equal to .1 FTE during the Reporting Period), but excluding vendors whose sole connection with Allina or its subsidiaries is selling medical supplies and equipment to them; and

5. All other individuals responsible for the provision, marketing or documentation of items or services reimbursable by Federal health care programs, or for the preparation of claims, reports or other requests for reimbursement for such items or services with Federal health care program requirements on a regular basis (i.e., greater than or equal to .1 FTE to all Allina entities during the Reporting Period).

Contemporaneously with this CIA, Allina is entering into a Settlement Agreement with the United States, and this CIA is incorporated by reference into the Settlement Agreement.

Prior to the execution of this CIA, Allina established a corporate compliance program (known as the “Allina Compliance Program”). The Allina Compliance Program includes written policies and procedures, an education and training component, mechanisms for the ongoing monitoring and auditing of Allina operations to assess compliance, mechanisms for employees and agents to report incidents of noncompliance in an anonymous way, disciplinary actions for individuals violating compliance policies and procedures, and oversight of the Allina Compliance Program by a Corporate Compliance Officer, a Compliance Oversight Committee, and a Compliance Steering Committee. Allina agrees to continue the operation of the Allina Compliance Program for the term of this CIA. Allina may modify the Allina Compliance Program as appropriate, but at a minimum, Allina shall ensure that it complies with the integrity obligations enumerated in this CIA.

## **II. TERM OF THE CIA**

The period of the compliance obligations assumed by Allina under this CIA shall be five years from the Effective Date of this CIA (unless otherwise specified). The “Effective Date” of this CIA shall be the date on which the final signatory of this CIA executes this CIA.

Sections VII, VIII, IX, X, and XI shall expire no later than 120 days from the OIG's receipt of: (1) Allina's final annual report; or (2) any additional materials submitted by Allina pursuant to a request of the OIG made prior to seven years from the Effective Date, whichever is later.

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

Allina hereby agrees to maintain a Compliance Program that includes the following elements:

#### **A. Corporate Compliance Officer and Compliance Committees.**

1. *Corporate Compliance Officer.* Allina has represented to OIG that, pursuant to the Allina Compliance Program, it has established the position of Corporate Compliance Officer and appointed an individual to serve in that capacity. The Corporate 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 Corporate Compliance Officer shall be a member of senior management of Allina, report directly to the Chief Executive Officer of Allina, shall make periodic (at least quarterly) reports regarding compliance matters directly to the Board of Directors of Allina, and shall be authorized to report on such matters to the Board of Directors at any time. The Corporate Compliance Officer shall be responsible for monitoring the day-to-day compliance activities engaged in by Allina as well as for any reporting obligations created under this CIA.

Allina shall report to the OIG, in writing, any changes in the identity or position description of the Corporate Compliance Officer, or any material actions or material changes that would affect the Corporate Compliance Officer's ability to perform the duties necessary to meet the obligations in this CIA within 30 days of such a change.

2. *Compliance Oversight Committee and Compliance Steering Committee.* Allina has represented to OIG that, pursuant to the Allina Compliance Program, it has established a Compliance Oversight Committee and a Compliance Steering Committee (collectively, "Compliance Committees"), and appointed individuals to serve on those Committees. The Corporate Compliance Officer shall chair the Compliance Oversight Committee. The Corporate Compliance Officer or his/her designee shall chair the

Compliance Steering Committee. The Compliance Committees shall support the Corporate 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).

Allina shall report to the OIG, in writing, any material changes in the composition of the Compliance Committees, or any material actions or material changes that would affect the Compliance Committees' ability to perform the duties necessary to meet the obligations in this CIA within 30 days of such a change.

B. Written Standards.

1. *Employee Standards of Business Conduct.* Allina has produced to OIG written Employee Standards of Business Conduct. Allina has represented to OIG that it has distributed the Employee Standards of Business Conduct to all officers, directors, and employees of Allina who are Covered Persons. Within 120 days, Allina shall complete distribution of the Employee Standards of Business Conduct to all Covered Persons. Allina shall make the promotion of, and adherence to, the Employee Standards of Business Conduct an element in evaluating the performance of all employees. The Employee Standards of Business Conduct set forth, and, at a minimum, shall continue to set forth throughout the term of this CIA, the following:

- a. Allina'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. Allina's requirement that all of its Covered Persons shall be expected to comply with all Federal health care program requirements and with Allina's own Policies and Procedures as implemented pursuant to Section III.B.2 (including the requirements of this CIA);
- c. the requirement that all of Allina's Covered Persons shall be expected to report to the Corporate Compliance Officer or other appropriate individual designated by Allina, suspected violations of any Federal health care program requirements or of Allina's own Policies and Procedures;

- d. the possible consequences to both Allina and Covered Persons of failure to comply with Federal health care program requirements and with Allina's own Policies and Procedures and the failure to report such non-compliance; and
- e. the right of all individuals to use the Disclosure Program described in Section III.E, and Allina's commitment to maintain confidentiality, as appropriate, and non-retaliation with respect to such disclosures.

To the extent not already certified, within 120 days of the Effective Date of the CIA, each Covered Person shall certify, in writing, that he or she has received, read, understood, and will abide by Allina's Employee Standards of Business Conduct. New Covered Persons shall receive the Employee Standards of Business Conduct and shall complete the required certification within 60 days after becoming a Covered Person or within 120 days of the Effective Date of the CIA, whichever is later.

Allina shall periodically review the Employee Standards of Business Conduct to determine if revisions are appropriate and shall make any necessary revisions based on such a review. Any such revised Employee Standards of Business Conduct shall be distributed within 60 days of finalizing such changes. The requirement to distribute a revision shall be satisfied by publishing it on the company intranet system, coupled with an electronic message to Covered Persons notifying them of the revision and the requirement to read, understand, and abide by it. To the extent there are material changes in the Employee Standards of Business Conduct, Covered Persons shall certify that they have received, read, understood and will abide by the revised Employee Standards of Business Conduct within 60 days of the distribution of such revisions.

2. *Policies and Procedures.* Allina has made available to OIG its written policies and procedures regarding the operation of Allina's compliance program and its compliance with Federal health care program requirements ("Policies and Procedures"). Allina has represented to OIG that it has implemented these Policies and Procedures. These Policies and Procedures address, and at a minimum shall continue to address throughout the term of this CIA, the following:

- a. the subjects relating to the Employee Standards of Business Conduct identified in Section III.B.1;
- b. 42 U.S.C. § 1320a-7b(b) (the “Anti-Kickback Statute”) and 42 U.S.C. § 1395nn (the “Stark Law”), the regulations and other guidance documents related to these statutes;
- c. Areas of OIG concern or risk areas outlined in OIG Model Compliance Program Guidances relevant to each business unit (available through the Internet at <http://oig.hhs.gov/modcomp/index.htm>; and
- d. Credit balances and the timely refunding of Federal health care program credit balances in accordance with payor requirements. For purposes of this CIA, a credit balance is an improper or excess payment made to a provider as the result of patient billing or claims processing errors.

To the extent not already done, within 120 days of the Effective Date of the CIA, Allina shall make available the relevant portions of the Policies and Procedures to all Covered Persons whose functions relate to those Policies and Procedures. Appropriate and knowledgeable staff should be available to explain the Policies and Procedures.

At least annually (and more frequently if appropriate), Allina shall assess and update as necessary the Policies and Procedures. Within 30 days of the effective date of any revisions, the relevant portions of any such revised Policies and Procedures shall be made available to all Covered Persons whose functions relate to those Policies and Procedures. This requirement shall be satisfied by publishing the revised Policies and Procedures on the company intranet system, coupled with an electronic message to all individuals whose job functions relate to those revised Policies and Procedures notifying them of the revisions.

### C. Training and Education.

Allina shall continue the education and training elements of the Allina Compliance Program as they pertain to all Covered Persons, with the following modifications:

1. *General Training.* Within 120 days of the Effective Date of this CIA, Allina shall provide at least one hour of general training to each Covered Person. This training, at a minimum, shall:

- a. Explain Allina's CIA requirements;
- b. Explain Allina's Compliance Program (including the Employee Standards of Business Conduct and the Policies and Procedures as they pertain to general compliance issues); and
- c. Provide feedback and information regarding the relevant portions of the compliance auditing and/or monitoring (as required by Allina's Compliance Program and Section III.D to all Covered Persons whose job functions are subject to auditing and/or monitoring).

Unmonitored self-study shall not be an option for training for any Covered Person.

New Covered Persons shall receive the general training described above within 30 days of becoming a Covered Person or within 120 days after the Effective Date of this CIA, whichever is later. After receiving the initial training described above, each Covered Person shall receive at least one hour of general training annually.

2. *Documentation Training.* Within 120 days of the Effective Date of this CIA, each Covered Person who is directly involved in the delivery of patient care items or services, but who is not a "Relevant Covered Person" as defined in Section III.C.3 below (including special transportation drivers and dispatchers employed by Allina Medical Transportation), shall receive documentation training in addition to the general training required above. This documentation training shall include a discussion of:

- a. policies, procedures, and other requirements applicable to the documentation of medical services; and
- b. the importance of accurate documentation in the billing and coding processes.

Persons providing the training must be knowledgeable about the subject area. Unmonitored self-study shall not be an option for documentation training for any Covered Person.

Covered Persons subject to this subsection shall receive this training within 30 days of the beginning of their employment or becoming Covered Persons or within 120 days of the Effective Date of this CIA, whichever is later. An Allina employee who has completed the documentation training shall monitor a new Covered Person's work, to the extent that the work relates to the delivery of patient care items or services, until such time as the new Covered Person completes his/her applicable training.

After receiving the initial training described in this Section, every Covered Person shall receive refresher documentation training annually.

Training provided to Covered Persons within one year prior to the Effective Date that satisfies the requirement of this Section III.C.2 shall be deemed to meet the initial training requirements of this subsection.

3. *Specific Training.* Within 120 days of the Effective Date of this CIA, each Covered Person who is directly involved in either: (i) delivering patient care items or services reimbursable by Federal health care programs as a health care professional; (ii) preparing or submitting claims for reimbursement from any Federal health care program; or (iii) supervising, administering, or managing the foregoing individuals, including any individual having corporate authority to execute contracts on behalf of Allina for patient care items or services (hereinafter referred to as "Relevant Covered Persons") shall receive at least four hours of specific training in addition to the general training required above. For purposes of this Section, "health care professional" includes individuals licensed under health-related licensing boards, as defined in Minn. Stat. § 214.01, subd. 2 (2000), and ambulance service personnel, as defined in Minn. Stat. § 144E.01, subd. 3a (2000). This specific training shall include a discussion of:

- a. the submission of accurate bills for services rendered to Federal health care program beneficiaries;
- b. policies, procedures and other requirements applicable to the documentation of medical services;



- c. the personal obligation of each individual involved in the billing process to ensure that such billings are accurate;
- d. applicable reimbursement statutes, regulations, and program requirements and directives;
- e. the legal sanctions for improper billings;
- f. examples of proper and improper billing practices;
- g. business relationships that implicate the Anti-Kickback Statute and the Stark Law, as well as the regulations and other guidance documents related to these statutes;
- h. areas of OIG concern or risk areas outlined in OIG Model Compliance Program Guidances relevant to each business unit (available through the Internet at <http://oig.hhs.gov/modcomp/index.htm>; and
- i. For Relevant Covered Persons involved in the resolution of credit balances: appropriate training on credit balances, including a discussion of the software system used by Allina for cash posting; payor regulations (e.g., Medicare, Medicaid, and other insurers); and Explanation of Benefits reading and coding.

Persons providing the training must be knowledgeable about the subject area. Unmonitored self-study shall not be an option for training for any Relevant Covered Person.

Relevant Covered Persons shall receive this training within 30 days of the beginning of their employment or becoming Relevant Covered Persons or within 120 days of the Effective Date of this CIA, whichever is later. An Allina employee who has completed the specific training shall monitor a new Relevant Covered Person's work, to the extent that the work relates to the delivery of patient care items or services and/or in the preparation or submission of claims for reimbursement from any Federal health care program, until such time as the new Relevant Covered Person completes his/her applicable training.

After receiving the initial training described in this Section, every Relevant Covered Person shall receive at least four hours of specific training annually.

Training provided to Relevant Covered Persons within one year prior to the Effective Date that satisfies the requirement of this Section III.C.3 shall be deemed to meet the initial training requirements of this subsection.

4. *Exception for Certain Physicians.* Notwithstanding any other provision of this Section, Allina shall make the General Training and the Specific Training of Section II.C.1 and 3, available to (i) all Covered Staff Physicians; and (ii) contracted physicians who submit claims directly to the Federal health care program for their professional services (e.g., Medicare Part B claims) and for whom Allina does not submit any claims to the Federal health care programs (“Excepted Physician Contractors”), and shall use its best efforts to encourage their attendance and participation at such training. Each Covered Staff Physician or Excepted Physician Contractor who attends training shall certify, in writing, (or in electronic form, if they have received computer-based training) that he or she has received the training. The certification shall specify the type of training received and the date received. The Corporate Compliance Officer (or his or her designee) shall retain the certifications, along with all course materials. The certifications shall be made available to OIG, upon request.

The Corporate Compliance Officer shall also maintain records of the number of Covered Staff Physician and Excepted Physician Contractors and the percentage of all Covered Staff Physicians and Excepted Physician Contractors who attend General and Specific Training, and shall provide such records to OIG as part of its Implementation and Annual Reports.

After evaluating the records provided by Allina regarding the Excepted Physician Contractors, OIG may, in its sole discretion, and at any point during the term of this CIA, terminate the exception provided by this Section III.C.4 for Excepted Physician Contractors.

5. *Certification.* Each individual who is required to attend training shall certify, in writing, (or in electronic form, if they have received computer-based training) that he or she has received the required training. The certification shall specify the type of training received and the date received. The Corporate Compliance Officer (or his or

her designee) shall retain the certifications, along with all course materials. These shall be made available to OIG, upon request.

D. Review Procedures.

1. *Annual Claims Review.*

a. Allina shall conduct a Claims Review that addresses its billing and coding to the Federal health care programs. The Claims Review shall be performed annually and shall cover each of the one-year periods beginning with the Effective Date of this CIA.

b. The Claims Review shall identify any Overpayments through an appraisal of Claims submitted by Allina to the Federal health care programs. The Claims Review shall be performed in accordance with the procedures set forth in Appendix A to this CIA.

c. Currently, Allina is performing Claims Reviews for each of its business units. Allina shall prepare an annual report for the OIG based upon each of the Claims Reviews including: Allina Medical Transportation, Allina Medical Clinics (including Allina Behavioral Health Services and Minneapolis Cardiology Associates), Allina Homecare and Hospice, Allina Home Medical Equipment, and Allina Hospitals.

d. Prior to each Claims Review, Allina shall prepare a work plan describing the protocol it proposes to follow in conducting the Review. At a minimum, the work plan must show that the review is designed to determine the accuracy, validity and appropriateness of claims submitted for reimbursement to the Federal health care programs and to identify patterns or significant single occurrences where claims are filed in contravention of applicable Federal health care program standards. The number of randomly selected claims reviewed should be representative of the universe of claims from which the sample was selected. The work plan for the first Annual Report shall be submitted to the OIG with the Implementation Report. Any material change to the work plan during the term of the

CIA shall be submitted to OIG at least 30 days in advance of implementing the change.

2. *Special Reviews.* In the event that a Material Deficiency is identified, Allina shall conduct a Special Review in accordance with the guidelines set forth in Appendix B.

3. *Credit Balances Reviews.* Allina shall conduct a Credit Balances Review. The Credit Balances Review shall be performed annually and shall cover each of the one-year periods beginning with the Effective Date of this CIA. The Credit Balances Review shall confirm:

- a. Federal health care program credit balances were identified within a reasonable time once payment was received and posted;
- b. credit balance status was analyzed, documented and appropriately refunded;
- c. all credit balances for Federal health care programs are refunded or otherwise resolved upon request of the fiscal intermediary in a timely manner;
- d. a controller or accountant, on a monthly or quarterly basis, reviews the credit balance reports and associated adjustments;
- e. the credit balance was reported on CMS Form 838 and that Medicare guidelines were followed (e.g., documenting the reason for the credit balance); and
- f. the appropriate signatures exist on the CMS Form 838 per Medicare guidelines.

4. *Anti-Kickback Statute and Stark Law Compliance Reviews.* Allina has represented to OIG that it has created Policies and Procedures reasonably designed to prevent violations or potential violations of the Antikickback Statute and Stark Law. Allina's Legal Department shall continue to review for compliance with the Antikickback Statute and Stark Law any new or existing relationships with contractors, vendors,

agents, and physicians in a position to refer or recommend Federal health care program beneficiaries to Allina for the furnishing, purchasing, leasing, or ordering of any item or service for which payment may be made in whole or in part by any Federal health care program.

5. *Retention of Records.*

a. Allina shall retain and make available to the OIG, upon request, all work papers, supporting documentation, correspondence, and draft reports related to the Annual Claims Reviews, any Special Reviews, and the Credit Balances Reviews conducted pursuant to Section III.D.1 - 3.

b. Allina shall retain and make available to the OIG, upon request, (1) copies of all contracts subject to the Anti-Kickback Statute and Stark Law Compliance Review required pursuant Section III.D.4; (2) all documents relating to the actual performance of duties under the contracts, including time sheets, service logs, and payment documentation (e.g., Form 1099s and records of checks or wire transfers); and (3) all nonprivileged communications, including work papers, supporting documentation, correspondence, and draft reports, related to the contracts and the performance of duties under the contracts.

c. Nothing in this CIA or any other communication or report made pursuant to this CIA, shall constitute a waiver by Allina of Allina's attorney-client, attorney work-product, or other applicable privileges. Notwithstanding that fact, the existence of any such privilege shall not be used by Allina to avoid its obligations to comply with the provisions of this CIA.

6. *Validation Review.* In the event the OIG has reason to believe that: (a) Allina's Annual Claims Review fails to conform to the requirements of this CIA; or (b) the findings or Claims Review results are inaccurate, the OIG may, at its sole discretion, conduct its own review to determine whether the Annual Claims Review complies with the requirements of the CIA and/or the findings or Claims Review results are inaccurate. Allina agrees to pay for the reasonable cost of any such review performed by the OIG or any of its designated agents so long as it is initiated before one year after the final submission (as described in Section II) is received by the OIG.

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

#### E. Disclosure Program.

Allina has represented to OIG that it has established a confidential disclosure program (“Integrity Line”), that includes a mechanism (e.g., a toll-free compliance telephone line) to enable individuals to disclose, to the Corporate Compliance Officer or some other person who is not in the disclosing individual’s chain of command, any identified issues or questions associated with Allina’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. Allina shall maintain the Integrity Line for the term of this CIA. Allina shall appropriately publicize the existence of the Integrity Line (e.g., via periodic e-mails to employees or by posting the information in prominent common areas).

The Integrity Line shall emphasize a non-retribution, non-retaliation policy, and shall include a reporting mechanism for anonymous communications for which appropriate confidentiality will be maintained. Upon receipt of a disclosure, the Corporate Compliance Officer (or his/her designee) shall gather all relevant information from the disclosing individual. The Corporate Compliance Officer (or his/her 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 related to a Federal health care program or abuse or neglect of patients 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, Allina

shall conduct an internal review of the allegations set forth in such a disclosure and ensure that proper follow-up is conducted.

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

#### F. Ineligible Persons.

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

2. *Screening Requirements.* Allina shall not hire as employees, engage as contractors, or grant staff privileges to any Ineligible Person. To prevent hiring or contracting with any Ineligible Person, Allina shall screen all prospective employees and prospective contractors prior to engaging their services and screen physicians prior to granting staff privileges by: (a) requiring applicants to disclose whether they are Ineligible Persons; and (b) appropriately querying the General Services Administration’s List of Parties Excluded from Federal Programs (available through the Internet at <http://epls.arnet.gov>) and the HHS/OIG List of Excluded Individuals/Entities (available through the Internet at <http://oig.hhs.gov>) (these lists will hereinafter be referred to as the “Exclusion Lists”). Nothing in this Section affects the responsibility of (or liability for) Allina to refrain from billing Federal health care programs for services of the Ineligible Person.

3. *Review and Removal Requirement.* Within 90 days of the Effective Date of this CIA, Allina shall review its list of current employees, contractors, and physicians with staff privileges against the Exclusion Lists. Thereafter, Allina shall review its list of current employees, contractors, and physicians with staff privileges against the Exclusion Lists annually. In addition, Allina shall require employees and

contractors to disclose immediately any debarment, exclusion, or other event that makes the employee an Ineligible Person.

If Allina has actual notice that an employee, contractor, and physician with staff privileges has become an Ineligible Person, Allina shall remove such person from responsibility for, or involvement with, Allina's business operations related to the Federal health care programs and shall remove such person from any position for which the person's salary or the items or services rendered, ordered, or prescribed by the person are paid in whole or part, directly or indirectly, by Federal health care programs or otherwise with Federal funds at least until such time as the person is reinstated into participation in the Federal health care programs.

4. *Pending Charges and Proposed Exclusions.* If Allina has actual notice that an employee or contractor is charged with a criminal offense related to any Federal health care program, or is proposed for exclusion during his or her employment or contract term, Allina shall take all appropriate actions to ensure that the responsibilities of that employee or contractor have not and shall not adversely affect the quality of care rendered to any beneficiary, patient or resident, or the accuracy of any claims submitted to any Federal health care program.

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

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

#### H. Reporting.

##### 1. *Overpayments*

a. *Definition of Overpayments.* For purposes of this CIA, an "Overpayment" shall mean the amount of money Allina has received



in excess of the amount due and payable under any Federal health care program requirements. Allina may not subtract any underpayments for purposes of determining the amount of relevant Overpayments for CIA reports.

b. *Reporting of Overpayments.* If, at any time, Allina identifies or learns of any Overpayments, Allina shall notify the payor (e.g., Medicare fiscal intermediary or carrier) within 30 days of identification of the Overpayment and take remedial steps within 60 days of identification (or such additional time as may be agreed to by the payor) to correct the problem, including preventing the underlying problem and the Overpayments from recurring. Also, within 30 days of identification of the Overpayment, Allina shall repay the Overpayment to the appropriate payor to the extent such Overpayment has been quantified. If not yet quantified, within 30 days of identification, Allina 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 should be done in accordance with the payor's policies, and for Medicare contractors, must include the information contained on the Overpayment Refund Form, provided as Appendix C 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. *Material Deficiencies.*

a. *Definition of Material Deficiency.* For purposes of this CIA, a "Material Deficiency" 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 Material Deficiency may be the result of an isolated event or a series of occurrences.

*b. Reporting of Material Deficiencies.* If Allina determines through any means that there is a Material Deficiency, Allina shall notify OIG, in writing, within 30 days of making the determination that the Material Deficiency exists. The report to the OIG shall include the following information:

(i) If the Material Deficiency results in an Overpayment, the report to the OIG shall be made at the same time as the notification to the payor required in Section III.H.1, and shall include all of the information on the Overpayment Refund Form, 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 Material Deficiency, including the relevant facts, persons involved, and legal and Federal health care program authorities implicated;

(iii) a description of Allina's actions taken to correct the Material Deficiency; and

(iv) any further steps Allina plans to take to address the Material Deficiency and prevent it from recurring.

3. *Credit Balances.* Allina shall report its Credit Balances to its Fiscal Intermediary on a quarterly basis. The credit balance reports shall include all Federal

health care credit balances reflected in Allina's hospital accounting system, including transfer, holding or other general accounts used to accumulate credit balance funds. Allina's billing system shall be able to identify and separate the individual patient account credit balances by payor class (e.g., Medicare, Medicaid). Allina shall report its credit balances on CMS Form 838. Allina shall complete, sign and submit on a quarterly basis, CMS Form 838 (including both the detailed page and certification page). CMS Form 838 shall be submitted even if no credit balance exists.

#### **IV. NEW BUSINESS UNITS OR LOCATIONS**

In the event that, after the Effective Date of this CIA, Allina changes locations or sells, closes, purchases or establishes new business units related to the furnishing of items or services that may be reimbursed by Federal health care programs, Allina shall notify OIG of this fact as soon as possible, but no later than within 60 days of the date of change of location, sale, closure, purchase or establishment. This notification shall include the location of the new operation(s), phone number, fax number, Medicare Allina number(s) (if any), and the corresponding contractor's name and address that has issued each Medicare Allina number. All Covered Persons at such locations shall be subject to the applicable requirements in this CIA (e.g., completing certifications and undergoing training).

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

A. Implementation Report. Within 120 days after the Effective Date of this CIA, Allina shall submit a written report to OIG summarizing the status of its implementation of the requirements of this CIA. This Implementation Report shall include:

1. Any changes between August 20, 2001 and the date of the Implementation Report to the names and positions of the members of the Compliance Committees required by Section III.A;
2. If revised between August 20, 2001 and the date of the Implementation Report, a copy of Allina's revised Employee Standards of Business Conduct;
3. a description of all training required by Section III.C, including a description of the targeted audiences, length of sessions, which sessions

were mandatory and for whom, percentage of attendance, a schedule of when the training sessions were held, and the other information required by that Section;

4. a certification by the Corporate Compliance Officer that:
  - a. the Policies and Procedures required by Section III.B have been developed, are being implemented, and have been made available to all appropriate Covered Persons;
  - b. all Covered Persons have completed the Employee Standards of Business Conduct certification required by Section III.B.1; and
  - c. all Covered Persons and/or Relevant Covered Persons have completed the applicable training and executed the certification(s) required by Section III.C.

The documentation supporting this certification shall be available to OIG, upon request.

5. a description of any changes to the Disclosure Program between August 20, 2001 and the date of the Implementation Report;
6. a summary of personnel actions (other than hiring) taken pursuant to Section III.F.;
7. a list of all of Allina's locations where either (i) patient care items or services are provided to Federal health care program beneficiaries; or (ii) claims are prepared for submission to any Federal health care program. The list shall include the location and mailing addresses, the corresponding name under which each location is doing business, the corresponding phone numbers and fax numbers, each location's Medicare provider identification number(s), if applicable, and the names and addresses of the Medicare contractors to which Allina currently submits claims;

8. a description of Allina's corporate structure, including identification of any parent and sister companies, subsidiaries and their respective lines of business;
9. The work plan for the Annual Claims Review for the first Annual Report required by Section V.D.1.d; and
10. the certification required by Section V.C.

Allina shall also make available to OIG upon request copies or summaries of all compliance-related Policies and Procedures required by Section III.B.2 and copies of all training materials for the training required pursuant to Section III.C.

B. Annual Reports. Allina shall submit to OIG Annual Reports with respect to the status of, and findings regarding, Allina's compliance activities for each of the five one-year periods beginning on the Effective Date of the CIA. (The one-year period covered by each Annual Report shall be referred to as "the Reporting Period").

Each Annual Report shall include:

1. any changes in the identity, position description, or other noncompliance job responsibilities of the Corporate Compliance Officer, any material actions or material changes that would affect the Corporate Compliance Officer's ability to perform the duties necessary to meet the obligations in the CIA, and any change in the membership of the Compliance Committees described in Section III.A;
2. a certification by the Corporate Compliance Officer that:
  - a. all Covered Persons have completed any Employee Standards of Business Conduct certifications required by Section III.B.1;
  - b. all Covered Persons and/or Relevant Covered Person have completed the applicable training and executed the certification(s) required by Section III.C;

c. Allina has complied with its obligations under the Settlement Agreement: (i) not to resubmit to any Federal health care program payors any previously denied claims related to the Covered Conduct addressed in the Settlement Agreement, and not to appeal any such denials of claims; (ii) not to charge to or otherwise seek payment from Federal or State payors for unallowable costs (as defined in the Settlement Agreement); and (iii) to identify and adjust any past charges or claims for unallowable costs;

The documentation supporting this certification shall be available to OIG, upon request.

3. a summary of any significant changes or amendments to the Policies and Procedures required by Section III.B and the reasons for such changes (e.g., change in contractor policy);
4. a description of all training required by Section III.C conducted during the Reporting Period, including a description of the targeted audiences, length of sessions, which sessions were mandatory and for whom, percentage of attendance, a schedule of when the training sessions were held, and the other information required by that Section. Allina shall also make copies of all training materials available to the OIG upon request;
5. a complete copy of all reports prepared pursuant to the review requirements of Section III.D, including a copy of the methodology used;
6. Allina's response and corrective action plan(s) related to any issues raised by the reviews;
7. a summary of Material Deficiencies (as defined in Section III.H) identified during the Reporting Period and the status of any corrective and preventative action relating to all such Material Deficiencies;
8. a report of the aggregate Overpayments that have been returned to the Federal health care programs. Overpayment amounts should be broken down into the following categories: inpatient Medicare, outpatient Medicare, Medicaid (report each applicable state separately, 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;

9. a summary of the disclosures in the disclosure log required by Section III.E that: (a) relate to Federal health care programs; or (b) allege abuse or neglect of patients;

10. a description of any personnel actions (other than hiring) taken by Allina as a result of the obligations in Section III.F, and the name, title, and responsibilities of any person that falls within the ambit of Section III.F.4, and the actions taken in response to the obligations set forth in that Section;

11. a summary describing any ongoing investigation or legal proceeding required to have been reported pursuant to Section III.G. The summary shall include a description of the allegation, the identity of the investigating or prosecuting agency, and the status of such investigation or legal proceeding;

12. a description of all changes to the most recently provided list (as updated) of Allina's locations (including locations and mailing addresses) as required by Section V.A.11, the corresponding name under which each location is doing business, the corresponding phone numbers and fax numbers, each location's Federal health care program Allina identification number(s), and the contractor name and address that issued each Allina identification number;

13. an index of the materials and information available on the Allina Knowledge Network;

14. A summary of Allina's reviews during the Reporting Period of its relationships with contractors, vendors, agents, and employees, for compliance with the Antikickback Statute and Stark Law;

15. A summary of Allina's pending credit balances related to the Federal health care programs and its efforts to effect timely resolution of those credit balances during the Reporting Period; and

16. the certification required by Section V.C.

The first Annual Report shall be received by the 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 Corporate Compliance Officer that: (1) except as otherwise described in the applicable report, Allina is in compliance with all of the requirements of this CIA, to the best of his or her knowledge; and (2) the Corporate Compliance Officer has reviewed the Report and has made reasonable inquiry regarding its content and believes that the information is accurate and truthful.

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

## **VI. NOTIFICATIONS AND SUBMISSION OF REPORTS**

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



OIG:

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

Allina:

David Orbuch  
Corporate Compliance Officer  
Allina Health System  
9800 Bren Road East  
Minnetonka, MN 55343

Mailing Address:  
P.O. Box 1469  
Minneapolis, MN 55343  
Phone 952.992.2795  
Fax 952.992.3196

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 Allina's books, records, and other documents and supporting materials and/or conduct on-site reviews of any of Allina's locations for the purpose of verifying and evaluating: (a) Allina's compliance with the terms of this CIA; and (b) Allina's compliance with the requirements of the Federal health care programs in which it participates. The

documentation described above shall be made available by Allina 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 Allina'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. Allina agrees to assist OIG or its duly authorized representative(s) in contacting and arranging interviews with such individuals upon OIG's request. Allina's employees may elect to be interviewed with or without a representative of Allina present. The rights of Allina under this Section shall be subject to the provisions of Section III.D.3 regarding Allina's attorney-client, work-product, or other applicable privileges.

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

Allina 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, the OIG shall make a reasonable effort to notify Allina prior to any release by OIG of information submitted by Allina pursuant to its obligations under this CIA and identified upon submission by Allina as trade secrets, or information that is commercial or financial and privileged or confidential, under the FOIA rules. With respect to such releases, Allina shall have the rights set forth at 45 C.F.R. § 5.65(d). Allina shall refrain from identifying any information as exempt from release if that information does not meet the criteria for exemption from disclosure under FOIA.

#### **X. BREACH AND DEFAULT PROVISIONS**

Allina 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, Allina and OIG hereby agree that failure to comply with certain obligations set forth in this CIA may lead to the imposition of the following monetary

penalties (hereinafter referred to as “Stipulated Penalties”) in accordance with the following provisions.

1. A Stipulated Penalty of \$2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day Allina fails to have in place any of the obligations described in Section III:

- a. a Corporate Compliance Officer;
- b. a Compliance Oversight Committee and Compliance Steering Committee;
- c. written Employee Standards of Business Conduct;
- d. written Policies and Procedures;
- e. a requirement that Covered Persons and Relevant Covered Persons be trained, as applicable; and
- f. a Disclosure Program.

2. A Stipulated Penalty of \$2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day Allina fails to meet any of the deadlines for the submission of the Implementation Report or the Annual Reports to OIG.

3. A Stipulated Penalty of \$2,000 (which shall begin to accrue on the date the failure to comply began) for each day Allina employs or contracts with, or grants staff privileges to an Ineligible Person and that person: (i) has responsibility for, or involvement with, Allina’s business operations related to the Federal health care programs; or (ii) is in a position for which the person’s salary or the items or services rendered, ordered, or prescribed by the person are paid in whole or part, directly or indirectly, by Federal health care programs or otherwise with Federal funds (the Stipulated Penalty described in this paragraph shall not be demanded for any time period during which Allina can demonstrate that it did not discover the person’s exclusion or other ineligibility after making a reasonable inquiry (as described in Section III.F) as to the status of the person).

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

5. A Stipulated Penalty of \$1,000 for each day Allina fails to comply fully and adequately with any obligation of this CIA. In its notice to Allina, OIG shall state the specific grounds for its determination that Allina has failed to comply fully and adequately with the CIA obligation(s) at issue and steps Allina must take to comply with the CIA. (This Stipulated Penalty shall begin to accrue 10 days after the Allina receives notice from the OIG of the failure to comply.) A Stipulated Penalty as described in this paragraph shall not be demanded for any violation for which the OIG has sought a Stipulated Penalty under paragraphs 1-4 of this Section.

B. Timely Written Requests for Extensions. Allina 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 Allina 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 Allina 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 Allina 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 Allina of: (a) Allina's failure to comply; and (b) the OIG's exercise of its contractual right to demand payment of the Stipulated Penalties (this notification is hereinafter referred to as the "Demand Letter").

2. *Response to Demand Letter*. Within 10 days of the receipt of the Demand Letter, Allina 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 Allina elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until Allina 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 Allina 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 Allina to report a Material Deficiency, take corrective action and make the appropriate refunds, as required in Section III.H;

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

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

2. *Notice of Material Breach and Intent to Exclude.* The parties agree that a material breach of this CIA by Allina constitutes an independent basis for Allina’s

exclusion from participation in the Federal health care programs. Upon a determination by OIG that Allina has materially breached this CIA and that exclusion should be imposed, OIG shall notify Allina of: (a) Allina'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.* Allina 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. Allina is in compliance with the obligations of the CIA cited by the 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) Allina has begun to take action to cure the material breach; (ii) Allina is pursuing such action with due diligence; and (iii) Allina has provided to OIG a reasonable timetable for curing the material breach.

4. *Exclusion Letter.* If at the conclusion of the 30-day period, Allina fails to satisfy the requirements of Section X.D.3, OIG may exclude Allina from participation in the Federal health care programs. OIG will notify Allina in writing of its determination to exclude Allina (this letter shall be referred to hereinafter as the "Exclusion Letter"). Subject to the Dispute Resolution provisions in Section X.E, below, the exclusion shall go into effect 30 days after the date of the Exclusion Letter. The exclusion shall have national effect and shall also apply to all other Federal procurement and non-procurement programs. Reinstatement to program participation is not automatic. If at the end of the period of exclusion, Allina wishes to apply for reinstatement, Allina must submit 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 Allina 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, Allina 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 of the receipt of the Demand Letter and the request for a hearing involving exclusion shall be made within 25 days of receipt of the Exclusion Letter.

2. *Stipulated Penalties Review.* Notwithstanding any provision of Title 42 of the United States Code or Chapter 42 of the Code of Federal Regulations, the only issues in a proceeding for Stipulated Penalties under this CIA shall be: (a) whether Allina was in full and timely compliance with the obligations of this CIA for which the OIG demands payment; and (b) the period of noncompliance. Allina shall have the burden of proving its full and timely compliance and the steps taken to cure the noncompliance, if any. The 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 Allina to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable 20 days after the ALJ issues such a decision unless Allina requests review of the ALJ decision by the DAB. If the ALJ decision is properly appealed to the DAB and the DAB upholds the determination of OIG, the Stipulated Penalties shall become due and payable 20 days after the DAB issues its decision.

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

- a. whether Allina 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) Allina had begun to take action to cure the material breach within that period;
- (ii) Allina has pursued and is pursuing such action with due diligence; and
- (iii) Allina provided to OIG within that period a reasonable timetable for curing the material breach and Allina 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 Allina, only after a DAB decision in favor of OIG. Allina's election of its contractual right to appeal to the DAB shall not abrogate the OIG's authority to exclude Allina upon the issuance of an ALJ's decision in favor of the OIG. If the ALJ sustains the determination of the OIG and determines that exclusion is authorized, such exclusion shall take effect 20 days after the ALJ issues such a decision, notwithstanding that Allina 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. Allina agrees to 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 Allina, Allina will be reinstated effective on the date of the original exclusion.

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

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

- A. This CIA shall be binding on the successors, assigns, and transferees of Allina;
- 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 Allina's obligations under the CIA in the event of Allina's cessation of participation in Federal health care programs. If Allina withdraws from participation in Federal health care programs and is relieved from its CIA obligations by the OIG, Allina agrees to notify OIG 30 days in advance of Allina's intent to reapply as a participating provider or supplier with the Federal health care programs. Upon receipt of such notification, OIG will evaluate whether the CIA should be reactivated or modified.

E. The undersigned Allina 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.

FROM ALLINA LEGAL DEPT.

(SUN) 12. 30' 01 23:00 ST. 23:02/NO. 4861144821 P 1

**ON BEHALF OF ALLINA**



**David B. Jones**  
**Interim Chief Operating Officer**  
**and Chief Financial Officer**  
**Allina Health System**

12/31/01  
DATE

\_\_\_\_\_  
**Mark G. Mishek**  
**Senior Vice President, Law & Public Affairs,**  
**General Counsel**  
**Allina Health System**

\_\_\_\_\_  
DATE

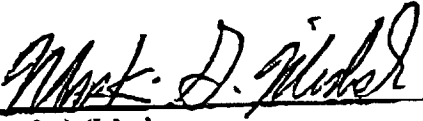
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**David B. Orbuch**  
**Corporate Compliance Officer**  
**Allina Health System**

\_\_\_\_\_  
DATE


**ON BEHALF OF ALLINA**

\_\_\_\_\_  
David B. Jones  
Interim Chief Operating Officer  
and Chief Financial Officer  
Allina Health System

\_\_\_\_\_  
DATE

  
\_\_\_\_\_  
Mark G. Mishek  
Senior Vice President, Law & Public Affairs,  
General Counsel  
Allina Health System

12/31/01  
DATE

  
\_\_\_\_\_  
David B. Orbuch  
Corporate Compliance Officer  
Allina Health System

12/31/01  
DATE

**ON BEHALF OF ALLINA**

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David B. Jones  
Interim Chief Operating Officer  
and Chief Financial Officer  
Allina Health System

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Mark G. Mishek  
Senior Vice President, Law & Public Affairs,  
General Counsel  
Allina Health System

\_\_\_\_\_  
DATE



\_\_\_\_\_  
David B. Orbuch  
Corporate Compliance Officer  
Allina Health System

\_\_\_\_\_  
12/31/01  
DATE

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



\_\_\_\_\_  
LEWIS MORRIS

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

12/31/07  
\_\_\_\_\_  
DATE

## Appendix A Allina Claims Review Procedures

### I. Introduction

Allina has developed a protocol for reviewing, on a regular basis, a sample of claims for services rendered by each of Allina's business units. The objective of the review is to verify compliance with the Federal health care program requirements.

Each Allina business unit shall be audited at least once per year. Allina Internal Audit, in collaboration with the Corporate Compliance Officer, shall conduct the claims reviews for each business unit including Allina Hospitals, Allina Medical Clinics (including Allina Behavioral Health Services and Minneapolis Cardiology Associates), Allina Homecare and Hospice, Allina Home Medical Equipment, and Allina Medical Transportation.

### II. Audit Staff

The individuals conducting the claims reviews shall have relevant experience conducting claims reviews, in statistical sampling, and in the Federal health care program requirements for each business unit reviewed. Allina shall include the name and qualifications of the individuals completing the claims reviews.

### III. Audit Process

The Allina Internal Audit Department shall send each business unit an engagement letter setting forth a list of claims to be reviewed. The business units shall have five (5) business days to gather the information (e.g., medical records) necessary to support the requested claims. If, however, the claims were submitted by an Allina clinic for services performed in a hospital or nursing facility setting, the business unit shall have fifteen (15) business days to gather the information necessary to support those particular claims.

Allina's annual claims review work plans shall include detailed explanations for Allina's sample size determinations. The OIG or Allina, with the OIG's approval, may choose to alter the sample size or otherwise modify the work plan based on historical data and/or changes in Allina's organizational structure or practices. Unless specifically explained, the payor mix will be 50% Medicare and 50% Medicaid.

### IV. OIG Review.

At least once during the term of the CIA, the OIG or one of its contractors will perform a review to determine whether Allina's Annual Claims Review conforms with the requirements of this CIA and whether the findings or Claims Review results are accurate. The OIG shall bear its own costs for such a review.

## APPENDIX B - Special Review Guidelines

A Special Review pursuant to Section III.D.2 of the Corporate Integrity Agreement (“CIA”) shall consist of a review of either: (1) all the claims affected by the Material Deficiency, or (2) a statistically valid random sample of the claims that can be projected to the population of claims affected by the Material Deficiency for the relevant period. This Appendix B sets forth guidelines for conducting the Special Review.

### A. Special Review.

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

- a. Special Review Sample: A statistically valid, randomly selected, sample of items selected for appraisal in the Special Review.
- b. Item: Any discrete unit that can be sampled (e.g., code, line item, beneficiary, patient encounter, etc.).
- c. Overpayment: Consistent with the definition of Overpayment as articulated in Section III.H.1.a of the CIA, the amount of money Allina has received in excess of the amount due and payable under any Federal health care program requirements. For the purposes of the Special Review and all reporting to the OIG under this CIA, Allina shall not subtract or “net out” underpayments when determining the amount of relevant Overpayments.
- d. Claim: A code or line item submitted by Allina and for which Allina has requested reimbursement from the Medicare or Medicaid programs.
- e. Population: All Items for which Allina has submitted a code or line item and for which Allina has received reimbursement from the Medicare or Medicaid programs (i.e., all Claims) during the relevant period covered by the Special Review.
- f. Probe Sample: A sample of Items selected through simple random sampling from the Population for the purpose of estimating the mean and standard deviation of Overpayments in the Population. The estimated mean and standard deviation of Overpayments in the Population shall be used to calculate the minimum number of Items that shall be included in the Special Review Sample in order to achieve the required confidence and



precision levels.

g. RAT-STATS: OIG's Office of Audit Services Statistical Sampling Software. RAT-STATS is publicly available to download through the Internet at "[www.hhs.gov/oig/oas/ratstat.html](http://www.hhs.gov/oig/oas/ratstat.html)".

2. ***Description of Special Review.*** The Special Review shall consist of an appraisal of a statistically valid sample of Items (the Special Review Sample) that can be projected to the total Population. The individuals conducting the Special Review shall have relevant experience conducting claims reviews, in statistical sampling, and in the Federal health care program requirements for each business unit reviewed.

a. Confidence and Precision Requirements. The Special Review Sample shall contain a sufficient number of Items (according to the RAT-STATS calculation) so that if the Overpayments identified in the Special Review Sample were projected to the Population, the projection would provide a 90% confidence level and a maximum relative precision (i.e., semi-width of the confidence interval) of plus or minus 25% of the point estimate. In other words, if the Special Review Overpayment results were projected to the Population at a 90% confidence level, the confidence interval (expressed in dollars) shall be sufficiently narrow that the upper bound of the confidence interval would not exceed 125% of the midpoint of the confidence interval (the point estimate), and the lower bound of the confidence interval shall not be less than 75% of the midpoint of the confidence interval.

b. Use of a Probe Sample to Determine Special Review Sample Size. To determine how many Items shall be included in the Special Review Sample to meet the 90% confidence level and 25% precision requirements, the mean and the standard deviation of Overpayments in the Population shall be estimated. Estimates for each unique Population may be determined from the Annual Claims Review results that triggered the Special Review. In the alternative or where the sample size for the Annual Claims Review does not meet the minimum size requirements set forth below, Allina may determine the minimum Special Review sample size through one of the two following options:

i. *Probe Sample with a Minimum Size of Thirty Items.* The Probe Sample shall include at least 30 Items, and shall be selected through

the use of RAT-STATS' "Random Numbers" function. Once all Claims associated with the Items included in the Probe Sample have been reviewed, the estimated mean and standard deviation of Overpayments in the Population shall be determined. This determination is based on the Overpayment amount received by Allina for each Item in the sample. The "Difference Values Only" function located under the "Variable Appraisals" component of RAT-STATS shall be used to calculate the estimated mean and standard deviation of Overpayments in the Population. For purposes of estimating the mean and standard deviation of Overpayments in the Population, and entering this information into the "Variable Appraisals", "Difference Values Only" function of RAT-STATS, any underpayment identified for a Claim in the Probe Sample shall be treated as a zero overpayment. If no Overpayments are found in this Probe Sample, then a second Probe Sample, of at least 30 Items, shall be selected and reviewed. The estimated mean and standard deviation of Overpayments in the Population (based on the amount of Overpayments received by Allina for each sample Item) shall be determined from this Probe Sample, using RAT-STATS' "Difference Values Only" function located under the "Variable Appraisals" component. If no Overpayments are found in this second Probe Sample, then the Special Review can be terminated with the results of the second Probe Sample, and the results of the two Probe Samples shall be reported in lieu of the Special Review when preparing and submitting the Special Review Report (see section B, below); or

ii. *Probe Sample with a Minimum Size of Fifty Items.* The Probe Sample shall include at least 50 Items, and shall be selected through the use of RAT-STATS' "Random Numbers" function. Once all Claims associated with the Items included in the Probe Sample have been reviewed, the estimated mean and standard deviation of Overpayments in the Population shall be determined. This determination is based on the Overpayment amount received by Allina for each Item in the sample. The "Difference Values Only" function located under the "Variable Appraisals" component of RAT-STATS shall be used to calculate the estimated mean and standard deviation of Overpayments in the Population. For purposes of estimating the mean and standard deviation of Overpayments in the Population, and entering this information into the "Variable

Appraisals”, “Difference Values Only” function of RAT-STATS, any underpayment identified for a Claim in the Probe Sample shall be treated as a zero overpayment. If no Overpayments are found in this 50 Item Probe Sample, then the Special Review may be terminated with the review of the Probe Sample and the results of the Probe Sample shall be reported in lieu of the results of the Special Review when preparing and submitting the Special Review Report (see Section B, below).

c. Calculation of Special Review Sample Size and Selection of the Special Review Sample. The estimates of the mean and the standard deviation of Overpayments in the Population obtained through the review of the Probe Sample shall be used to estimate the minimum size of the Special Review Sample. In order to estimate the number of Items that shall be included in the Claims Review Sample to meet the 90% confidence level and 25% precision requirements, RAT-STATS’ “Sample Size Estimators” (located under the “Utility Programs” file) shall be used. Whereas the Special Review Sample size is estimated from the results of the Probe Sample, there is a possibility that examining the number of Items identified by RAT-STATS may not achieve the 90% confidence and 25% precision levels. If the reviewer can demonstrate that the review was properly conducted, but the 90% confidence level and 25% precision interval could not be achieved, the reviewer shall not be required to examine additional items.

The Special Review Sample shall be selected by using RAT-STATS’ “Random Numbers” function, and shall be selected from the entire Population, with the Population including those Items reviewed as part of the Probe Sample or Annual Claims Review Sample, so that all Items in the Population have an equal chance of inclusion in the Special Review Sample.

d. Item Appraisal. Every Claim in the Special Review Sample shall be evaluated to determine whether it was correctly coded, submitted, and reimbursed. Each appraisal shall be sufficient to provide all information required under the Special Review Report.

e. Claims without Supporting Documentation. For the purpose of appraising Items included in the Special Review and/or the Probe Sample, any Claim for which Allina cannot produce documentation sufficient to

support the Claim shall be considered an error and the total reimbursement received by Allina for such Claim shall be deemed an Overpayment. Replacement sampling for Claims with missing documentation shall not be permitted.

f. Use of First Samples Drawn. For the purposes of all samples (Probe Sample(s) and Special Review Sample(s)) discussed in this Appendix, the Claims associated with the Items selected in the first sample (or first sample for each strata, if applicable) shall be used. In other words, it is not permissible to generate a number of random samples and then select one for use as the Probe Sample or Special Review Sample.

**B. Special Review Report**. The following information shall be included in each Special Review Report:

1. *Special Review Methodology*

a. Special Review Objective: A clear statement of the objective intended to be achieved by the Special Review.

b. Sampling Unit: A description of the Item as that term is utilized for the Special Review. As noted in Section A.1.b above, for purposes of this Billing Engagement, the term "Item" may refer to any discrete unit that can be sampled (e.g., claim, line item, beneficiary, patient encounter, etc.).

c. Special Review Population: A description of the Population subject to the Special Review.

d. Sampling Frame: A description of the sampling frame, which is the totality of Items from which the Probe and Special Review Sample have been selected and an explanation of the methodology used to identify the sampling frame. In most circumstances, the sampling frame will be identical to the Population.

e. Sources of Data: A description of the documentation relied upon by the auditor when performing the Special Review (e.g., medical records, physician orders, certificates of medical necessity, requisition forms, local medical review policies, CMS program memoranda, Medicare carrier or intermediary manual or bulletins, other policies, regulations, or directives).

f. Review Protocol: A narrative description of how the Special Review was conducted and what was evaluated.

## 2. *Statistical Sampling Documentation*

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

## 3. *Special Review Results*

- a. Total number and percentage of instances in which the auditor determined that the Claim differed from what should have been submitted (“Correct Claim”), regardless of the effect on the payment.
- b. Total number and percentage of instances in which the Claim differed from the Correct Claim and in which such difference resulted in an Overpayment to Allina.
- c. The total dollar amount of all Claims in the Special Review Sample and the total dollar amount of Overpayments associated with the Claims identified by the Special Review. (This is the total dollar amount of the Overpayments identified in Section B.3.b above.) The auditor may, in its report to Allina, identify underpayments, but any underpayments identified during the Special Review shall not be offset or “netted out” of the total dollar amount of Claims or of the Overpayments when reporting these amounts in the Special Review Report to the OIG.

d. The level of precision achieved by the Special Review at a 90% confidence level.

e. A spreadsheet of the Special Review results that includes the following information for each Claim appraised: Federal health care program billed, beneficiary health insurance claim number, date of service, procedure code submitted, procedure code reimbursed, allowed amount reimbursed by payor, correct procedure code (as determined by the auditor), correct allowed amount (as determined by the auditor), dollar difference between allowed amount reimbursed by payor and the correct allowed amount. (See Attachment 1 to this Appendix.)

4. ***Credentials.*** The names, titles and credentials of the individuals who were involved in any aspect of the Special Review, including those individuals who: (1) designed the statistical sampling procedures and the review methodology utilized for the Special Review; and (2) performed the Special Review.

