INTEGRITY AGREEMENT
BETWEEN THE
OFFICE OF INSPECTOR GENERAL
OF THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND
VNA OF GREATER TIFT, INC.

I. PREAMBLE

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

II. TERM AND SCOPE OF THE IA

A. This IA shall have a term of five years from the Effective Date. The Effective Date shall be the date on which the final signatory signs this IA. Each one-year period, beginning with the one-year period following the Effective Date, shall be referred to as a "Reporting Period."

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

C. The term "Covered Persons" includes:

1. all owners, officers, members of the Board of Directors, and employees of VNA; and

2. all contractors, agents, and other persons who furnish patient care items or services or who perform billing or coding functions on behalf of VNA.

III. INTEGRITY OBLIGATIONS

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

A. Compliance Contact

Within 30 days after the Effective Date, VNA shall designate a Covered Person to be responsible for compliance activities (Compliance Contact). VNA shall maintain a Compliance Contact for the term of this IA. The Compliance Contact shall be responsible for: (1) monitoring VNA's day-to-day compliance activities; (2) meeting all reporting obligations created under this IA; and (3) responding to questions and concerns from Covered Persons and the OIG regarding compliance with the IA.

VNA shall report to OIG, in writing, any changes in the identity or job responsibilities of the Compliance Contact, or any actions or changes that would affect the Compliance Contact's ability to perform the duties necessary to meet the obligations in this IA within five days after such change.

B. Policies and Procedures

Within 90 days after the Effective Date, VNA shall develop and implement written policies and procedures regarding appropriate billing and medical record documentation for compliance with Federal health care program requirements (Policies and Procedures). Throughout the term of this IA, VNA shall enforce and comply with its Policies and Procedures and shall make such compliance an element of evaluating the performance of all employees.

Within 90 days after the Effective Date, the Policies and Procedures shall be distributed to all Covered Persons. Appropriate and knowledgeable staff shall be available to explain the Policies and Procedures.

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

C. Posting of Notice

Within 30 days after the Effective Date, VNA shall post in a prominent place accessible to all patients and Covered Persons a notice that provides the name and phone number of the HHS OIG Fraud Hotline telephone number (1-800-HHS-TIPS) as a

confidential means by which suspected fraud or abuse in the Federal health care programs may be reported.

D. Training and Education

1. *Training.* All Covered Persons shall receive at least three hours of training during the first Reporting Period, including at least one hour of training to be completed within 60 days after the Effective Date. Any individuals who become Covered Persons after the Effective Date and during the term of this IA shall receive at least three hours of training within 60 days of becoming a Covered Person.

Training may be completed in-person or on-line. These training requirements may be satisfied only by the completion of courses provided by the Centers for Medicare & Medicaid Services (CMS) Medicare Learning Network (MLN), VNA's Medicare contractor, or other training courses such as VNA's internal training courses, provided they are that are submitted to OIG, prior to registration for the training course, for review and approval.

At a minimum, the required training sessions must include the following topics:

a. the Federal health care program billing, coding and claim submission statutes, regulations, and program requirements and directives relating to home health or other services furnished by VNA;

b. the Federal health care program medical record documentation requirements relating to services furnished by VNA; and

c. the personal obligation of each individual involved in the medical record documentation and claims submission processes to ensure that medical records and claims are accurate.

The OIG may, in its discretion, require that VNA and other Covered Persons complete additional hours of training regarding the topics identified above, or additional topics, in the second or third years of the IA. The OIG shall provide notice to VNA of such additional required training at least 180 days prior to the required completion date for such training.

2. *Certification.* VNA shall maintain written documentation (e.g., written or electronic certificates of completion from the training provider) that all Covered Persons required to receive training have in fact completed such training. The documentation shall specify the type of training received, the individual who completed the training, and the date received.

E. Review Procedures

1. *General Description.*

a. *Engagement of Independent Review Organization.* Within 120 days after the Effective Date, VNA shall engage an individual or entity, such as an accounting, auditing, or consulting firm (hereinafter "Independent Review Organization" or "IRO"), to perform the reviews listed in this Section III.E. The applicable requirements relating to the IRO are outlined in Appendix A to this IA, which is incorporated by reference.

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

2. *Claims Review.* The IRO shall review VNA's coding, billing, and claims submission to the Medicare and state Medicaid programs and the reimbursement received (Claims Review) and shall prepare a Claims Review Report, as outlined in Appendix B to this IA, which is incorporated by reference.

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

Prior to initiating a Validation Review, OIG shall notify VNA in writing of its intent to do so and provide an explanation of the reasons OIG has determined a Validation Review is necessary. VNA shall have 30 days following the date of the OIG's written notice to submit a written response to OIG that includes any additional or relevant information to clarify the results of the Claims Review or to correct the inaccuracy of the Claims Review and/or propose alternatives to the proposed Validation Review. The final determination as to whether or not to proceed with a Validation Review shall be made at the sole discretion of OIG.

4. *Independence and Objectivity Certification.* The IRO shall include in its report(s) to VNA a certification that the IRO has (a) evaluated its professional independence and objectivity with respect to the reviews required under this Section III.E and (b) concluded that it is, in fact, independent and objective, in accordance with the requirements specified in Appendix A to this IA.

F. Ineligible Persons

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

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

i. is currently excluded, debarred, or suspended from participation in the Federal health care programs or in Federal procurement or nonprocurement programs; or

ii. has been convicted of (a) a criminal offense that is related to the delivery of an item or service under Medicare or any state health care program; (b) a criminal offense relating to neglect or abuse of patients; (c) a felony criminal offense relating to fraud, theft, embezzlement, breach of fiduciary responsibility, or other financial misconduct in connection with the delivery of a health care item or service or with respect to a government funded health care program (other than Medicare or a state health care program); or (d) a felony criminal offense relating to the unlawful manufacture, distribution, prescription or dispensing of a controlled substance, but has not yet been excluded, debarred, suspended, or otherwise declared ineligible.

b. "Exclusion Lists" include:

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

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

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

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

b. VNA shall screen all current Covered Persons against the Exclusion Lists within 30 days after the Effective Date and thereafter shall screen against the LEIE on a monthly basis and screen against SAM on an annual basis.

c. VNA shall require all Covered Persons to immediately disclose any debarment, exclusion, or suspension.

VNA shall maintain documentation demonstrating that VNA: (1) has checked the Exclusion Lists (e.g., print screens from search results) and determined that such individuals or entities are not Ineligible Persons; and (2) has required individuals and entities to disclose if they are an Ineligible Person (e.g., employment applications).

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

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

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

G. Notification of Government Investigation or Legal Proceeding

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

H. Overpayments

1. *Definition of Overpayments.* For purposes of this IA, an "Overpayment" shall mean the amount of money VNA has received in excess of the amount due and payable under any Federal health care program requirements but shall not include interim requests for anticipated payment (RAPs) under Medicare.

2. *Overpayment Policies and Procedures.* Within 90 days after the Effective Date, VNA shall develop and implement written policies and procedures regarding the identification, quantification and repayment of Overpayments received from any Federal health care program.

3. *Repayment of Overpayments*. If, at any time, VNA identifies any Overpayment that has not already been recouped by the payor, VNA shall repay the Overpayment to the appropriate payor (e.g., Medicare contractor) within 60 days after VNA's identification of the Overpayment and take steps to correct the problem and prevent the Overpayment from recurring within 90 days after identification (or such additional time as may be agreed to by the payor). If not yet quantified within 60 days after identification, VNA shall notify the payor at that time of its efforts to quantify the Overpayment amount and provide a schedule of when such work is expected to be completed. VNA should follow the payor's policies regarding the form of notification and the repayment process for any Overpayment refunds. Any questions regarding the repayment process should be directed to the payor.

I. Reportable Events

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

a. a substantial Overpayment;

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

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

d. the filing of a bankruptcy petition by VNA.

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

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

3. *Reportable Events under Sections III.I.1.a. and III.I.1.b.* For Reportable Events under Sections III.I.1.a and b, the report to OIG shall include:

a. a complete description of all details relevant to the Reportable Event, including, at a minimum, the types of

claims, transactions or other conduct giving rise to the Reportable Event; the period during which the conduct occurred; and the names of individuals and entities believed to be implicated, including an explanation of their roles in the Reportable Event;

b. a statement of the Federal criminal, civil or administrative laws that are probably violated by the Reportable Event, if any;

c. the Federal health care programs affected by the Reportable Event;

d. a description of the steps taken by VNA to identify and quantify any Overpayments; and

e. a description of VNA's actions taken to correct the Reportable Event and prevent it from recurring.

If the Reportable Event involves an Overpayment, within 60 days of identification of the Overpayment, VNA shall repay the Overpayment, in accordance with the requirements of 42 U.S.C. § 1320a-7k(d) and 42 C.F.R. § 401.301-305 (and any applicable CMS guidance) and provide OIG with a copy of the notification and repayment.

4. *Reportable Events under Section III.I.1.c.* For Reportable Events under Section III.I.1.c, the report to OIG shall be made within 30 days after making the determination that a Reportable Event has occurred and shall include:

a. the identity of the Ineligible Person and the job duties performed by that individual;

b. the dates of the Ineligible Persons employment or contractual relationship;

c. a description of the Exclusion Lists screening that VNA completed before and/or during the Ineligible Person's employment or contract and any flaw or breakdown in the Ineligible Persons screening process that led to the hiring or contracting with the Ineligible Person;

d. a description of how the Reportable Event was discovered;

and

e. a description of any corrective action implemented to prevent future employment or contracting with an Ineligible Person.

5. *Reportable Events under Section III.I.1.d.* If the Reportable Event involves the filing of a bankruptcy petition, the report to the OIG shall be made within 30 days after the filing and include documentation of the bankruptcy filing and a description of any Federal health care program authorities implicated.

6. *Reportable Events Involving the Stark Law.* Notwithstanding the reporting requirements outlined above, any Reportable Event that involves solely a probable violation of section 1877 of the Social Security Act, 42 U.S.C. §1395nn (the Stark Law) should be submitted by VNA to the Centers for Medicare & Medicaid Services (CMS) through the self-referral disclosure protocol (SRDP), with a copy to the OIG. The requirements of Section III.I.3 that require repayment to the payor of any identified Overpayment within 60 days shall not apply to any Overpayment that may result from a probable violation of solely the Stark Law that is disclosed to CMS pursuant to the SRDP. If VNA identifies a probable violation of the Stark Law and repays the applicable Overpayment directly to the CMS contractor, then VNA is not required by this Section III.I to submit the Reportable Event to CMS through the SRDP.

IV. SUCCESSOR LIABILITY; CHANGES TO LOCATIONS OR BUSINESS

A. Change or Closure of Location

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

B. Purchase or Establishment of New Location or Business

In the event that, after the Effective Date, VNA purchases or establishes a new location or business related to the furnishing of items or services that may be reimbursed by Federal health care programs, VNA shall notify OIG at least 30 days prior to such purchase or the operation of the new location or business. This notification shall include the address of the new location or business, phone number, fax number, Medicare and state Medicaid program provider number and/or supplier number, and the name and address of each Medicare and state Medicaid program contractor to which VNA currently submits claims. Each new location or business and all Covered Persons at each new

location or business shall be subject to the applicable requirements of this IA, unless otherwise determined and agreed to in writing by OIG.

C. Sale of Location or Business

In the event that, after the Effective Date, VNA proposes to sell any or all of its locations or businesses that are subject to this IA, VNA shall notify OIG at least 30 days prior to the proposed sale. This notification shall include a description of the location or business to be sold, a brief description of the terms of the sale, and the name and contact information of the prospective purchaser. This IA shall be binding on the purchaser of such location or business, unless otherwise determined and agreed to in writing by OIG.

V. IMPLEMENTATION REPORT, IRO REPORTS AND ANNUAL REPORTS

A. Implementation Report

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

1. the name, address, phone number, and position description of the Compliance Contact required by Section III.A;

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

3. a copy of the notice required by Section III.C, a description of where the notice is posted, and the date the notice was posted;

4. the following information regarding the IRO: (a) identity, address, and phone number; (b) a copy of the engagement letter; (c) information to demonstrate that the IRO has the qualifications outlined in Appendix A to this IA; (d) a summary and description of any and all current and prior engagements and agreements between VNA and the IRO; and (e) a certification from the IRO regarding its professional independence and objectivity with respect to VNA;

5. a copy of the documentation demonstrating that VNA has screened all Covered Persons against the Exclusion Lists, as required by Section III.F within 30 days of the Effective Date;

6. a copy of VNA's policies and procedures regarding the identification, quantification and repayment of Overpayments required by Section III.H;

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

8. a certification by the Compliance Contact and a certification by the Chief Executive Officer that: (a) he or she has reviewed the IA in its entirety, understands the requirements described within, and maintains a copy for reference; (b) to the best of his or her knowledge, except as otherwise described in the Implementation Report, VNA is in compliance with all of the requirements of this IA; and (c) he or she has reviewed the Implementation Report and has made a reasonable inquiry regarding its content and believes that the information is accurate and truthful.

B. Annual Reports

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

1. the name, address, phone number, and position description of the Compliance Contact required by Section III.A;

2. a description of any changes to the Policies and Procedures required by Section III.B;

3. a description of any changes to the notice required by Section III.C, and the reason for such changes, along with a copy of the revised notice;

4. (in the first Annual Report) the following information regarding the training required by Section III.D: a copy of the training program registration for each Covered Person who completed the training, the name of the training course, the name of the entity that provided the training, the location, date and length of the training; and a training program brochure or other materials from the training program or training program sponsor that describe the content of the training program. A copy of all training materials shall be made available to OIG upon request;

5. a complete copy of all reports prepared pursuant to Section III.E, along with a copy of the IRO's engagement letter and VNA's response to the reports, along with corrective action plan(s) related to any issues raised by the reports;

6. a summary and description of any and all current and prior engagements and agreements between VNA and the IRO (if different from what was submitted as part of the Implementation Report) and a certification from the IRO regarding its professional independence and objectivity with respect to VNA;

7. a copy of the documentation demonstrating that VNA screened all prospective and current Covered Persons against the Exclusion Lists, as required by Section III.F;

8. 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;

9. a description of any changes to the Overpayment policies and procedures required by Section III.H, including the reasons for such changes;

10. a report of the aggregate Overpayments that have been returned to the Federal health care programs during the Reporting Period. Overpayment amounts shall be broken down into the following categories: Medicare, Medicaid, and other Federal health care programs;

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

12. a description of all changes to the most recently provided list of VNA's locations (including addresses) as required by Section V.A.7; and

13. a certification signed by VNA's Chief Executive Officer and one signed by VNA's Compliance Contact that: (a) he or she has reviewed the IA in its entirety, understands the requirements described within, and maintains a copy for reference; (b) to the best of his or her knowledge, except as otherwise described in the Annual Report, VNA is in compliance with all of the requirements of this IA; and (c) he or she has reviewed the Annual Report and has made a reasonable inquiry regarding its content and believes that the information 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.

C. Designation of Information

VNA 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. VNA shall refrain from identifying any information as exempt from disclosure if that information does not meet the criteria for exemption from disclosure under FOIA.

VI. NOTIFICATIONS AND SUBMISSION OF REPORTS

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

OIG:

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

VNA:

Compliance Contact
VNA of Greater Tift
2014 U.S. Highway 41 North
Post Office Box 289
Tifton, Georgia 31793
Telephone: (229) 386-8571
Facsimile: (229) 386-1525

Unless otherwise specified, all notifications and reports required by this IA shall be made by certified mail, overnight mail, hand delivery, or other means, provided that there is proof that such notification was received. For purposes of this requirement, internal facsimile confirmation sheets do not constitute proof of receipt. Upon request by OIG, VNA may be required to provide OIG with an electronic copy of each notification or report required by this IA in searchable portable document format (pdf), in addition to a paper copy.

VII. OIG INSPECTION, AUDIT, AND REVIEW RIGHTS

In addition to any other rights OIG may have by statute, regulation, or contract, OIG or its duly authorized representative(s) may examine and/or request copies of VNA's books, records, and other documents and supporting materials and/or conduct on-site reviews of any of VNA's locations for the purpose of verifying and evaluating: (a) VNA's compliance with the terms of this IA and (b) VNA's compliance with the requirements of the Federal health care programs. The documentation described above shall be made available by VNA to OIG or its duly authorized representative(s) at all reasonable times for inspection, audit, and/or reproduction. Furthermore, for purposes of this provision, OIG or its duly authorized representative(s) may interview any of VNA's Covered Persons 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. VNA shall assist OIG or its duly authorized representative(s) in contacting and arranging interviews with such individuals upon OIG's request. VNA's Covered Persons may elect to be interviewed with or without a representative of VNA present.

VIII. DOCUMENT AND RECORD RETENTION

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

IX. DISCLOSURES

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

privileged or confidential, under the FOIA rules. With respect to such releases, VNA shall have the rights set forth at 45 C.F.R. § 5.65(d).

X. BREACH AND DEFAULT PROVISIONS

VNA is expected to fully and timely comply with all of its IA obligations.

A. Stipulated Penalties for Failure to Comply with Certain Obligations

As a contractual remedy, VNA and OIG hereby agree that failure to comply with certain obligations set forth in this IA 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 $1,000 (which shall begin to accrue on the day after the date the obligation became due) for each day VNA fails to:

   a. designate and maintain a Compliance Contact in accordance with the requirements of Section III.A;

   b. establish and implement the Policies and Procedures required by Section III.B;

   c. post a notice in accordance with the requirements of Section III.C;

   d. complete the training required for Covered Persons and maintain training certifications, in accordance with the requirements of Section III.D;

   e. screen Covered Persons in accordance with the requirements of Section III.F or require Covered Persons to disclose if they are debarred, excluded, or suspended in accordance with the requirements of Section III.F; and maintain documentation of screening and disclosure requirements in accordance with the requirements of Section III.F;

   f. notify OIG of a government investigation or legal proceeding, in accordance with the requirements of Section III.G;

g. establish policies and procedures regarding the repayment of Overpayments;

h. repay any Overpayments as required by Section III.H and Appendix B;

i. report a Reportable Event in accordance with Section III.I; or

j. disclose any changes to locations or business under Section IV.

2. A Stipulated Penalty of $1,500 (which shall begin to accrue on the day after the date the obligation became due) for each day VNA fails to engage and use an IRO, as required by Section III.E, Appendix A or Appendix B.

3. A Stipulated Penalty of $1,500 (which shall begin to accrue on the day after the date the obligation became due) for each day VNA fails to submit the Implementation Report, IRO Report, or any Annual Report to OIG in accordance with the requirements of Section V by the deadlines for submission.

3. A Stipulated Penalty of $1,000 for each day VNA fails to grant access as required in Section VII. (This Stipulated Penalty shall begin to accrue on the date VNA fails to grant access.)

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

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

B. Timely Written Requests for Extensions

VNA 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 IA. 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 VNA 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 days after VNA 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 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 VNA 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 VNA of: (a) VNA's failure to comply; and (b) OIG's exercise of its contractual right to demand payment of the Stipulated Penalties. (This notification shall be referred to as the "Demand Letter.")

2. *Response to Demand Letter.* Within 10 days after the receipt of the Demand Letter, VNA 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 VNA elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until VNA 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 IA and shall be grounds for exclusion under Section X.D.

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

4. *Independence from Material Breach Determination.* Except as set forth in Section X.D.1.c, these provisions for payment of Stipulated Penalties shall not affect or otherwise set a standard for OIG's decision that VNA has materially breached this IA, 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 IA

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

a. a failure by VNA to report a Reportable Event, take corrective action, or make the appropriate refunds, as required in Section III.I;

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

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

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

2. *Notice of Material Breach and Intent to Exclude.* The parties agree that a material breach of this IA by VNA constitutes an independent basis for VNA's exclusion from participation in the Federal health care programs. The length of the exclusion shall be in the OIG's discretion, but not more than five years per material breach. Upon a determination by OIG that VNA has materially breached this IA and that exclusion is the appropriate remedy, OIG shall notify VNA of: (a) VNA's material breach; and (b) OIG's intent to exercise its contractual right to impose exclusion. (This notification shall be referred to as the "Notice of Material Breach and Intent to Exclude.")

3. *Opportunity to Cure.* VNA shall have 30 days from the date of receipt of the Notice of Material Breach and Intent to Exclude to demonstrate that:

a. the alleged material breach has been cured; or

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

4. *Exclusion Letter.* If, at the conclusion of the 30 day period, VNA fails to satisfy the requirements of Section X.D.3, OIG may exclude VNA from

participation in the Federal health care programs. OIG shall notify VNA in writing of its determination to exclude VNA. (This letter shall be referred to as the "Exclusion Letter.") Subject to the Dispute Resolution provisions in Section X.E, below, the exclusion shall go into effect 30 days after the date of VNA's receipt of the Exclusion Letter. The exclusion shall have national effect. Reinstatement to program participation is not automatic. At the end of the period of exclusion, VNA 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 VNA of its Demand Letter or of its Exclusion Letter, and as an agreed-upon contractual remedy for the resolution of disputes arising under this IA, VNA 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 IA. 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. The procedures relating to the filing of a request for a hearing can be found at http://www.hhs.gov/dab/divisions/civil/procedures/divisionprocedures.html.

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 IA shall be: (a) whether VNA was in full and timely compliance with the obligations of this IA for which OIG demands payment; and (b) the period of noncompliance. VNA 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 IA and orders VNA to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable 20 days after the ALJ issues such a decision unless VNA 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 IA shall be whether VNA was in material breach of this IA and, if so, whether:

a. VNA cured such breach within 30 days of its receipt of the Notice of Material Breach; or

b. the alleged material breach could not have been cured within the 30 day period, but that, during the 30 day period following VNA's receipt of the Notice of Material Breach: (i) VNA had begun to take action to cure the material breach; (ii) VNA pursued such action with due diligence; and (iii) VNA provided to OIG a reasonable timetable for curing the material breach.

For purposes of the exclusion herein, exclusion shall take effect only after an ALJ decision favorable to OIG, or, if the ALJ rules for VNA, only after a DAB decision in favor of OIG. VNA's election of its contractual right to appeal to the DAB shall not abrogate OIG's authority to exclude VNA 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 VNA 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. VNA 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 VNA, VNA 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 IA agree that the DAB's decision (or the ALJ's decision if not appealed) shall be considered final for all purposes under this IA.

XI. EFFECTIVE AND BINDING AGREEMENT

VNA and OIG agree as follows:

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

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

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

D. All requirements and remedies set forth in this IA are in addition to and do not affect (1) VNA's responsibility to follow all applicable Federal health care program requirements or (2) the government's right to impose appropriate remedies for failure to follow applicable Federal health care program requirements.

E. The undersigned VNA signatories represent and warrant that they are authorized to execute this IA. The undersigned OIG signatories represent that they are signing this IA in their official capacity and that they are authorized to execute this IA.

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

ON BEHALF OF VNA OF GREATER TIFT, INC.

/Sandy Albertson/

SANDY ALBERTSON
Vice President and Chief Financial Officer
VNA of Greater Tift, Inc.

7/25/17
DATE

/Lynn M. Adam/

LYNN M. ADAM
Counsel for VNA of Greater Tift, Inc.
The Khayat Law Firm

July 25, 2017
DATE

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

/Lisa M. Re/

7/14/17

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

/Sarah Kessler/

7/13/2017

SARAH KESSLER
DATE
Senior Counsel
Office of Inspector General
U. S. Department of Health and Human Services

APPENDIX A

INDEPENDENT REVIEW ORGANIZATION

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

A. IRO Engagement

1. VNA shall engage an IRO that possesses the qualifications set forth in Paragraph B, below, to perform the responsibilities in Paragraph C, below. The IRO shall conduct the review in a professionally independent and objective fashion, as set forth in Paragraph D. Within 30 days after OIG receives the information identified in Section V.A.4 of the IA or any additional information submitted by VNA in response to a request by OIG, whichever is later, OIG will notify VNA if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, VNA may continue to engage the IRO.

2. If VNA engages a new IRO during the term of the IA, that IRO must also meet the requirements of this Appendix. If a new IRO is engaged, VNA shall submit the information identified in Section V.A.4 of the IA to OIG within 30 days of engagement of the IRO. Within 30 days after OIG receives this information, or any additional information submitted by VNA at the request of OIG, whichever is later, OIG will notify VNA if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, VNA may continue to engage the IRO.

B. IRO Qualifications

The IRO shall:

1. assign individuals to conduct the Claims Review who have expertise in the billing, coding, claims submission and other applicable Medicare and state Medicaid program requirements;

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

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

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

C. IRO Responsibilities

The IRO shall:

1. perform each Claims Review in accordance with the specific requirements of the IA;

2. follow all applicable Medicare and state Medicaid program rules and reimbursement guidelines in making assessments in the Claims Review;

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

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

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

D. IRO Independence and Objectivity

The IRO must perform the Claims Review in a professionally independent and objective fashion, as defined in the most recent Government Auditing Standards issued by the U.S. Government Accountability Office.

E. IRO Removal/Termination

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

2. *OIG Removal of IRO.* In the event OIG has reason to believe the IRO does not possess the qualifications described in Paragraph B, is not independent and objective as set forth in Paragraph D, or has failed to carry out its responsibilities as described in Paragraph C, OIG shall notify VNA in writing regarding OIG's basis for determining that the IRO has not met the requirements of this Appendix. VNA shall have 30 days from the date of OIG's written notice to provide information regarding the IRO's qualifications, independence or performance of its responsibilities in order to resolve the concerns identified by OIG. If, following OIG's review of any information provided by

VNA regarding its IRO, OIG determines that the IRO has not met the requirements of this Appendix, OIG shall notify VNA in writing that VNA shall be required to engage a new IRO in accordance with Paragraph A of this Appendix. VNA must engage a new IRO within 60 days of receipt of OIG's written notice. The final determination as to whether or not to require VNA to engage a new IRO shall be made at the sole discretion of OIG.

APPENDIX B

CLAIMS REVIEW

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

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

a. Overpayment: The amount of money VNA has received in excess of the amount due and payable under Medicare or any state Medicaid program requirements, as determined by the IRO in connection with the claims reviews performed under this Appendix B, including any extrapolated Overpayments determined in accordance with Section A.3 of this Appendix B.

b. Paid Claim: A claim submitted by VNA and for which VNA has received reimbursement from the Medicare program or a state Medicaid program but not including interim payments such as a payment on a Request for Anticipated Payment (RAP).

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

d. Error Rate: The Error Rate shall be the percentage of net Overpayments identified in the sample. The net Overpayments shall be calculated by subtracting all underpayments identified in the sample from all gross Overpayments identified in the sample.

The Error Rate is calculated by dividing the net Overpayment identified in the sample by the total dollar amount associated with the Paid Claims in the sample.

2. *Discovery Sample.* The IRO shall randomly select and review a sample of 100 Paid Claims (Discovery Sample). The Paid Claims shall be reviewed based on the supporting documentation available at VNA's office or under VNA's control and applicable billing and coding regulations and guidance to determine whether the claim was correctly coded, submitted, and reimbursed.

If the Error Rate (as defined above) for the Discovery Sample is less than 5%, no additional sampling is required, nor is the Systems Review required. (Note: The

guidelines listed above do not imply that this is an acceptable error rate. Accordingly, VNA should, as appropriate, further analyze any errors identified in the Discovery Sample. VNA recognizes that OIG or other HHS component, in its discretion and as authorized by statute, regulation, or other appropriate authority may also analyze or review Paid Claims included, or errors identified, in the Discovery Sample or any other segment of the universe.)

3. *Full Sample.* If the Discovery Sample indicates that the Error Rate is 5% or greater, the IRO shall select an additional sample of Paid Claims (Full Sample) using commonly accepted sampling methods. The Paid Claims selected for the Full Sample shall be reviewed based on supporting documentation available at VNA or under VNA's control and applicable billing and coding regulations and guidance to determine whether the claim was correctly coded, submitted, and reimbursed. For purposes of calculating the size of the Full Sample, the Discovery Sample may serve as the probe sample, if statistically appropriate. Additionally, the IRO may use the Paid Claims sampled as part of the Discovery Sample, and the corresponding findings for those Paid Claims, as part of its Full Sample, if: (1) statistically appropriate and (2) the IRO selects the Full Sample Paid Claims using the seed number generated by the Discovery Sample. The findings of the Full Sample shall be used by the IRO to estimate the actual Overpayment in the Population with a 90% confidence level and with a maximum relative precision of 25% of the point estimate. OIG, in its sole discretion, may refer the findings of the Full Sample (and any related workpapers) received from VNA to the appropriate Federal health care program payor (e.g., Medicare contractor), for appropriate follow-up by that payor.

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

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

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

5. *Other Requirements.*

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

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

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

6. *Repayment of Identified Overpayments.* VNA shall repay within 60 days any Overpayment(s) in the Discovery Sample, regardless of the Error Rate, and (if applicable), the Full Sample, including any extrapolated Overpayments determined by the IRO in accordance with Section A.3 above, and VNA shall make available to OIG all documentation that reflects the refund of the Overpayment(s) to the payor.

B. Claims Review Report. The IRO shall prepare a Claims Review Report as described in this Appendix for each Claims Review performed. The following

information shall be included in the Claims Review Report for each Discovery Sample and Full Sample (if applicable).

1. *Claims Review Methodology.*

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

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

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

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

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

2. *Statistical Sampling Documentation.*

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

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

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

3. *Claims Review Findings.*

   a. Narrative Results.

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

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

b. Quantitative Results.

i. Total number and percentage of instances in which the IRO determined that the Paid Claims submitted by VNA (Claim Submitted) differed from what should have been the correct claim (Correct Claim), regardless of the effect on the payment.

ii. Total number and percentage of instances in which the Claim Submitted differed from the Correct Claim and in which such difference resulted in an Overpayment to VNA.

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

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

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

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

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

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

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

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

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

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

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