

**INTEGRITY AGREEMENT
BETWEEN THE
OFFICE OF INSPECTOR GENERAL
OF THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND
ROBERT G. COOK, M.D. AND KENOSHA VASCULAR LAB**

I. PREAMBLE

Robert G. Cook, M.D. and Kenosha Vascular Lab (collectively “Cook”) hereby enter into this Integrity Agreement (“Agreement”) 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, program requirements, 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”) by Cook. This commitment to promote compliance applies to any entity that Cook owns or in which Cook has a control interest, as defined in 42 U.S.C. § 1320a-3(a)(3), and Cook’s and any such entity’s employees, agents, contractors, and all third parties with whom Cook or such entity may choose to engage to act as billing or coding consultants for purposes of claiming reimbursement from the Federal health care programs and all other individuals responsible for the provision, marketing, or documentation of items or services reimbursable by Federal health care programs, or in the preparation of claims, reports, or other requests for reimbursement for such items or services (“Covered Persons”). Contemporaneously with this Agreement, Cook is entering into a Settlement Agreement with the United States, and this Agreement is incorporated by reference into the Settlement Agreement.

II. TERM OF THE AGREEMENT

Except as otherwise provided, the period of compliance obligations assumed by Cook under this Agreement shall be five (5) years from the effective date of this Agreement. The effective date of this Agreement shall be the date on which the final signatory of this Agreement executes this Agreement.

Sections VII, VIII, IX, X and XI shall expire no later than 120 days from the OIG’s receipt of: (1) the Cook’s final annual report; or (2) any additional materials

submitted by Cook pursuant to OIG's request, whichever is later.

III. INTEGRITY OBLIGATIONS

Cook hereby agrees to establish a Compliance Program that, at minimum, includes the following elements:

A. Compliance Contact

Within 30 days from the effective date of this Agreement, Cook shall designate a person to be the Compliance Contact for purposes of developing and implementing policies, procedures, and practices designed to ensure compliance with the obligations herein and with Federal health care program requirements. In addition, the Compliance Contact is responsible for responding to questions and concerns from Covered Persons and the OIG regarding compliance with the Agreement obligations. The name and phone number of the Compliance Contact shall be included in the Implementation Report. In the event a new Compliance Contact is appointed during the term of this Agreement, Cook shall notify the OIG, in writing, within 15 days of such a change.

B. Posting of Notice

Within 30 days from the effective date of this Agreement, Cook shall post in a prominent place accessible to all patients and Covered Persons a notice detailing his commitment to comply with all Federal health care program requirements in the conduct of his business. This notice shall include a means (*i.e.*, telephone number, address, etc.) by which instances of misconduct may be reported anonymously. A copy of this notice shall be included in the Implementation Report.

C. Written Policies and Procedures

Within 120 days of the effective date of this Agreement, Cook shall develop, implement, and make available to all Covered Persons written policies that address the following:

1. Cook's commitment to operate his business in full compliance with all Federal health care program requirements;
2. Cook's requirement that all Covered Persons shall be expected to comply with all Federal health care program requirements and with

Cook's own Policies and Procedures as implemented pursuant to Section III.C (including the requirements of this Agreement);

3. The requirement that all of Cook's Covered Persons shall be expected to report to Cook or the Compliance Contact suspected violations of any Federal health care program requirements or Cook's own Policies and Procedures. Any Covered Person who makes an inquiry regarding compliance with Federal health care program requirements shall be able to do so without risk of retaliation or other adverse effect.

4. The requirement that Cook shall not hire, employ, or engage as contractors any Ineligible Person. For purposes of this Agreement, an "Ineligible Person" shall be any individual or entity who: (i) is currently excluded, debarred, or otherwise ineligible to participate in the Federal health care programs or in Federal procurement or non-procurement programs; or (ii) has been convicted of a criminal offense that falls within the ambit of 42 U.S.C. § 1320a-7(a), but has not yet been excluded, debarred, or otherwise declared ineligible. To prevent hiring or contracting with any Ineligible Person, Cook shall check all prospective employees and contractors prior to engaging their services against the HHS/OIG List of Excluded Individuals/Entities (available through the Internet at <http://www.oig.hhs.gov>) and the General Services Administration's List of Parties Excluded from Federal Programs (available through the Internet at <http://epls.arnet.gov>). In addition to prospective checks, Cook shall conduct annual checks of all employees against each exclusion list.

5. The commitment of Cook to remain current with all Federal health care program requirements by obtaining and reviewing program memoranda, newsletters, and any other correspondence from the carrier related to Federal health care program requirements.

6. The proper procedures for the accurate preparation and submission of claims in accordance with Federal health care program requirements;

7. The proper documentation of services and billing information and the retention of such information in a readily retrievable form;

8. Cook's commitment to the accurate preparation and submission of claims involving the professional and technical components of furnishing

and interpreting vascular tests in accordance with Federal health care program requirements.

9. The requirement that Cook and every other physician who is a Covered Person provide appropriate documentation of the place of service when billing the Federal health care programs for the technical component of vascular tests.

10. The commitment of Cook to ensure that the Federal health care programs are only billed for services actually rendered, including, but not limited to, ensuring that when a physician bills for the professional component for furnishing vascular tests, the physician meets the applicable level of physician supervision necessary to bill the Federal health care programs for each study.

At least annually (and more frequently if appropriate), Cook 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 individuals whose job functions are related to those Policies and Procedures.

Within 90 days of the effective date of the Agreement and annually thereafter, each Covered Person shall certify in writing that he or she has read, understood, and will abide by Cook's Policies and Procedures. New Covered Persons shall review the Policies and Procedures and shall complete the required certification within two weeks after becoming a Covered Person or within 90 days of the effective date of the Agreement, whichever is later.

Copies of the written policies and procedures shall be included in the Implementation Report. Copies of any written policies and procedures that are subsequently revised shall be included in the Annual Report.

D. Training and Certification

Within 120 days from the effective date of this Agreement and at least once each year thereafter, Cook and all Covered Persons involved in 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 shall receive at least four (4) hours of training from an individual or entity, other than Cook or another Covered Person. The training shall be

conducted by individuals with expertise in the relevant subject areas, e.g., preparation or submission of claims to Federal health care programs for the types of services provided by Cook, including vascular surgeries and studies.

New Covered Persons involved in 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 shall receive the training described above within 30 days after becoming a Covered Person or within 90 days of the effective date of this Agreement, whichever is later. The training for New Covered Persons may either be provided internally by Covered Persons who have completed the required annual training or externally by a qualified individual or entity. Until they have received the requisite training, such New Covered Persons shall work under the direct supervision of a Covered Person who has received such training.

At a minimum, the annual and new employee training sessions shall cover the following topics:

1. Federal health care program requirements related to the proper submission of accurate bills for services rendered and/or items provided to Federal health care program patients;
2. The written Policies and Procedures developed pursuant to Section III.C., above;
3. The legal sanctions for improper billing or other violations of the Federal health care program requirements; and
4. Examples of proper and improper billing practices including, but not limited to, examples involving billing solely for the professional component for vascular studies and billing for both the professional and technical components for vascular studies.

Each Covered Person shall annually certify in writing that he or she has received the required training. The certification shall specify the type of training received and the date received. Cook shall retain the certifications, along with the training course materials. The training course materials shall be provided in the Annual Report.

E. Annual Review Procedures

1. *General Description.*

a. Retention of Independent Review Organization. Within 90 days of the effective date of this CIA, Cook shall retain an entity (or entities), such as an accounting, auditing or consulting firm (hereinafter "Independent Review Organization" or "IRO"), to perform reviews to assist Cook in assessing and evaluating its billing and coding practices and certain compliance obligations pursuant to this CIA and the Settlement Agreement. Each IRO retained by Cook shall have expertise in the billing, coding, reporting and other requirements of the particular section of the health care industry pertaining to this CIA and in the general requirements of the Federal health care program(s) from which Cook seeks reimbursement. Each IRO shall assess, along with Cook, whether it can perform the IRO review in a professionally independent fashion taking into account any other business relationships or other engagements that may exist. The IRO(s) review shall address and analyze Cook's billing and coding to the Federal health care programs ("Claims Review") and if applicable, shall analyze whether Cook sought payment for certain unallowable costs ("Unallowable Cost Review").

b. Frequency of Claims Review. The Claims Review shall be performed annually and shall cover each of the one-year periods of the CIA beginning with the effective date of this CIA. The IRO(s) shall perform all components of each annual Claims Review.

c. Frequency of Unallowable Cost Review. If applicable, the Unallowable Cost Review shall be performed by the IRO for the first one-year reporting period beginning with the effective date of the CIA.

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

2. *Claims Review.* The Claims Review shall include a Discovery Sample and, if necessary, a Full Sample. The applicable definitions, procedures, and reporting requirements are outlined in Appendix A to this CIA, which is incorporated by reference.

a. Discovery Sample. The IRO shall randomly select and review a sample of 50 Medicare Paid Claims submitted by or on behalf of Cook. The Paid Claims shall be reviewed based on the supporting documentation available at Cook or under Cook's control and applicable billing and coding regulations and guidance to determine whether the claim submitted was correctly coded, submitted, and reimbursed.

i. If the Error Rate (as defined in Appendix A) for the Discovery Sample is less than 5%, no additional sampling is required, nor is the Systems Review required. (Note: The threshold listed above does not imply that this is an acceptable error rate. Accordingly, Cook should, as appropriate, further analyze any errors identified in the Discovery Sample. Cook recognizes that the 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.)

ii. If the Discovery Sample indicates that the Error Rate is 5% or greater, the IRO shall perform a Full Sample and a Systems Review, as described below.

b. Full Sample. If necessary, as determined by procedures set forth in Section III.E.2.a, the IRO shall perform an additional sample of Medicare Paid Claims using commonly accepted sampling methods and in accordance with Appendix A. The Full Sample should be designed to (1) estimate the actual Overpayment in the population with a 90% confidence level and with a maximum relative precision of 25% of the point estimate and (2) conform with the Centers for Medicare and Medicaid Services' statistical sampling for overpayment estimation guidelines. The Paid Claims shall be reviewed based on supporting documentation available at Cook or under Cook's control and applicable billing and coding regulations

and guidance to determine whether the claim submitted 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, Cook may use the Items sampled as part of the Discovery Sample, and the corresponding findings for those 50 Items, as part of its Full Sample. The OIG, in its full discretion, may refer the findings of the Full Sample (and any related workpapers) received from Cook to the appropriate Federal health care program payor, including the Medicare contractor (e.g., carrier, fiscal intermediary, or DMERC), for appropriate follow-up by that payor.

c. Systems Review. If Cook's Discovery Sample identifies an Error Rate of 5% or greater, Cook's IRO shall also conduct a Systems Review. Specifically, for each claim in the Discovery Sample and Full Sample that resulted in an Overpayment, the IRO should perform a "walk through" of the system(s) and process(es), that generated the claim to identify any problems or weaknesses that may have resulted in the identified Overpayments. The IRO shall provide to Cook observations and recommendations on suggested improvements to the system(s) and the process(es) that generated the claim.

d. Repayment of Identified Overpayments. In accordance with Section III.F.1, Cook agrees to repay within 30 days any Overpayment(s) identified in the Discovery Sample or the Full Sample (if applicable), regardless of the Error Rate, to the appropriate payor and in accordance with payor refund policies. Cook agrees to make available to the OIG any and all documentation that reflects the refund of the Overpayment(s) to the payor and the associated documentation.

3. *Claims Review Report*. The IRO shall prepare a report based upon the Claims Review performed (the "Claims Review Report"). Information to be included in the Claims Review Report is detailed in Appendix A.

4. *Unallowable Cost Review*. If applicable, the IRO shall conduct a review of Cook's compliance with the unallowable cost provisions of the Settlement Agreement.

The IRO shall determine whether Cook has complied with its obligations not to charge to, or otherwise seek payment from, Federal or State payors for unallowable costs (as defined in the Settlement Agreement) and its obligation to identify to applicable Federal or State payors any unallowable costs included in payments previously sought from the United States, or any State Medicaid program. This unallowable cost analysis shall include, but not be limited to, payments sought in any cost reports, cost statements, information reports, or payment requests already submitted by Cook or any of its subsidiaries, and to request, and agree, that such cost reports, cost statements, information reports or payment requests, even if already settled, be adjusted to account for the effect of the inclusion of the unallowable costs. In making this determination, the IRO may need to review cost reports and/or financial statements from the year in which the Settlement Agreement was executed, as well as from previous years.

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

6. *Validation Review.* In the event the OIG has reason to believe that: (a) Cook's Claims Review or Unallowable Cost Review fails to conform to the requirements of this CIA; or (b) the IRO's findings or Claims Review results are inaccurate, the OIG may, at its sole discretion, conduct its own review to determine whether the Claims Review or Unallowable Cost Review complied with the requirements of the CIA and/or the findings or Claims Review results are inaccurate ("Validation Review"). Cook 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 Cook's final submission (as described in Section II) is received by the OIG.

Prior to initiating a Validation Review, the OIG shall notify Cook 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, Cook may request a meeting with the OIG to discuss the results of any Claims Review or Unallowable Cost Review submissions or findings; present any additional or relevant information to clarify the results of the Claims Review or Unallowable Cost Review to correct the inaccuracy of the Claims Review; and/or propose alternatives to the proposed Validation Review.

Cook 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 or Unallowable Cost Review with Cook 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.

7. *Independence Certification.* The IRO shall include in its report(s) to Cook a certification or sworn affidavit that it has evaluated its professional independence with regard to the Claims Review or Unallowable Cost Review and that it has concluded that it was, in fact, independent.

F. Reporting of Overpayments and Material Deficiencies

1. *Overpayments*

a. *Definition of Overpayments.* For purposes of this Agreement, an “overpayment” shall mean the amount of money Cook has received in excess of the amount due and payable under any Federal health care program requirements. Cook may not subtract any underpayments for purposes of determining the amount of relevant “overpayments” for purposes of reporting under this Agreement.

b. *Reporting of Overpayments.* If, at any time, Cook identifies or learns of any overpayments, Cook 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, Cook 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, Cook shall notify the payor of its efforts to quantify the overpayment amount along with a schedule of when such work is expected to be completed. Notification and repayment to the payor shall be done in accordance with the payor’s policies, and for Medicare contractors, shall include the information contained on the Overpayment Refund Form, provided as Appendix B to this Agreement. 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 shall be handled in accordance with such policies and procedures.

2. *Material Deficiencies.*

a. *Definition of Material Deficiency.* For purposes of this Agreement, 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 Cook determines, by any means, that there is a Material Deficiency, Cook 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.F.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) on 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 Cook's actions taken to correct the Material Deficiency; and

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

G. Notification of Government Investigations or Legal Proceedings

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

IV. NEW BUSINESS UNITS OR LOCATIONS

In the event that, after the effective date of this Agreement, Cook changes locations or sells, closes, purchases, or establishes a new business related to the furnishing of items or services that may be reimbursed by Federal health care programs, Cook shall notify OIG of this fact as soon as possible, but no later than within 30 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 provider or supplier number(s) (if any), and the corresponding contractor's name and address that has issued each Medicare provider number. All Covered Persons at such locations shall be subject to the applicable requirements in this Agreement (e.g., completing certifications and undergoing training).

V. REPORTS

A. Implementation Report

Within 150 days after the effective date of this Agreement, Cook shall submit a

written report to OIG summarizing the status of its implementation of the requirements of this Agreement. This report, known as the "Implementation Report," shall include:

1. The name, address, and phone number of Cook's Compliance Contact;
2. A copy of the notice Cook posted in his office as described in Section III.B and a description of where and when the notice has been posted;
3. A copy of the written policies and procedures required by Section III.C. of this Agreement;
4. A certification signed by Cook's Compliance Contact or Robert G. Cook, M.D. attesting that the Policies and Procedures are being implemented and have been made available to all Covered Persons;
5. A copy of all training materials used for the training required by Section III.D., a description of the training, including a summary of the topics covered, the length of the session(s) and a schedule of when the training session(s) were held;
6. A certification signed by Cook's Compliance Contact or Robert G. Cook, M.D. attesting that all employees have completed the initial training required by Section III.D. and have executed the required certifications;
7. The name and qualifications of the IRO Cook has selected, a summary/description of all engagements between Cook and the IRO, including, but not limited to, any outside financial audits, compliance program engagements, or reimbursement consulting, and the proposed start and completion dates of the first annual review;
8. A certification from the IRO regarding its professional independence from Cook;
9. A list of all Cook's locations (including and mailing addresses), the corresponding name under which each location is doing business,

the corresponding phone numbers and fax numbers, each location's Medicare provider identification number(s) and the name and address of the Medicare contractor to which Cook currently submits claims; and

10. A certification from Cook stating that he has reviewed the Implementation Report, he has made a reasonable inquiry regarding its content and believes that, upon such inquiry, the information is accurate and truthful.

B. Annual Reports

Cook shall submit to OIG Annual Reports with respect to the status of and findings regarding Cook's compliance activities for each of the five (5) one-year periods beginning on the effective date of the Agreement. (The one-year period covered by each Annual Report shall be referred to as "the Reporting Period"). 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.

Each Annual Report shall include:

1. If revisions were made to the written policies and procedures developed pursuant to Section III.C., a copy of any policies and procedures that were revised;
2. A certification by Cook that all Covered Persons have executed the annual Policies and Procedures certification required by Section III.C.;
3. A certification by Cook that if the Federal health care programs were billed for the technical component of vascular tests, such vascular tests were not rendered in an inpatient hospital setting;
4. A certification by Cook that if the Federal health care programs were billed for the professional component of vascular tests, such vascular tests were furnished and interpreted with the appropriate level of physician supervision;

5. A schedule, topic outline, and copies of the training materials for the training programs attended in accordance with Section III.D. of this Agreement;
6. A certification signed by Cook's Compliance Contact or Robert G. Cook, M.D. certifying that he/she is maintaining written certifications from all Covered Persons that they received training pursuant to the requirements set forth in Section III.D. of this Agreement;
7. A complete copy of all reports prepared pursuant to the IRO's Claims Review, including the Claims Review Report and Unallowable Cost Review Report, along with a copy of the IRO's engagement letter;
8. Cook's response and corrective action plan(s) related to any issues raised or recommendations made by the IRO;
9. A summary/description of all engagements between Cook and the IRO, including, but not limited to, any outside financial audits, compliance program engagements, or reimbursement consulting, if different from what was submitted as part of the Implementation Report;
10. A certification from the IRO regarding its professional independence from Cook;
11. A summary of Material Deficiencies (as defined in Section III.F.) identified during the Reporting Period and the status of any corrective and preventative action relating to all such Material Deficiencies;
12. 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;
13. A certification signed by Cook's Compliance Contact or Robert G.

Cook, M.D. certifying that all prospective employees and contractors are being screened against the HHS/OIG List of Excluded Individuals/Entities and the General Services Administration's List of Parties Excluded from Federal Programs; and

14. A certification signed by Cook's Compliance Contact or Robert G. Cook, M.D. certifying that he has reviewed the Annual Report, has made a reasonable inquiry regarding its content and believes that, upon such inquiry, the information is accurate and truthful.

VI. NOTIFICATIONS AND SUBMISSION OF REPORTS

Unless otherwise stated subsequent to the execution of this Agreement, all notifications and reports required under the terms of this Agreement shall be submitted to the following:

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

Cook: Robert G. Cook
Kenosha Vascular Lab
Kenosha Medical Center
6308 8th Ave., Suite 301
Kenosha, WI 53143
Phone: 414.656.8265

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

VIII. DOCUMENT AND RECORD RETENTION

Cook shall maintain for inspection all documents and records relating to reimbursement from the Federal health care programs, or to compliance with this Agreement, for six (6) 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 Cook prior to any release by OIG of information submitted by Cook pursuant to its obligations under this Agreement and identified upon submission by Cook as trade secrets, or information that is commercial or financial and privileged or confidential, under the FOIA rules. With respect to such releases, Cook shall have the rights set forth at 45 C.F.R. § 5.65(d). Cook 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

Full and timely compliance by Cook is expected throughout the duration of this Agreement with respect to all of the obligations herein agreed to by Cook.

A. Stipulated Penalties for Failure to Comply with Certain Obligations

As a contractual remedy, Cook and OIG hereby agree that failure to comply with certain obligations set forth in this Agreement 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 Cook fails to:

- a. have in place a Compliance Contact as required in Section III.A;
- b. post the notice required in Section III.B;
- c. implement and make available the Policies and Procedures required in Section III.C;
- d. require that Covered Persons attend the training required by Section III.D. of the Agreement within the time frames required in that Section;
- e. retain an IRO within the timeframe required in Section III.E.1, or to submit the IRO’s annual Claims Review Report and Unallowable Cost Review Report as required in Section III.E and Appendix A; or
- f. meet any of the deadlines for the submission of the Implementation Report or the Annual Reports to OIG.

2. A Stipulated Penalty of \$750 (which shall begin to accrue on the date the failure to comply began) for each day Cook employs or contracts with an Ineligible Person and that person: (i) has responsibility for, or involvement with, Cook’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 Subsection shall not be demanded for any time period during which Cook can demonstrate that Cook did

not discover the person's exclusion or other ineligibility after making a reasonable inquiry (as described in Section III.C.5) as to the status of the person).

3. A Stipulated Penalty of \$750 for each day Cook fails to grant access to the information or documentation as required in Section VII of this Agreement. (This Stipulated Penalty shall begin to accrue on the date Cook fails to grant access.)

4. A Stipulated Penalty of \$750 for each day Cook fails to comply fully and adequately with any obligation of this Agreement. In its notice to Cook, OIG shall state the specific grounds for its determination that Cook has failed to comply fully and adequately with the Agreement obligation(s) at issue and steps the Cook must take to comply with the Agreement. (This Stipulated Penalty shall begin to accrue 10 days after the date Cook 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 Subsections 1-3 of this Section.

B. Timely Written Requests for Extensions

Cook 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 Agreement. 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 Cook 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 Cook 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 Cook 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 Cook of: (a) Cook's failure to comply; and (b) OIG's exercise of its contractual right to demand payment of the Stipulated Penalties (this notification is hereinafter referred to as the "Demand Letter").

2. *Response to Demand Letter.* Within 10 days of the receipt of the Demand Letter, Cook shall respond by either: (a) curing the breach to OIG's satisfaction and paying the applicable Stipulated Penalties; or (b) sending in writing to OIG a request for 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 Cook elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until Cook 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 Agreement 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 Cook has materially breached this Agreement, 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 Agreement

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

- a. a failure by Cook to report a Material Deficiency, take corrective action and make the appropriate refunds, as required in Section III.F;
- b. a repeated or flagrant violation of the obligations under this Agreement, 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 retain and use an Independent Review Organization in accordance with Section III.E.

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

4. *Exclusion Letter.* If at the conclusion of the 30-day period, Cook fails to satisfy the requirements of Section X.D.3, OIG may exclude Cook from participation in the Federal health care programs. OIG will notify Cook in writing of its determination to exclude Cook (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, Cook wishes to apply for reinstatement, Cook shall 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 Cook of its Demand Letter or of its Exclusion Letter, and as an agreed-upon contractual remedy for the resolution of disputes arising under this Agreement, Cook 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 Agreement. 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 Agreement shall be: (a) whether Cook was in full and timely compliance with the obligations of this Agreement for which OIG demands payment; and (b) the period of noncompliance. Cook 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 Agreement and orders Cook to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable 20 days after the ALJ issues such a decision unless Cook 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 Agreement shall be:

- a. whether Cook was in material breach of this Agreement;
- 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) Cook had begun to take action to cure the material breach within that period;

(ii) Cook has pursued and is pursuing such action with due diligence; and

(iii) Cook provided to OIG within that period a reasonable timetable for curing the material breach and Cook 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 Cook, only after a DAB decision in favor of OIG. Cook's election of its contractual right to appeal to the DAB shall not abrogate OIG's authority to exclude Cook 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 Cook 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. Cook agrees to waive his 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 Cook, Cook 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 Agreement is entered, and into which this Agreement is incorporated, Cook and the OIG agree as follows:

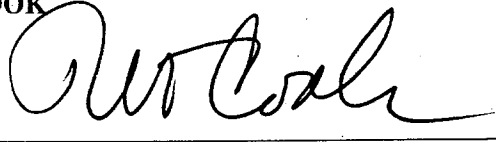
1. This Agreement shall be binding on the successors, assigns and transferees of Cook;
2. This Agreement shall become final and binding on the date the final signature is obtained on the Agreement;
3. Any modifications to this Agreement shall be made with the prior written

consent of the parties to this Agreement;

4. OIG may agree to a suspension of Cook's obligations under this Agreement in the event of Cook's cessation of participation in Federal health care programs. If Cook withdraws from participation in Federal health care programs and is relieved from its Agreement obligations by the OIG, Cook shall notify the OIG 30 days in advance of Cook'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;
5. The undersigned Cook signatories represent and warrant that they are authorized to execute this Agreement. The undersigned OIG signatory represents that he is signing this Agreement in his official capacity and that he is authorized to execute this Agreement.

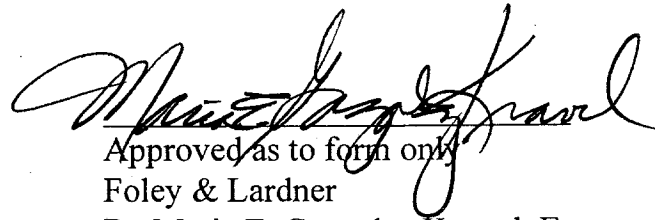
IN WITNESS WHEREOF, the parties hereto affix their signatures:

7/12/02
Date

COOK


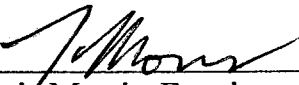
Robert G. Cook
Kenosha Vascular Lab
Kenosha Medical Center
6308 8th Ave., Suite 301
Kenosha, WI 53143

07-12-02
Date


Approved as to form only
Foley & Lardner
By Maria E. Gonzalez Knavel, Esq.
Counsel for Robert G. Cook

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

8/2/02
Date


Lewis Morris, Esquire
Assistant Inspector General for Legal Affairs
Office of Counsel to the Inspector General
Office of Inspector General
U. S. Department of Health and Human Services

APPENDIX A

A. Claims Review.

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

- a. Overpayment: The amount of money Cook has received in excess of the amount due and payable under any Federal health care program requirements.
- b. Item: Any discrete unit that can be sampled (e.g., code, line item, beneficiary, patient encounter, etc.).
- c. Paid Claim: A code or line item submitted by Cook and for which Cook has received reimbursement from the Medicare program.
- d. Population: All Items for which Cook has submitted a code or line item and for which Cook has received reimbursement from the Medicare program (i.e., a Paid Claim) during the 12-month period covered by the Claims Review. To be included in the Population, an Item must have resulted in at least one Paid Claim.
- e. Error Rate: The Error Rate shall be the percentage of net 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 Items in the sample.

2. **Other Requirements.**

- a. Paid Claims without Supporting Documentation. For the purpose of appraising Items included in the Claims Review, any Paid Claim for which Cook cannot produce documentation sufficient to support the Paid Claim shall be considered an error and the total reimbursement received by Cook for such Paid Claim shall be deemed an Overpayment. Replacement sampling for Paid Claims with missing documentation is not permitted.

b. 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 associated with the Items selected in each first sample (or first sample for each strata, if applicable) shall be used. In other words, 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.

B. Claims Review Report. 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. Sampling Unit. A description of the Item as that term is utilized for the Claims Review. For purposes of this Claims Review, the term "Item" may refer to any discrete unit that can be sampled (e.g., claim, line item, beneficiary, patient encounter, etc.).

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

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

d. Sampling Frame: A description of the sampling frame, which is the totality of Items from which the Discovery Sample and, if any, Full Sample has 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. Source of Data: A description of the 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, CMS program memoranda, Medicare carrier or intermediary manual or bulletins, other policies, regulations, or directives).

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

2. Claims Review Findings.

- a. a description of Cook's billing and coding system(s), including the identification, by position description, of the personnel involved in coding and billing;
- b. the IRO's findings, supporting rationale, and a summary of such findings and rationale regarding the Claims Review, including the results of the Discovery Sample, and the results of the Full Sample (if any) with the gross Overpayment amount, the net Overpayment amount, and the corresponding Error Rate(s) related to the net Overpayment. Note: for the purpose of this reporting, any potential cost settlements or other supplemental payments should not be included in the net Overpayment calculation. Rather, only underpayments identified as part of the Discovery Sample or Full Sample (as applicable) shall be included as part of the net Overpayment calculation; and
- c. the IRO's findings and recommendations concerning the Systems Review (if any).

3. Statistical Sampling Documentation.

- a. The number of Items appraised in the Discovery Sample and, if applicable, in the Full Sample.
- b. A copy of the printout of the random numbers generated by the "Random Numbers" function of the statistical sampling software used by the IRO.
- c. A copy of the statistical software printout(s) estimating how many Items are to be included in the Full Sample.
- d. A description or identification of the statistical sampling software package used to conduct the sampling.

4. Claims Review Results.

- a. Total number and percentage of instances in which the IRO determined

that the Paid Claims submitted by Cook ("Claims Submitted") differed from what should have been the correct claim ("Correct Claim"), regardless of the effect on the payment.

b. 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 Cook.

c. Total dollar amount of paid Items included in the sample and the net Overpayment associated with the sample.

d. Error Rate in the sample.

e. A spreadsheet of the Claims Review results that includes the following information for each Paid 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 IRO), correct allowed amount (as determined by the IRO), dollar difference between allowed amount reimbursed by payor and the correct allowed amount. (See Attachment 1 to this Appendix.)

5. Systems Review. Observations and recommendations on possible improvements to the system(s) and process(es) that generated the Overpayment(s) in the sample Population.

6. 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.

OVERPAYMENT REFUND

TO BE COMPLETED BY MEDICARE CONTRACTOR

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

TO BE COMPLETED BY PROVIDER/PHYSICIAN/SUPPLIER

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

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

REFUND INFORMATION

For each Claim, provide the following:

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

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

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

For Institutional Facilities Only:

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

For OIG Reporting Requirements:

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

Reason Codes:

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