INTEGRITY AGREEMENT
BETWEEN THE
OFFICE OF INSPECTOR GENERAL
OF THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND
ROBERT BOOTH, M.D.

I. PREAMBLE

Robert Booth, M.D. ("Dr. Booth") hereby enters 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 Dr. Booth's 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"). This commitment to promote compliance applies to any entity that Dr. Booth owns or in which Dr. Booth has a control interest, as defined in 42 U.S.C. § 1320a-3(a)(3), and Dr. Booth's and any such entity's employees, agents, contractors and all third parties with whom Dr. Booth 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 ("Covered Persons"). Contemporaneously with this Agreement, Dr. Booth 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 Dr. Booth under this Agreement shall be five years from the effective date of this Agreement. The effective date of this Agreement shall be the date on which the final signatory executes this Agreement.

Sections VII, VIII, IX, X and XI shall remain in effect until OIG has completed its review of the final annual report and any additional materials submitted by Dr. Booth pursuant to OIG's request, but in no event later than 120 days after the OIG's receipt of (1) Dr. Booth's final annual report; or (2) any additional materials submitted by Dr. Booth

pursuant to the OIG's request, whichever is later.

III. INTEGRITY OBLIGATIONS

Dr. Booth hereby agrees to establish and maintain a Compliance Program that, at minimum, includes the following elements:

A. Compliance Contact

Within 60 days of execution of this Agreement, Dr. Booth 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, Dr. Booth shall notify the OIG, in writing, within 15 days of such a change.

B. Posting of Notice

Within the first 30 days following the effective date of this Agreement, Dr. Booth 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 90 days of the effective date of this Agreement, Dr. Booth agrees to develop, implement, and make available to all Covered Persons written policies that address the following:

1. Dr. Booth's commitment to operate his business in full compliance with all Federal health care program requirements;

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

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

4. The requirement that all of Dr. Booth's Covered Persons shall be expected to report to Dr. Booth or the Compliance Contact suspected violations of any Federal health care program requirements or Dr. Booth'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.

5. The requirement that Dr. Booth 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 related to the provision of health care items or services, but has not yet been excluded, debarred, or otherwise declared ineligible. To prevent hiring or contracting with any Ineligible Person, Dr. Booth 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.hhs.gov/oig) and the General Services Administration's List of Parties Excluded from Federal Programs (available through the Internet at http://epls.arnet.gov) and, as appropriate, the state list of exclusions from Medicaid or Medical Assistance programs.

6. The commitment of Dr. Booth 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.

7. The requirement that, with respect to services for which reimbursement is sought from Federal health care programs, Dr. Booth and every other physician who is a Covered Person provide appropriate documentation of the nature of the services they render and/or observe in the operating room, including, but not limited to, documentation of their time of entrance and exit from the operating room and a specific description of the portion of the operation for which they were present.

8. The requirement that a daily log be kept that sets forth each surgical procedure performed by each physician who is a Covered Person; the date, time and operating room in which it was performed; and the patient's name.

At least annually (and more frequently if appropriate), Dr. Booth 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 Dr. Booth'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 90 days following the effective date of this Agreement and at least once each year thereafter, Dr. Booth and 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 two hours of training from an individual or entity other than Dr. Booth 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 Dr. Booth. All covered person who, within six months prior to the effective date of this Agreement, participated in training that met the requirements of this section shall not be required to take the first year of such training.

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 60 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 Polices and Procedures developed pursuant to Section III.C., above, including the requirement that with respect to services for which reimbursement is sought from Federal health care programs, Dr. Booth and every other physician who is a Covered Person provide appropriate documentation of the nature of the services they render and/or observe in the operating room, including, but not limited to, documentation of their time of entrance and exit from the operating room and a specific description of the portion of the operation for which they were present;

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.

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. Dr. Booth shall retain the certifications, along with the training course materials. The training course materials shall be provided in the Annual Report.

E. Third Party Billing

Dr. Booth represents that he presently does not contract with a third party billing company to submit claims to the Federal health care programs; instead he represents that his bills are submitted through 3B Orthopaedics, Inc., a company in which he possesses an ownership or control interest (as defined in 42 U.S.C.§ 1320a-3(a)(3)).

In the event that Dr. Booth contracts with a third party billing company to submit claims to any Federal health care programs during the term of this Agreement, then within 30 days thereafter, Dr. Booth shall obtain and include in the Annual Report a certification from the third party billing company that (i) it is presently in compliance with all Federal health care program requirements as they relate to submission of claims to the Federal health care programs; (ii) it has a policy of not knowingly employing any person who has been excluded, debarred or declared ineligible to participate in Medicare or other Federal health care programs, and who has not yet been reinstated to participate in those programs; and (iii) it provides the required training in accordance with section III.D. of the Agreement for those employees involved in the preparation and submission of claims to Federal health care programs. If Dr. Booth contracts with a new third party billing company during the term of this Agreement, Dr. Booth shall, within 30 days of entering into such contract, obtain and send to OIG the certification described in this paragraph.

F. Annual Review Procedures

1. *Retention of Independent Review Organization.* Within 90 days of the effective date of this Agreement, Dr. Booth shall retain a person or entity, such as a nurse reviewer, an accounting, auditing or consulting firm (hereinafter "Independent Review Organization" or "IRO"), to perform billing reviews to assess Dr. Booth's and other Covered Persons' billing and coding practices ("Billing Engagement"). The Independent

Review Organization retained by Dr. Booth shall have expertise in the billing, coding, reporting and other requirements of the particular section of the health care industry pertaining to this Agreement and in the Federal health care program requirements. The IRO shall assess, along with Dr. Booth, whether it can perform the Billing Engagement in a professionally independent fashion, taking into account any other business relationships or other engagements that may exist.

2. *Frequency of the Billing Engagement.* Each component of the Billing Engagement ("Billing Review") shall be performed at least annually and shall cover each of the one-year periods beginning with the effective date of this Agreement. The IRO shall perform each Billing Review in accordance with the procedures detailed in section II.F of this CIA and in Appendix A to this Agreement, which is incorporated by reference into this Agreement. The IRO shall prepare a report for each Billing Review in accordance with the guidelines set forth in Appendix A.

3. *Description of the Billing Reviews.* The IRO shall perform a total of two separate Billing Reviews annually.

a. Billing Review One: The objective of Billing Review One is twofold: (1) to ensure that Dr. Booth rendered the services billed and that Dr. Booth's inpatient surgical services were performed, coded, billed, and reimbursed in accordance with the appropriate Medicare statutes, regulations, program requirements and written directives, including but not limited to those applicable to concurrent procedures and physician's presence in the operating room; and (2) to ensure that a Covered Person who billed for a surgery actually performed the procedure as opposed to Dr. Booth performing the procedure. For purposes of ensuring that a Covered Person who billed for a surgery actually performed the surgery, as opposed to Dr. Booth having performed the surgery, the IRO need only review surgeries performed by Covered Persons which have the same code as the surgeries performed by Dr. Booth within the 12 months being reviewed (e.g., knee replacement, knee revision, hip replacement, hip revision). The population for this Billing Review shall consist of all calendar days on which Dr. Booth performed three or more surgeries ("Surgical Calendar Days"). From this population the IRO shall randomly select 15 Surgical Calendar Days using RAT-STATS, the OIG's statistical sampling software. The IRO shall review all of Dr. Booth's surgical procedures on the selected Surgical Calendar Days in accordance with the first objective of this Billing Review. In accordance with the second objective of this Billing Review, the IRO shall review the surgical procedures performed by every other Covered Person on the selected Surgical Calendar Days (limited to codes used by Booth in the review period), regardless of whether a claim was submitted and regardless of the identity of the payor.

If the IRO determines that there were billings in violation of the Medicare statutes, regulations, program requirements or written directives applicable to the objectives of this Billing Review that involve Dr. Booth, the IRO will consider such procedures to be overpayments. For example, if the IRO determines that a surgery billed by another Covered Person was in fact performed by Dr. Booth, the IRO will consider this procedure to have been performed by Dr. Booth for purposes of determining if there were billings in violation of the Medicare statutes, regulations, program requirements and written directives applicable to concurrent procedures and physician's presence, and therefore this procedure shall be considered an overpayment. Any claim for which Dr. Booth can not produce documentation sufficient to support the claim shall be considered an error and the total reimbursement received by Dr. Booth for such claim shall be considered an overpayment.

The IRO shall identify the total paid Medicare dollars associated with the population, the total paid Medicare dollars associated with the sample, the total Medicare dollar overpayment in the sample, and any Medicare dollar underpayments in the sample. If the IRO identifies a Medicare service that was not billed, this claim may be submitted to the appropriate Medicare contractor, in accordance with Medicare guidelines, for a payment determination. If the Medicare contractor determines that this claim should be paid, the amount Medicare reimburses shall be considered an underpayment so long as it does not violate any of the Medicare statutes, regulations, program requirements and written directives that are being examined in this Billing Review. For calculation purposes, the IRO may net the Medicare overpayments and the Medicare underpayments, regardless of Medicare's underpayment resubmission timelines. The net result shall be divided by the total paid Medicare dollars associated with the sample. This calculation yields the Medicare financial error rate. The Medicare financial error rate shall be multiplied by the total paid Medicare dollars in the population. This result yields the projected overpayment amount. Dr. Booth agrees to voluntarily refund the projected overpayment amount to the appropriate Medicare contractor within 30 days of determination of the amount due. Included in each Annual Report shall be the IRO's Billing Review Report findings presented in accordance with the guidelines set forth in Appendix A.

c. Billing Review Two: The objective of Billing Review Two is to ensure that Dr. Booth's outpatient services were performed, coded, billed, and reimbursed in accordance with the appropriate Medicare guidelines. Billing Review Two will be a claims review and shall be performed in accordance with Appendix A, unless otherwise specified in this paragraph. The population for this review will be all of Dr. Booth's paid Medicare outpatient claims (e.g., office visits) for the review period. The IRO will

randomly select 30 claims, using RAT-STATS, from the population for review. As set forth in Appendix A, Dr. Booth agrees to voluntarily refund any projected overpayment amount to the appropriate Medicare contractor within 30 days of determination of the amount due.

4. *Retention of Records.* The IRO and Dr. Booth shall retain and make available to the OIG upon request all work papers, supporting documentation, correspondence, and draft reports related to the engagements.

5. *Independence Certification.* The IRO shall include in its report to Dr. Booth a certification or sworn affidavit that it has evaluated its professional independence with regard to the Billing Engagement and that it has concluded that it was, in fact, independent.

6. *Validation Review.* In the event the OIG has reason to believe that: (a) any of the Billing Reviews fail to conform to the requirements of this Agreement; or (b) any of the findings or Billing Review results are inaccurate, the OIG may, at its sole discretion, conduct its own review to determine whether the Billing Review complies with the requirements of the Agreement and/or the findings or Billing Review results are inaccurate. Dr. Booth agrees to pay for the reasonable cost of any such review performed by the OIG or any of its designated agents so long as it is initiated before one year after the final Annual Report is submitted and received by the OIG. To the extent consistent with the requirements of the Freedom of Information Act (FOIA), Dr. Booth may request copies of any work papers underlying the validation review.

Prior to initiating a Validation Review, the OIG shall notify Dr. Booth of its intent to do so and provide an explanation for believing why such a review is necessary. In order to resolve any concerns raised by the OIG, Dr. Booth may request a meeting with the OIG to discuss the results of any Engagement submissions or any Billing Review findings; present any additional or relevant information to clarify the results of the Engagements or to correct the inaccuracy of the Billing Review(s); and/or propose alternatives to the proposed Validation Review. Dr. Booth 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 Billing Review issues with Dr. Booth 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. If the Validation Review concludes that Dr. Booth's Billing Review(s) conformed to the requirements of this Agreement and that the findings or Billing Review results are accurate, then Dr. Booth will not pay for the cost of the Validation Review.

G. 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 Dr. Booth has received in excess of the amount due and payable under any Federal health care program requirements. Dr. Booth 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, Dr. Booth identifies or learns of any overpayments, Dr. Booth shall notify the payor within 30 days of identification of the overpayment and take remedial steps within 60 days of discovery (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, Dr. Booth 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, Dr. Booth 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 contractor should be done in accordance with the contractor policies, and for Medicare contractors, must include the information contained on the Overpayment Refund Form, provided as Appendix B to this Agreement. Nothing set forth herein prevents Dr. Booth from subtracting underpayments for purposes of determining the amount of repayment for any Overpayment, consistent with the instructions of his Medicare contractor.

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 potential 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 Dr. Booth determines, by any means, that there is a Material Deficiency, Dr. Booth 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 Dr. Booth's actions taken to correct the Material Deficiency; and

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

H. Notification of Government Investigations or Legal Proceedings

Within 30 days of discovery, Dr. Booth shall notify OIG, in writing, of any ongoing investigation or legal proceeding conducted or brought by a governmental entity or its agents involving an allegation that Dr. Booth 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. Dr. Booth 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, Dr. Booth changes locations or purchases or establishes a new business related to the furnishing of items or services that may be reimbursed by Federal health care programs, Dr. Booth shall notify OIG of this fact as soon as possible, but no later than within 30 days of the date of change of location, 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 120 days after the effective date of this Agreement, Dr. Booth 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 and phone number of Dr. Booth's Compliance Contact;

2. A copy of the notice Dr. Booth 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 Dr. Booth attesting that the Policies and Procedures are being implemented and have been made available to all Covered Persons;

5. A description of the training required by Section.III.D., including a summary of the topics covered and a schedule of when the training session(s) were held;

6. A certification signed by Dr. Booth attesting that all employees have completed the initial training required by Section III.D. and have executed the required certifications;

7. A copy of the certification from the third party billing company, if any, as required by Section III.E of the Agreement;

8. The name and qualifications of the IRO Dr. Booth has retained to conduct the billing engagement and the proposed start and completion dates of the first annual review;

9. A certification from the IRO regarding its professional independence from Dr. Booth;

10. A list of all Dr. Booth's locations (including locations and mailing addresses), the corresponding name under which each location is doing business, the corresponding phone numbers and fax numbers, each location's Medicare provider identification number(s) and the contractor's name and address that issued each provider identification number; and

11. A certification from Dr. Booth 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

Dr. Booth shall submit to OIG Annual Reports with respect to the status of and findings regarding Dr. Booth's compliance activities for each of the five 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 90 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. of this Agreement, a copy of any policies and procedures that were revised;

2. A certification by Dr. Booth that all Covered Persons have executed the annual Policies and Procedures certification required by section III.C.;

3. A schedule, topic outline and copies of the training materials for the training programs attended in accordance with section III.D. of this Agreement;

4. A certification signed by Dr. Booth certifying that he 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;

5. A complete copy of all reports prepared pursuant to the IRO's Billing Engagement, including the Claims Review Report and Process Review Report, along with a copy of the IRO's engagement letter;

6. Dr. Booth's response and corrective action plan(s) related to any issues raised or recommendations made by the IRO;

7. A summary/description of all engagements between Dr. Booth and the IRO, including, but not limited to, any outside financial audits,

compliance program engagements, or reimbursement consulting;

8. A summary of any Material Deficiencies (as defined in III.G.) identified during the Reporting Period and the status of any corrective and preventative action relating to all such Material Deficiencies;

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

10. A certification signed by Dr. Booth 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

11. A certification signed by Dr. Booth certifying that he has reviewed the Annual Report, he 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:

If to the 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
330 Independence Avenue, SW
Cohen Building, Room 5527
Washington, DC 20201
Ph. 202.619.2078
Fax 202.205.0604

If to Dr. Booth: Robert E. Booth, MD
101 Righters Mill Road
Gladwynne, PA 19035
Ph. 215 829 2213

with a copy to: David Richman
Barry H. Boise
Pepper Hamilton LLP
3000 Two Logan Square
Philadelphia, PA 19103

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

VIII. DOCUMENT AND RECORD RETENTION

Dr. Booth 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 years (or longer if otherwise required).

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

A. Stipulated Penalties for Failure to Comply with Certain Obligations

As a contractual remedy, Dr. Booth 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 Dr. Booth:

a. Fails to have in place a Compliance Contact as required in section III.A;

b. Fails to post the notice required in section III.B;

c. Fails to have in place the Policies and Procedures required in section III.C;

d. Fails to require that each applicable Covered Person attends the training required by section III.D. of the Agreement within the time frames required in that section;

e. Fails to retain an IRO within the timeframe required in section III.F.1, or annually submit the IRO's Claims Review Report and Process Review Report as required in section III.F and Appendix A; or

f. Fails to 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 Dr. Booth employs or contracts with an Ineligible Person and that person: (i) has responsibility for, or involvement with, Dr. Booth's business operations related to the Federal health care programs; or (ii) is in a position for which the person's salary or the items or services rendered, ordered, or prescribed by the person are paid in whole or part, directly or indirectly, by Federal health care programs or otherwise with Federal funds (the Stipulated Penalty described in this paragraph shall not be demanded for any time period during which Dr. Booth can demonstrate that Dr. Booth 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 Dr. Booth 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 Dr. Booth fails to grant access.)

4. A Stipulated Penalty of $750 for each day Dr. Booth fails to comply fully and adequately with any obligation of this Agreement. In its notice to Dr. Booth, OIG shall state the specific grounds for its determination that Dr. Booth has failed to comply fully and adequately with the Agreement obligation(s) at issue and steps the Dr. Booth must take to comply with the Agreement. (This Stipulated Penalty shall begin to accrue 10 days after the date that OIG provides notice to Dr. Booth of the failure to comply.) A Stipulated Penalty as described in this paragraph shall not be demanded for any violation for which the OIG has sought a Stipulated Penalty under paragraphs 1-3 of this section.

B. Timely Written Requests for Extensions

Dr. Booth 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 Dr. Booth 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 Dr. Booth 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 Dr. Booth 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 Dr. Booth of: (a) Dr. Booth'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, Dr. Booth shall respond by either: (a) curing the breach to OIG's satisfaction, notifying OIG of his[her] corrective actions, 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 Dr. Booth elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until Dr. Booth 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 Dr. Booth 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 Dr. Booth to report a material deficiency, take corrective action and make the appropriate refunds, as required in section III.G;

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.D.

2. *Notice of Material Breach and Intent to Exclude.* The parties agree that a material breach of this Agreement by Dr. Booth constitutes an independent basis for Dr. Booth's exclusion from participation in the Federal health care programs. Upon a determination by OIG that Dr. Booth has materially breached this Agreement and that exclusion should be imposed, OIG shall notify Dr. Booth of: (a) Dr. Booth'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.* Dr. Booth 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. Dr. Booth 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) Dr. Booth has begun to take action to cure the

material breach; (ii) Dr. Booth is pursuing such action with due diligence; and (iii) Dr. Booth has provided to OIG a reasonable timetable for curing the material breach.

4. *Exclusion Letter.* If at the conclusion of the 30-day period, Dr. Booth fails to satisfy the requirements of section X.D.3, OIG may exclude Dr. Booth from participation in the Federal health care programs. OIG will notify Dr. Booth in writing of its determination to exclude Dr. Booth (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, Dr. Booth wishes to apply for reinstatement, Dr. Booth must submit a written request for reinstatement in accordance with the provisions at 42 C.F.R. §§ 1001.3001-.3004.

E. Dispute Resolution

1. *Review Rights.* Upon OIG's delivery to Dr. Booth 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, Dr. Booth 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 Dr. Booth was in full and timely compliance with the obligations of this Agreement for which OIG demands payment; and (b) the period of noncompliance. With respect to the Stipulated Penalties set forth in sections X.A.1, X.A.2, and X.A.3, Dr. Booth shall have the burden of proving his full and timely compliance and the steps taken to cure the noncompliance, if any. With respect to the Stipulated Penalty set forth in section X.A.4,

the OIG shall have the burden of proving non-compliance and Dr. Booth shall have the burden of proving the steps taken to cure the noncompliance, if any. If the ALJ agrees with OIG with regard to a finding of a breach of this Agreement and orders Dr. Booth to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable 20 days after the ALJ issues such a decision unless Dr. Booth 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 Dr. Booth 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) Dr. Booth had begun to take action to cure the material breach within that period;

(ii) Dr. Booth has pursued and is pursuing such action with due diligence; and

(iii) Dr. Booth provided to OIG within that period a reasonable timetable for curing the material breach and Dr. Booth 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 Dr. Booth, only after a DAB decision in favor of OIG. Dr. Booth's election of its contractual right to appeal to the DAB shall not abrogate OIG's authority to exclude Dr. Booth 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 Dr. Booth 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. Dr. Booth agrees to waive his/her right to any notice of such an exclusion if a decision upholding the exclusion is rendered by the ALJ

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, Dr. Booth and the OIG agree as follows:

1. This Agreement shall be binding on the successors, assigns and transferees of Dr. Booth;

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 Dr. Booth's obligations under this Agreement in the event of Dr. Booth's cessation of participation in Federal health care programs. If Dr. Booth withdraws from participation in Federal health care programs and is relieved from his Agreement obligations by the OIG, Dr. Booth agrees to notify the OIG 30 days in advance of his 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. Dr. Booth represents that this agreement is freely and voluntarily entered into without any degree of duress or compulsion whatsoever, and acknowledges that he has been represented by and has had the full advice of his counsel prior to executing 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:

ROBERT BOOTH, M.D.

_____ _____

Date Robert Booth, M.D.

_____ _____

Date Counsel for Dr. Booth

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

20 August 2001 Lewis Morris

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

IN WITNESS WHEREOF, the parties hereto affix their signatures:

ROBERT BOOTH, M.D.

8/24/01
Date

R E Booth Jr MD
Robert Booth, M.D.

8/24/01
Date

Barry H. Boals
Counsel for Dr. Booth

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

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. Claims Review Sample: A statistically valid, randomly selected, sample of items selected for appraisal in the Claims Review.

b. Item: Any discrete unit that can be sampled (e.g., code, line item, beneficiary, patient encounter, etc.). For purposes of Billing Review One, the term "Item" refers to a Surgical Calendar Day as defined in the CIA. For purposes of Billing Review Two, the term "Item" refers to one of Dr. Booth's paid Medicare outpatient claims (e.g., office visits).

c. Overpayment: Consistent with the definition of Overpayment as articulated in section III.H.1.a of the CIA, the amount of money Dr. Booth has received in excess of the amount due and payable under any Federal health care program requirements.

d. Population: For Billing Review One, the population shall consist of all calendar days in which Dr. Booth performed three or more surgeries ("Surgical Calendar Days"). For Billing Review Two, the population is defined as Dr. Booth's paid Medicare outpatient claims (e.g., office visits) with dates of service during the review period.

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

2. ***Description of Claims Review.*** The Claims Review, which is applicable only to Billing Review Two, shall consist of a variable appraisal of a statistically valid sample of claims (the Claims Review Sample). To perform this Claims Review the IRO shall randomly select 30 paid Medicare claims from the Population, using RAT-STATS, and determine if the service(s) on the claim were performed, coded, billed, and reimbursed in accordance with Medicare guidelines.

a. Item Appraisal. For each Item appraised (as part of any Claims Review Sample), only paid claims shall be evaluated. Each claim in any of the Claims Review Samples shall be evaluated by the IRO to determine whether the service(s) on the claim was performed, coded, billed, and reimbursed in accordance with Medicare guidelines. Each appraisal must be sufficient to provide all information required under the Billing Review Report.

b. Paid Claims without Supporting Documentation. For the purpose of appraising claims in any of the Billing Reviews, any claim for which Dr. Booth cannot produce documentation sufficient to support the claim shall be considered an error and the total reimbursement received by Dr. Booth for such claim shall be deemed an Overpayment. Replacement sampling for claims with missing documentation is not permitted.

c. Use of First Samples Drawn. For the purposes of all Billing Review samples, the first sample drawn shall be used. In other words, it is not permissible to generate a number of random samples and then select one for use as the sample.

Upon completion of Billing Review Two's 30 Claims Review Sample, Dr. Booth will have two options:

Option 1: Dr. Booth may project the overpayment amount to the Medicare program based on the results of the 30 Claims Review Sample. This calculation will be computed by dividing the total Medicare dollar overpayment associated with the sample (Medicare overpayments and underpayments may be netted) by the total paid Medicare dollars associated with the sample. This result yields the Medicare financial error rate. The Medicare financial error rate is then multiplied by the total paid Medicare dollars in the Population. This result yields the projected overpayment amount. Dr. Booth agrees to voluntarily refund the projected overpayment amount to the appropriate Medicare contractor.

Option 2: Dr. Booth may conduct a Full Claims Review that yields results with 90% confidence and 25% precision. The IRO shall use the results of the 30 Claims Review Sample to estimate the number of claims to be reviewed in the Full Claims Review Sample. For each claim that is reviewed as part of the 30 Claim Review Sample, the IRO will make an

overpayment determination. A data file consisting of this list of overpayments is created. The IRO then uses the "Difference Values Only" function located under the "Variable Appraisals" component of RAT-STATS to calculate the estimated mean and standard deviation of Overpayments in the Population. For purposes of estimating the mean and standard deviation of Overpayments in the Population, and entering this information into RAT-STATS, any underpayment identified for a claim in the 30 Claims Review Sample shall be treated as a zero overpayment. Dr. Booth agrees to voluntarily refund the projected overpayment amount to the appropriate Medicare contractor.

In order to estimate the number of Items that must be included in the Full Claims Review Sample RAT-STATS' "Sample Size Estimators" (located under the "Utility Programs" file) shall be used. Whereas the Full Claims Review Sample size is estimated from the results of the 30 Claim Review Sample, there is a possibility that examining the number of claims identified by RAT-STATS may not achieve the 90% confidence and 25% precision levels. If the reviewer can demonstrate that the review was properly conducted, but the 90% confidence and 25% precision level could not be achieved, the reviewer will not be required to examine additional items.

For overpayment projection and refund purposes, Dr. Booth may net the underpayments and overpayments. In so doing, Dr. Booth shall use the calculation methodology set forth in Option 1 of this Appendix

The Full Claims Review Sample shall be selected by using RAT-STATS' "Random Numbers" function, and shall be selected from the entire Population, with the Population including those claims reviewed as part of the 30 Claims Review Sample, so that all claims in the Population have an equal chance of inclusion in the Full Claims Review Sample.

B. <u>Billing Review Report</u>. The IRO shall prepare a separate report for each Billing Review. All Billing Review reports shall be included in the submission of the Annual Report. The following information shall be included in each Billing Review Report, unless otherwise specified:

1. ***Billing Review Methodology***

a. Objective: A clear statement of the objective(s) intended to be achieved by the Billing Review.

b. Sampling Unit: A description of the Item as that term is utilized for the Billing Review. For purposes of Billing Review One, the sampling unit is a Surgical Calendar Day, as defined in section II.F.3.a of the CIA and in section A.1.b above. For purposes of Billing Review Two, the sampling unit is one of Dr. Booth's paid Medicare outpatient claims (e.g., office visits).

c. Billing Review Population: A description of the Population subject to the Billing Review. For purposes of Billing Review One, the Population shall consist of all of Dr. Booth's Surgical Calendar Days for the reporting period. For purposes of Billing Review Two, the Population shall consist of all of Dr. Booth's paid Medicare outpatient claims for the reporting period of this CIA.

d. Sampling Frame: A description of the sampling frame, which is the totality of Items from which each 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. Sources of Data: A description of the documentation relied upon by the IRO when performing the Billing Review (e.g., medical records, physician orders, surgical log, local medical review policies, HCFA program memoranda, Medicare carrier or intermediary manual or bulletins, other policies, regulations, or directives).

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

2. ***Statistical Sampling Documentation***

a. The number of Items appraised in each Billing Review Sample.

b. A copy of the RAT-STATS printout of the random numbers generated

by the "Random Numbers" function for each Billing Review performed.

c. If applicable for Billing Review Two, a copy of the RAT-STATS printout of the "Sample Size Estimators" results used to calculate the minimum number of claims for inclusion in the Full Claims Review Sample.

d. If applicable for Billing Review Two, a copy of the RAT-STATS printout of the "Variable Appraisals", "Difference Values Only" function results for the 30 Claim Review Sample, including a copy of the data file.

e. The Sampling Frame used in any of the Billing Reviews shall be available to the OIG upon request.

3. ***Billing Review Results***. Each Billing Review Report shall contain the following components unless otherwise specified:

a. Total number and percentage of instances in which the IRO determined that the claim submitted by Dr. Booth or other Covered Persons ("Claim Submitted") differed from what should have been the correct claim to have been submitted ("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.

c. The total dollar amount of all Medicare paid claims in each Billing Review and the total dollar amount of Overpayments associated with the Medicare paid claims in the sample.

d. If choosing option 2 in Billing Review Two, the level of precision achieved by the Full Claims Review at a 90% confidence level shall be reported.

e. A spreadsheet of the Billing Review results that includes the following information for each Medicare paid claim reviewed: 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, the correct allowed amount, and comments. (See Attachment 1 to this Appendix.) For Billing Review One, if a claim is disallowed due to a concurrency or presence issue, the IRO shall note in the comments field of this spreadsheet all other claims associated with the concurrency or presence issue (e.g., claim was disallowed because both this claim and claim XXX were billed as if Dr. Booth performed the surgeries). Option 1 of Billing Review Two consists of all Medicare paid claims in the 30 Claim Review Sample. Option 2 of Billing Review Two consists of all Medicare paid claims in the Full Claims Review Sample.

f. Please specify the following information for Billing Review One and if choosing option one for Billing Review Two: the total Medicare dollars in the sample, the total Medicare dollar underpayment in the sample, the Medicare financial error rate, and the Medicare dollar projected amount that is being refunding to the appropriate Medicare contractor.

4. ***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.

Attachment 1

Claim Review Results

Federal Health Care Program Billed	Bene HIC #	Date of Service	Procedure Code Submitted	Procedure Code Reimbursed	Allowed Amount Reimbursed	Correct Procedure Code (IRO determined)	Correct Allowed Amt (IRO determined)	Dollar Difference between Amount Reimbursed and Correct Allowed Amount	Comments