INTEGRITY AGREEMENT
BETWEEN THE
OFFICE OF INSPECTOR GENERAL
OF THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND
HENRY J. WISDOM, D.O.

I. PREAMBLE

Henry J. Wisdom, D.O. ("Dr. Wisdom") hereby agrees to enter into this Integrity Agreement ("Agreement") with the Office of Inspector General of the United States Department of Health and Human Services ("OIG") to provide for the establishment of certain integrity measures to ensure compliance with the requirements of the Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)) by Dr. Wisdom, by Dr. Wisdom's employees and agents, by any entity in which Dr. Wisdom is an owner or has a controlling interest (as defined in 42 U.S.C. § 1320a-3(a)(3)) and such entity's employees and agents, and by all third parties with whom Dr. Wisdom may choose to engage to act as billing or coding consultants for purposes of claiming reimbursement from the Federal health care programs. Contemporaneously with this Agreement, Dr. Wisdom is entering into a Settlement Agreement (the "Settlement Agreement") with the United States. For the purposes of this Agreement the term "Wisdom" shall refer to Dr. Wisdom and any entity in which Dr. Wisdom has an ownership or control interest (as defined in 42 U.S.C. § 1320a-3(a)(3)). This Agreement is incorporated by reference into the Settlement Agreement.

II. TERM OF THE AGREEMENT

Except as otherwise provided in this Agreement, the period of compliance obligations assumed by Dr. Wisdom 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 executes this Agreement.

III. INTEGRITY OBLIGATIONS

Within thirty (30) days of the effective date of this Agreement, Dr. Wisdom agrees to implement an Integrity Program (the "Program"), which shall include the following provisions:

A. COMPLIANCE CONTACT

Within fifteen (15) days of the effective date of this Agreement, Dr. Wisdom shall designate a person to be the contact person for purposes of the obligations herein. At all times during the term of this Agreement, there shall be a contact person who shall have operational responsibility for ensuring compliance with the integrity obligations in this Agreement. If a new contact person is designated during the term of this Agreement, Dr. Wisdom shall notify OIG, in writing, within ten (10) days of such a change.

B. POSTING OF NOTICE

Within fifteen (15) days of the effective date of this Agreement, Dr. Wisdom shall post in a prominent place accessible to all patients and employees a notice detailing his commitment to comply with all statutes, regulations and directives applicable to the Federal health care programs in the conduct of his medical practice and in seeking reimbursement from the Federal health care programs for services and items furnished to patients of the Federal health care programs. This notice shall identify a means (e.g., telephone number, address, etc.) through which matters of concern can be reported anonymously.

C. WRITTEN POLICIES AND PROCEDURES

Dr. Wisdom shall develop and implement written Policies and Procedures within sixty (60) days of the effective date of this Agreement, which written Policies and Procedures shall address the following:

a. Dr. Wisdom's commitment to adhere to honest and accurate billing practices;

b. The proper submission of claims to the Federal health care programs, including verification that all claims meet applicable reimbursement standards;

c. The assignment of appropriate CPT codes when billing for psychiatric treatment of Federal health care program patients;

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

e. A mechanism for employees and agents to make inquiries regarding compliance with Federal health care program reimbursement standards without risk of retaliation or other adverse effect; and

f. Dr. Wisdom's commitment not to hire or engage as contractor any Ineligible Person. For purposes of this Agreement, an "Ineligible Person" shall be any individual or entity who: (i) is currently excluded, suspended, debarred or otherwise ineligible to participate in the Federal health care programs; or (ii) has been convicted of a criminal offense related to the provision of health care items or services and has not been reinstated in the Federal health care programs after a period of exclusion, suspension, debarment, or ineligibility.

D. TRAINING AND CERTIFICATION

Within thirty (30) days of the effective date of this Agreement, Dr. Wisdom, Dr. Wisdom's employees and anyone else engaged by Wisdom to prepare or submit claims for reimbursement to the Federal health care programs shall be trained in the proper reimbursement standards, program policies, and verification and compliance procedures to ensure the propriety and accuracy of claims for services and items furnished to Federal health care program patients. The training shall be designed to ensure that Dr. Wisdom and all of his employees and agents are aware of all applicable Federal health care program statutes, regulations and guidelines and the consequences (e.g., overpayment demands, restitution, penalties, criminal, civil and administrative liability, exclusion from the Federal health care programs, etc.) both to the individual and Dr. Wisdom that may ensue from any violation of such requirements.

Dr. Wisdom shall arrange for each new employee to participate in such training no later than fifteen (15) days after the person begins to work for Dr. Wisdom. Until the person has received the requisite training, such new employee shall work under the direct supervision of an employee who has received the required training.

This training program shall provide for no less than six (6) hours of training annually for each person.

At a minimum, the training sessions shall cover the following topics:

1. Dr. Wisdom's obligations under this Agreement;

2. All applicable Federal health care program statutes, rules, regulations, and guidelines related to reimbursement, and the legal sanctions for improper billing or other violations of these standards; and

3. The written Policies and Procedures developed pursuant to section III.C, above.

Dr. Wisdom and each employee and agent shall date and sign a certification indicating attendance at the training session and further attesting to an understanding of the provisions in the Policies and Procedures and all applicable Federal health care program standards addressed in training. These certifications will be maintained by Dr. Wisdom and shall be made available for inspection by

OIG or its duly authorized representative(s). At least one copy of the training materials or a detailed description of the topics covered during the training session shall be kept with the certifications.

E. INDEPENDENT REVIEWS

On at least an annual basis and for the duration of this Agreement, Dr. Wisdom agrees to contract with an independent third-party reviewer (e.g., a health care billing auditor or a consultant) (hereinafter the "Independent Reviewer") to undertake a review of a statistically valid sample of the claims submitted by Wisdom and his agents and/or employees to the Federal health care programs for items or services provided by Dr. Wisdom. The purpose of this review is determine whether the claims are in compliance with the appropriate billing requirements. This review will be conducted by an independent and appropriately trained person or entity with knowledge of Federal health care program statutes, regulations, requirements, and reimbursement policies and procedures. These reviews shall cover, at a minimum, the preceding one (1) year period and shall seek to determine that the claims submitted to the Federal health care programs are for medically necessary and covered services under applicable program guidelines and that the claims are appropriately coded and billed. At the conclusion of each review, the Independent Reviewer shall prepare a report describing the review's parameters, methodologies and procedures, as well as presenting the review findings and the reviewer's conclusions and recommendations. The report shall include findings regarding Wisdom's appropriate use of CPT codes when billing for psychiatric treatment of Federal health care program beneficiaries. A copy of this report shall be included in Dr. Wisdom's Annual Reports to OIG.

A statistically valid sample means that if the overpayments identified in the sample were projected to the population of claims from which the sample is taken, the projection would provide a 90% confidence level and a maximum relative precision (i.e., semi-width of the confidence interval) of plus or minus 25% of the point estimate. In other words, if the overpayment results were projected to the population at a 90% confidence level, the confidence interval (expressed in dollars) must be sufficiently narrow that the upper bound of the confidence interval would not exceed 125% of the midpoint of the confidence interval (the point estimate), and the lower bound of the confidence interval would not be less than 75% of the midpoint of the confidence interval.

IV. REPORTING

A. Overpayments

1. Definition of Overpayments. For purposes of this CIA, an "overpayment" shall mean the amount of money Dr. Wisdom has received in excess of the amount due and payable under any Federal health care program requirements. Dr. Wisdom may not subtract any underpayments for purposes of determining the amount of relevant "overpayments."

2. Reporting of Overpayments. If, at any time, Dr. Wisdom identifies or learns of any overpayments, Dr. Wisdom shall notify the payor (e.g., Medicare fiscal intermediary or carrier) and repay any identified overpayments within 30 days of discovery 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. 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 Attachment 1 to this CIA.

B. Material Deficiencies.

1. Definition of Material Deficiency. For purposes of this CIA, a "Material Deficiency" means anything that involves:

(i) a substantial overpayment;

(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; or

A Material Deficiency may be the result of an isolated event or a series of occurrences.

2. Reporting of Material Deficiencies. If Dr. Wisdom determines that there is a Material Deficiency, Dr. Wisdom shall notify OIG, in writing, within 30 days of making the determination that the Material Deficiency exists. The report to the OIG shall include the following information:

(i) If the Material Deficiency results in an overpayment, the report to the OIG shall be made at the same time as the notification to the payor required in section III.H.1, and shall include all of the information on the Overpayment Refund Form, as well as:

(A) the payor's name, address, and contact person to whom the overpayment was sent; and

(B) the date of the check and identification number (or electronic transaction number) 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. Wisdom's actions taken to correct the Material Deficiency; and

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

V. OIG INSPECTION, AUDIT AND REVIEW RIGHTS

In addition to any other right OIG may have by statute, regulation, contract or pursuant to this Agreement, OIG or its duly authorized representative(s) may examine Dr. Wisdom's books, records, and other documents and supporting materials in his possession or under his control for the purpose of verifying and evaluating: (i) Dr. Wisdom's compliance with the terms of this Agreement; and (ii) Dr. Wisdom's compliance with the requirements of the Federal health care programs. OIG, HCFA, or the appropriate Federal health care program contractor may conduct unannounced on-site visits at any time to review patient medical records and other related documentation for the purpose of verifying and evaluating Dr. Wisdom's compliance with the statutory and regulatory requirements of the Federal health care programs.

VI. REPORTS

A. IMPLEMENTATION REPORT

Within ninety (90) days of the effective date of this Agreement, Dr. Wisdom shall provide the OIG with a written report demonstrating that he has complied with the Program's requirements. This report, known as the "Implementation Report," shall include:

1. A copy of the notice Dr. Wisdom posted in his office as described in Section III.B.

2. A certification signed by Dr. Wisdom attesting that all employees have completed the initial training required by Section III.D as well as a summary of what the training included. The training materials will be made available to OIG upon request.

3. A copy of the written Policies and Procedures required by section III.C of this Agreement.

4. A certification from Dr. Wisdom stating that he has reviewed the Implementation Report, he has made a reasonable inquiry regarding its content and believes that, upon his inquiry, the information is accurate and truthful.

B. ANNUAL REPORTS

Dr. Wisdom agrees to make annual written reports (each one of which is referred to throughout this Agreement as the "Annual Report") to OIG describing the measures he has taken to implement and maintain the Program and ensure compliance with the terms of this Agreement. In accordance with the provisions above, the Annual Report shall include:

1. A description, schedule and topic outline of the training programs implemented pursuant to section III.D of this Agreement, and a written certification from all appropriate personnel that they received training pursuant to the requirements set forth in section III.D of this Agreement.

2. A copy of the audits and reviews conducted pursuant to section III.E of this Agreement relating to the year covered by the Annual Report; a complete description of the findings made during the reviews; copies of any disclosure notice documents made by Dr. Wisdom pursuant to this section; and any corrective actions taken.

3. A certification signed by Dr. Wisdom certifying that he has reviewed the Annual Report, he has made a reasonable inquiry regarding its content and believes that, upon his inquiry, the information is accurate and truthful.

The Annual Reports shall be due within forty-five (45) days of the end of the one-year period covered by the Annual Report. The first one-year period shall commence on the effective date of this Agreement.

VII. NOTIFICATIONS AND SUBMISSION OF REPORTS

Unless otherwise modified in accordance with section IX below, all notifications and reports required under the terms of this Agreement shall be submitted to the entities listed below:

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
Telephone: (202) 619-2078
Facsimile: (202) 205-0604

Dr. Wisdom:

Dr. Henry J. Wisdom
P.O. Box 727
Kirksville, MO 63501
Telephone: (660) 627-1222
Facsimile: (660) 665-6664

VIII. BREACH AND DEFAULT PROVISIONS

Full and timely compliance by Dr. Wisdom shall be expected throughout the duration of this Agreement with respect to all of the obligations herein agreed to by Dr. Wisdom. In the event of Dr. Wisdom's failure to comply with any of the obligations in this Agreement, the Agreement may be deemed in breach and the parties shall proceed in

the appropriate manner as described below.

A. REMEDIES FOR MATERIAL BREACH OF THIS AGREEMENT

If Dr. Wisdom engages in conduct that OIG considers to be a material breach (as defined below) of this Agreement, OIG may determine to exclude Dr. Wisdom from participation in the Federal health care programs. Upon making its determination, OIG shall notify Dr. Wisdom of the alleged material breach by certified mail and of its intent to exclude as a result thereof (this notice shall be referred to hereinafter as the "Intent to Exclude Letter"). Dr. Wisdom shall have thirty-five (35) days from the date of the letter to:

(1) cure the alleged material breach; or

(2) demonstrate to OIG's satisfaction that the alleged material breach cannot be cured within the thirty-five (35) day period, but that Dr. Wisdom has begun to take action to cure the material breach and that Dr. Wisdom will pursue such action with due diligence. Dr. Wisdom shall, at this time, submit a timetable for curing the material breach for OIG's approval.

If at the conclusion of the thirty-five (35) day period (or other specific period as subsequently agreed by OIG and Dr. Wisdom), Dr. Wisdom fails to act in accordance with provisions (1) or (2) above, OIG may initiate steps to exclude Dr. Wisdom from participation in the Federal health care programs. OIG will notify Dr. Wisdom in writing of its determination to exclude him (this letter shall be referred to hereinafter as the "Exclusion Letter").

For purposes of this section, a "material breach" shall mean: (i) a failure to report a material deficiency, take corrective action and pay the appropriate refunds, as provided in section IV of this Agreement; (ii) repeated or flagrant violations of the obligations under this Agreement, including, but not limited to, the obligations addressed in section VI.A and VI.B of this Agreement; or (iii) a failure to retain and use an Independent Reviewer for the purposes described in section III.E.

B. DISPUTE RESOLUTION

Upon OIG's delivery to Dr. Wisdom of its Exclusion Letter, and as an agreed upon contractual remedy for the resolution of disputes arising under the obligations in this Agreement, Dr. Wisdom shall be entitled to certain due process rights similar to those afforded under 42 U.S.C. § 1320a-7(f) and 42 C.F.R. Part 1005. Specifically, OIG's determination to seek exclusion shall be subject to review by a Department of Health and Human Services ("HHS") Administrative Law Judge ("ALJ") in a manner consistent with the provisions in 42 C.F.R. §§ 1005.2-1005.21. The ALJ's decision, in turn, may be appealed to the HHS Departmental Appeals Board ("DAB") in a manner consistent with the provisions in 42 C.F.R. § 1005.21. OIG and Dr. Wisdom agree that the decision by the DAB, if any, shall constitute the final decision for purposes of the exclusion under this Agreement.

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

a. whether Dr. Wisdom was in material breach of this CIA;

b. whether such breach was continuing on the date of the Exclusion Letter; and

c. whether the alleged material breach could not have been cured within the 35 day period, but that:

(i) Dr. Wisdom had begun to take action to cure the material breach within that period;

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

(iii) Dr. Wisdom provided to OIG within that period a reasonable timetable for curing the material breach and Dr. Wisdom has followed the timetable.

IX. EFFECTIVE AND BINDING AGREEMENT

Consistent with the provisions in the Settlement Agreement pursuant to which this Integrity Agreement is entered, and into which this Integrity Agreement is incorporated, Dr. Wisdom and OIG agree as follows:

1. this Agreement shall become final and binding only upon signing by each respective party hereto; and

2. any modifications to this Agreement shall be made with the prior written consent of the parties to this Agreement.

IN WITNESS WHEREOF, the parties hereto affix their signatures:

FOR: HENRY J. WISDOM, D.O.

Henry J. Wisdom, D.O. Date

Counsel for Henry J. Wisdom, D.O. Date

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

Lewis Morris, Esquire 6/8/00
Date

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:

FOR: HENRY J. WISDOM, D.O.

Henry J. Wisdom, D.O. — Date: Aug 1st 00

Counsel for Henry J. Wisdom, D.O. — Date: 8-3-00

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

Lewis Morris, Esquire — Date
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

AMENDMENT TO THE INTEGRITY AGREEMENT BETWEEN THE OFFICE OF INSPECTOR GENERAL OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES AND HENRY J. WISDOM, D.O.

The Office of Inspector General ("OIG") of the Department of Health and Human Services and Dr. Wisdom entered into an Integrity Agreement ("Agreement") on August 3, 2000.

A. Pursuant to section IX.2 of Dr. Wisdom's Agreement, modifications to the Agreement may be made with the prior written consent of both the OIG and Dr. Wisdom. Therefore, the OIG and Dr. Wisdom hereby agree that Dr. Wisdom's Agreement will be amended as follows:

Section III.E., Independent Reviews of the Agreement is hereby superceded by the attached new section III.E., Review Procedures.

The attached Appendix A is hereby added to Dr. Wisdom's Agreement.

B. The OIG and Dr. Wisdom agree that all other sections of Dr. Wisdom's Agreement will remain unchanged and in effect, unless specifically amended upon the prior written consent of the OIG and Dr. Wisdom.

C. The undersigned signatory represents and warrants that he is authorized to execute this Amendment. The undersigned OIG signatory represents that he is signing the Amendment in his official capacity and that he is authorized to execute this Amendment.

D. The effective date of this Amendment will be the date on which the final signatory of this Amendment signs this Amendment.

ON BEHALF OF DR. WISDOM

Henry J. Wisdom, D.O.

7/2/02
DATE

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

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

7/20/02
DATE

E. Review Procedures.

1. *General Description.*

a. Retention of Independent Review Organization. Dr. Wisdom shall retain an independent third-party reviewer (e.g., a health care billing auditor or a consultant)(hereinafter the "Independent Reviewer") to perform a review to assist Dr. Wisdom in assessing and evaluating his billing and coding practices and systems pursuant to the Agreement. The Independent Reviewer retained by Dr. Wisdom 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 general requirements of the Federal health care program(s) from which Dr. Wisdom seeks reimbursement. The Independent Reviewer shall assess, along with Dr. Wisdom, whether it can perform the review in a professionally independent fashion taking into account any other business relationships or other engagements that may exist. The Independent Reviewer shall address and analyze Dr. Wisdom's billing and coding to the Federal health care programs ("Claims Review").

b. Frequency of Claims Review. The Claims Review shall be performed annually and shall cover each of the one-year periods of the Agreement beginning with the effective date of this Agreement. The Independent Reviewer shall perform all components of each annual Claims Review.

c. Retention of Records. The Independent Reviewer and Dr. Wisdom shall retain and make available to the OIG, upon request, all work papers, supporting documentation, correspondence, and draft reports (those exchanged between the Independent Reviewer and Dr. Wisdom) 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 Agreement, which is incorporated by reference.

a. Discovery Sample. The Independent Reviewer shall randomly select and review a sample of 50 Federal health care program Paid Claims submitted by or on behalf of Dr. Wisdom. The Paid Claims shall be reviewed based

on the supporting documentation available at Dr. Wisdom or under Dr. Wisdom'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, Dr. Wisdom should, as appropriate, further analyze any errors identified in the Discovery Sample. Dr. Wisdom 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 Independent Reviewer 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 Independent Reviewer shall perform an additional sample of 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 Dr. Wisdom or under Dr. Wisdom'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, Dr. Wisdom 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 Dr. Wisdom 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 Dr. Wisdom's Discovery Sample identifies an Error Rate of 5% or greater, Dr. Wisdom's Independent Reviewer shall also conduct a Systems Review. Specifically, for each claim in the Discovery Sample and Full Sample that resulted in an Overpayment, the Independent Reviewer 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 Independent Reviewer shall provide to Dr. Wisdom the Independent Reviewer's 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 IV of the Agreement, Dr. Wisdom 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. Dr. Wisdom agrees to make available to the OIG any and all documentation that reflects the refund of the Overpayment(s) to the payor.

3. *Claims Review Report.* The Independent Reviewer 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. *Validation Review.* In the event the OIG has reason to believe that: (a) Dr. Wisdom's Claims Review fails to conform to the requirements of this Agreement; or (b) the Independent Reviewer'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 complied with the requirements of the Agreement and/or the findings or Claims Review results are inaccurate ("Validation Review"). Dr. Wisdom 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 Dr. Wisdom's final Annual Report and any additional information requested by the OIG is received by the OIG.

Prior to initiating a Validation Review, the OIG shall notify Dr. Wisdom 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, Dr. Wisdom may request a

meeting with the OIG to discuss the results of any Claims Review submissions or findings; present any additional or relevant information to clarify the results of the Claims Review, or to correct the inaccuracy of the Claims Review; and/or propose alternatives to the Validation Review. Dr. Wisdom agrees to provide any additional information as may be requested by the OIG under this section in an expedited manner. The OIG will attempt in good faith to resolve any Claims Review issues with Dr. Wisdom 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.

5. *Independence Certification.* The Independent Reviewer shall include in its report to Dr. Wisdom a certification or sworn affidavit that it has evaluated its professional independence with regard to the Claims Review and that it has concluded that it is, in fact, independent.

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 Dr. Wisdom 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 Dr. Wisdom and for which Dr. Wisdom has received reimbursement from a Federal health care program.

d. Population: All Items for which Dr. Wisdom has submitted a code or line item and for which Dr. Wisdom has received reimbursement from a Federal health care 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 net Overpayments shall be calculated by subtracting all underpayments identified in the sample from all gross Overpayments identified in the sample. (Note: 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.)

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 Dr. Wisdom cannot produce documentation sufficient to support the Paid Claim shall be considered an error and the total reimbursement received by Dr. Wisdom 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.

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 Independent Reviewer 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. **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 Independent Reviewer.

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

d. A description or identification of the statistical sampling software package used to conduct the sampling.

3. **Claims Review Findings.**

a. Narrative Results.

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

ii. A narrative explanation of the Independent Reviewer's findings and supporting rationale (including reasons for errors, patterns noted, etc.) regarding the Claims Review, including the results of the Discovery Sample, and the results of the Full Sample (if any) with the gross Overpayment amount, the net Overpayment amount, and the corresponding Error Rate(s) related to the net Overpayment.

b. Quantitative Results.

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

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

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

iv. Error Rate in the sample.

v. 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 Independent Reviewer), correct allowed amount (as determined by the Independent Reviewer), dollar difference between allowed amount reimbursed by payor and the correct allowed amount. (See Attachment 1 to this Appendix.)

4. **Systems Review.** Observations, findings and recommendations on possible improvements to the system(s) and process(es) that generated the Overpayment(s).

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

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 (Independent Reviewer determined)	Correct Allowed Amt Reimbursed (IRO determined)	Dollar Difference between Amt Reimbursed and Correct Allowed Amt