INTEGRITY AGREEMENT
BETWEEN THE
OFFICE OF INSPECTOR GENERAL
OF THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND
DR. YEONG H. OH

I. PREAMBLE

Dr. Yeong H. Oh ("Dr. Oh") 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 ensure compliance with the requirements of Medicare, Medicaid and all other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)) by Dr. Oh, any corporation or partnership or health care practice in which he is an owner or has a control interest as defined in 42 U.S.C. § 1320a-3(a)(3), his employees, and all third parties with whom Dr. Oh may choose to engage to act as billing or coding consultants ("Covered Persons"). Dr. Oh's compliance with the terms and conditions in this Agreement shall constitute an element of his present responsibility with regard to participation in the Federal health care programs. Contemporaneously with this Agreement, Dr. Oh 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. Oh under this Agreement shall be three (3) years from the effective date of this Agreement. The effective date of this Agreement will be the date on which the final signatory executes this Agreement ("effective date").

Sections V, VIII, IX, X and XI shall remain in effect for purposes of compliance with this Agreement until OIG has completed its review of the final annual report and any additional materials submitted by Dr. Oh pursuant to OIG's request.

III. INTEGRITY OBLIGATIONS

Dr. Oh is currently employed by Mercy Family Care, Inc., which has its own compliance program that includes training, annual reviews of billings, and a compliance officer. Presently, no claims for items or services provided by Dr. Oh are submitted to

Federal health care programs except for those submitted by Mercy Family Care, Inc., for items and services provided by Dr. Oh as its employee. If, at any time during the term of this Agreement, Dr. Oh owns part or all of a health care practice, within ninety (90) days of assuming ownership, Dr. Oh agrees to establish and implement a Compliance Program that, at minimum, includes the following elements:

A. COMPLIANCE CONTACT

Dr. Oh 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. In the event a new Compliance Contact is appointed during the term of this Agreement, Dr. Oh shall notify the OIG, in writing, within 15 days of such a change.

B. POSTING OF NOTICE

Dr. Oh 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 Medicare, Medicaid and all other Federal health care programs 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 with the Annual Report.

C. WRITTEN POLICIES AND PROCEDURES

Dr. Oh will develop and implement written policies and procedures designed to assure that all claims submitted to Medicare and Medicaid are accurate and correctly identify the services rendered. Among other things, the policies and procedures will address the following:

1. Dr. Oh'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. Oh's Covered Persons shall be expected to report to Dr. Oh or the Compliance Contact suspected violations of any Federal health care program requirements or Dr. Oh's own Policies and Procedures. Any Covered Person who makes an inquiry regarding compliance with medical practice standards or Federal health care program requirements shall be able to do so without risk of retaliation or other adverse effect.

5. The commitment of Dr. Oh not to hire or engage as contractors or agents any Ineligible Person. For purposes of this Agreement, an "Ineligible Person" shall be any individual or entity who: (a) is currently excluded, debarred or otherwise ineligible to participate in the Federal health care programs or in Federal procurement or non-procurement programs; or (b) has been convicted of a criminal offense 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. Oh shall check all prospective employees or 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).

6. The commitment of Dr. Oh to remain current with all Federal health care program requirements by obtaining and reviewing program memoranda, newsletters, and any other correspondence from the Fiscal Intermediary or carrier related to Federal health care program requirements.

At least annually (and more frequently if appropriate), Dr. Oh 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.

A copy of these written policies and procedures shall be made available to the OIG upon request.

D. <u>TRAINING</u>

Dr. Oh and all of his staff and agents directly or indirectly involved in preparing or submitting bills to Medicare, Medicaid, and all other Federal health care programs for services and items provided by Dr. Oh shall be trained in the proper billing standards, methods, and procedures to ensure accurate billing for services rendered to these Federal health care programs. Included among the persons to be trained are all persons involved directly or indirectly in purchasing services from third parties which are subsequently billed to Federal health care programs. The training shall be designed to ensure that Dr. Oh and his employees and agents are aware of all applicable health care statutes, regulations, and program guidelines and with the standards of business conduct that they are expected to follow and the consequences (e.g., termination, legal sanctions, etc.) both to the individual and Dr. Oh that will ensue from any violation of such requirements. In addition, Dr. Oh will arrange for all new personnel directly or indirectly involved in billing for services to participate in such training no later than thirty (30) days after they begin working for Dr. Oh. Until they have had the requisite training, such new employees will work under the direct supervision of an employee who has received such training. This training program shall provide for no less than four (4) hours of training annually for each person.

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

1. The proper billing standards and procedures for the submission of accurate bills for services rendered and/or items provided to Medicare, Medicaid, and all other Federal health care programs to which Dr. Oh submits claims;

2. All applicable statutes, regulations, directives, and guidelines related to billing to and reimbursement from Medicare, Medicaid and other Federal health care programs, including those governing billing the Federal health care programs for purchased services offered to Dr. Oh at a discount;

3. All applicable statutes, rules, regulations, directives, and guidelines related to health care fraud and abuse and the legal sanctions for violating these laws;

4. The written Policies and Procedures developed pursuant to Section III.D above.

A schedule and topic outline of the training shall be included in the Annual Report.

Even if Dr. Oh remains solely as an employee of Mercy Family Care, Inc. throughout the term of this Agreement and does not assumes ownership of part or all of a health care practice, he shall still participate in the training required by this section III.D, and he shall annually submit a statement to the OIG certifying that he has participated in such training along with a schedule and topic outline of the training.

E. <u>ANNUAL REVIEW PROCEDURES</u>

1. *Scope of Obligations*. The obligations of this Section III.E apply to all claims submitted to Federal health care programs for items and services provided by Dr. Oh, regardless of whether Dr. Oh owns all or part of a health care practice and regardless of whether he is employed by Mercy Family Care or elsewhere.

2. *Retention of Independent Review Organization*. Dr. Oh shall retain a person or entity, such as an accounting, auditing or consulting firm (hereinafter "Independent Review Organization" or "IRO"), to perform a billing review to assess Dr. Oh's billing and coding practices ("Billing Engagement") with respect to all claims submitted to Federal health care programs for items and services provided by Dr. Oh, regardless of whether they were provided in his capacity as an employee of Mercy Family Care or in some other capacity and regardless of whether he owns all or part of a health care practice. The Independent Review Organization retained by Dr. Oh 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.

3. *Frequency of the Billing Engagement*. The Billing Engagement shall be performed annually and shall cover each of the one-year periods beginning with the effective date of this Agreement. The IRO shall perform all components of each annual Billing Engagement in accordance with the procedures detailed in Appendix A, which is attached to and incorporated by reference into this Agreement.

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

5. *Validation Review*. In the event the OIG has reason to believe that: (a) Dr. Oh's Billing Engagement fails to conform to the requirements of this Agreement or (b) the findings or Claims Review results are inaccurate, the OIG may, at its sole discretion, conduct its own review to determine whether the Billing Engagement complies

with the requirements of the Agreement and/or the findings or Claims Review results are inaccurate. Dr. Oh 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 report is submitted and received by the OIG.

6. Annual reviews of Dr. Oh's billings as an employee of Mercy Family Care, Inc., shall occur in the following manner:

a. As part of his first Annual Report required by Section VI below, Dr. Oh will submit all reports and results of the annual review of his billings conducted by Mercy Family Care, Inc.

b. In the event the OIG has reason to believe that: (i) the review conducted by Mercy Family Care, Inc., fails to conform to the requirements of this CIA or (b) the findings or Claims Review results are inaccurate, the OIG may, at its sole discretion, require Dr. Oh to retain and pay for an IRO to perform a billing engagement in accordance with the procedures detailed in Appendix A.

c. If the OIG is dissatisfied with the first annual review conduct by Mercy Family Care, Inc., and requires Dr. Oh to retain and pay for an IRO to perform a billing engagement pursuant to subsection b above, thereafter Dr. Oh will retain and pay for an IRO to perform all subsequent annual reviews under this CIA of his billings as a Mercy Family Care employee.

F. REPORTING OF OVERPAYMENTS AND MATERIAL DEFICIENCIES

1. *Overpayments*

a. Definition of Overpayments. For purposes of this Agreement, an "overpayment" shall mean the amount of money Dr. Oh has received in excess of the amount due and payable under any Federal health care program requirements. Dr. Oh 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. Oh identifies or learns of any overpayments, Dr. Oh 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 Appendix B to this Agreement

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. Oh determines that there is a Material Deficiency, Dr. Oh 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. Oh's actions taken to correct the Material Deficiency; and

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

G. NOTIFICATION OF GOVERNMENT INVESTIGATIONS OR LEGAL PROCEEDINGS

Within 30 days of discovery, Dr. Oh 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. Oh 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. Oh 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. Oh changes locations or purchases or establishes new business units related to the furnishing of items or services that may be reimbursed by Federal health care programs, Dr. Oh 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 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. 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. Oh's books, records, and other company documents and supporting materials, and/or conduct onsite reviews of any of Dr. Oh's locations for the purpose of verifying and evaluating: (i) Dr. Oh's compliance with the terms of this Agreement; and (ii) Dr. Oh's compliance with the requirements of the Medicare, Medicaid and other Federal health care programs. The documentation described above shall be made available by Dr. Oh at all reasonable times for inspection, audit or reproduction. OIG, HCFA, or the affected intermediary or carrier, 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. Oh's compliance with the statutory and regulatory requirements of Medicare, Medicaid and all other Federal health care programs.

VI. ANNUAL REPORTS

Dr. Oh shall make annual written reports (each one of which is referred to throughout this Agreement as the "Annual Report") to OIG describing the measures Dr. Oh 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 attended in accordance with section III.D. of this Agreement;

(2) A certification signed by Dr. Oh certifying that all appropriate personnel have received training pursuant to the requirements set forth in section III.D. of this Agreement;

(3) A complete copy of all reports prepared pursuant to the Mercy Family Care annual review of Dr. Oh's billings and the IRO's billing engagement, including a copy of the methodology used, along with a copy of the IRO's engagement letter;

(4) Dr. Oh's response and corrective action plan(s) related to any issues raised by the IRO;

(5) A summary of Material Deficiencies (as defined in III.F.) identified during

the Reporting Period and the status of any corrective and preventative action relating to all such Material Deficiencies;

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

(7) A certification signed by Dr. Oh 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

(8) A certification signed by Dr. Oh certifying that he has reviewed the Annual Report, he [or she] has made a reasonable inquiry regarding its content and believes that, upon his inquiry, the information is accurate and truthful.

VII. 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 entities listed below:

ATTN: Civil Recoveries Branch - Compliance Unit
Office of Counsel to the 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

All correspondence to Dr. Oh shall be sent to:

Dr. Yeong H. Oh
816 Katesford Road
Cockeysville, MD 21030
Ph. 410 560 2048

VIII. Breach and Default Provisions

Full and timely compliance by Dr. Oh shall be expected throughout the duration of this Agreement with respect to all of the obligations he has agreed to. As stated below in section IX. of this Agreement, any and all modifications to this Agreement (including changes to dates on which an obligation is due to be met) shall be requested in writing and agreed to by OIG in writing prior to the date on which the modification is expected to take effect.

A. Remedies for Material Breach of this Agreement

If Dr. Oh engages in conduct that OIG considers to be a material breach, defined below, of this Agreement, OIG may seek exclusion of Dr. Oh from participation in the Medicare, Medicaid and any other Federal health care programs. Upon making its determination, OIG shall notify Dr. Oh 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 "Exclusion Letter"). Dr. Oh 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. Oh has begun to take action to cure the material breach and that Dr. Oh will pursue such an action with due diligence. Dr. Oh 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. Oh), Dr. Oh fails to act in accordance with provisions 1 and 2 above, OIG may exclude Dr. Oh from participation in the Medicare, Medicaid and all other Federal health care programs. OIG will notify Dr. Oh in writing of its determination to exclude Dr. Oh (this letter shall be referred to hereinafter as the "Exclusion Letter").

B. Dispute Resolution

Upon OIG's delivery to Dr. Oh of its Exclusion Letter, and as an agreed upon contractual remedy for the resolution of disputes arising under the obligations in this

Agreement, OIG may initiate proceedings to undertake appropriate administrative action, including exclusion, for a material breach of this Agreement. Dr. Oh shall be entitled to certain due process rights afforded in 42 U.S.C. § 1320a-7(f) and 42 C.F.R. § 1005. Specifically, OIG's determination to seek exclusion shall be subject to review by an 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. However, Dr. Oh agrees that the decision by the DAB, if any, shall constitute the final decision and no appeal right shall be afforded to federal court.

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 III.E of this Agreement; (ii) repeated or flagrant violations of the obligations under this Agreement; or (iii) a failure to retain and use an Independent Review Organization in accordance with section III.E.

IX. Document and Record Retention

Dr. Oh shall maintain for inspection all documents and records relating to reimbursement from the Federal health care programs, or to compliance with this Agreement, for four years (or longer if otherwise required).

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

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. Oh and OIG agree as follows:

(1) this Agreement shall be binding on the successors, assigns and transferees of Dr. Oh;

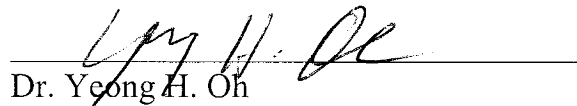
(2) this Agreement shall become final and binding only upon signing by each respective party hereto; and

(3) 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:

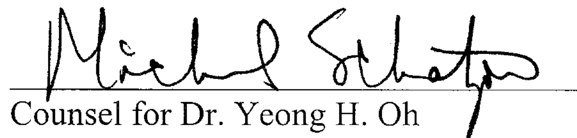
DR. YEONG H. OH

11/12/00
Date



Dr. Yeong H. Oh

11-16-00
Date



Counsel for Dr. Yeong H. Oh

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

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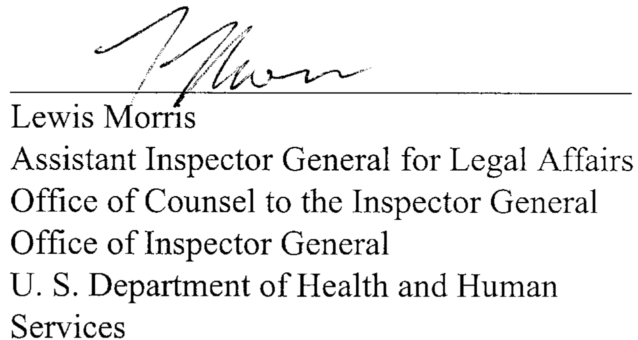


Lewis Morris
Assistant Inspector General for Legal Affairs
Office of Counsel to the Inspector General
Office of Inspector General
U. S. Department of Health and Human Services

AMENDMENT TO THE INTEGRITY AGREEMENT BETWEEN THE OFFICE OF INSPECTOR GENERAL OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES AND DR. YEONG H. OH

The Office of Inspector General ("OIG") of the Department of Health and Human Services and Dr. Yeong H. Oh ("Dr. Oh") entered into an Integrity Agreement ("IA") on November 16, 2000.

A. Pursuant to section XI.3 of Dr. Oh's IA, modifications to the IA may be made with the prior written consent of both the OIG and Dr. Oh. Therefore, the OIG and Dr. Oh hereby agree that Dr. Oh's IA will be amended as follows:

   Section III.E., Annual Review Procedures of the IA is hereby superceded by the attached new section III.E, Review Procedures.

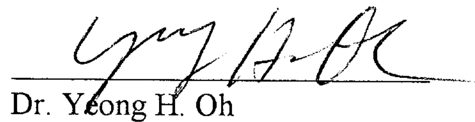
   Appendix A of Dr. Oh's IA is hereby superceded by the attached new Appendix A.

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

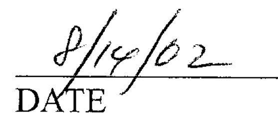
C. The undersigned Dr. Oh represents and warrants that he is authorized to execute this Amendment. The undersigned OIG signatory represents that he is signing the Amendment in his official capacity and that he is authorized to execute this Amendment.

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

ON BEHALF OF DR. YEONG H. OH



Dr. Yeong H. Oh



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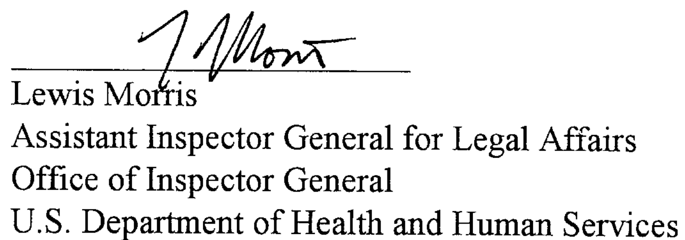
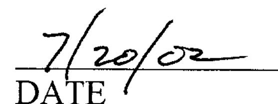
ON BEHALF OF THE OFFICE OF INSPECTOR GENERAL OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES



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



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E. Review Procedures.

1. *General Description.*

a. Retention of Independent Review Organization. Within 90 days of the effective date of this IA, Dr. Oh shall retain an entity (or entities), such as an accounting, auditing or consulting firm (hereinafter "Independent Review Organization" or "IRO"), to perform reviews to assist Dr. Oh in assessing and evaluating his billing and coding practices and systems pursuant to this IA and the Settlement Agreement. The IRO retained by Dr. Oh shall have expertise in the billing, coding, reporting, and other requirements of the particular section of the health care industry pertaining to this IA and in the general requirements of the Federal health care program(s) from which Dr. Oh seeks reimbursement. The IRO shall assess, along with Dr. Oh, whether it can perform the IRO review in a professionally independent fashion taking into account any other business relationships or other engagements that may exist. The IRO(s) review shall address and analyze Dr. Oh's billing and coding to the Federal health care programs ("Claims Review"). The claims review shall be performed regardless of whether the claims submitted to Federal health care programs for items or services provided by Dr. Oh were provided in his capacity as an employee of Mercy Family Care, or in some other capacity and regardless of whether he owns all or part of a health care practice.

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

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

a. Discovery Sample. The IRO shall randomly select and review a sample of 50 Federal Health Care program Paid Claims submitted by or on behalf of Dr. Oh. The Paid Claims shall be reviewed based on the supporting documentation available at Mercy Family Care or under Dr. Oh'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. Oh should, as appropriate, further analyze any errors identified in the Discovery Sample. Dr. Oh recognizes that the OIG or other HHS component, in its discretion and as authorized by statute, regulation, or other appropriate authority may also analyze or review Paid Claims included, or errors identified, in the Discovery Sample.)

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

b. Full Sample. If necessary, as determined by procedures set forth in Section III.E.2.a, the IRO shall perform an additional sample of 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 Mercy Family Care or under Dr. Oh'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. Oh 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. Oh 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. Oh's Discovery Sample identifies an Error Rate of 5% or greater, Dr. Oh's IRO shall also conduct a Systems Review. Specifically, for each claim in the Discovery Sample and Full Sample that resulted in an Overpayment, the IRO should perform a "walk through" of the system(s) and process(es) that generated the claim to identify any problems or weaknesses that may have resulted in the identified Overpayments. The IRO shall provide to Dr. Oh the IRO'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 III.F of the IA, Dr. Oh 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. Oh 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 IRO shall prepare a report based upon the Claims Review performed (the "Claims Review Report"). Information to be included in the Claims Review Report is detailed in Appendix A.

4. *Validation Review.* In the event the OIG has reason to believe that: (a) Dr. Oh's Claims Review fails to conform to the requirements of this IA; or (b) the IRO's findings or Claims Review results are inaccurate, the OIG may, at its sole discretion, conduct its own review to determine whether the Claims Review complied with the requirements of the IA and/or the findings or Claims Review results are inaccurate ("Validation Review"). Dr. Oh 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. Oh'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. Oh 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. Oh 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. Oh 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. Oh 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 IRO shall include in its report(s) to Dr. Oh 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. Oh 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. Oh and for which Dr. Oh has received reimbursement from the a Federal health care program.

d. Population: All Items for which Dr. Oh has submitted a code or line item and for which Dr. Oh 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. Oh cannot produce documentation sufficient to support the Paid Claim shall be considered an error and the total reimbursement received by Dr. Oh 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 IRO when performing the Claims Review (e.g., medical records, physician orders, certificates of medical necessity, requisition forms, local medical review policies, CMS program memoranda, Medicare carrier or intermediary manual or bulletins, other policies, regulations, or directives).

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

2. **Statistical Sampling Documentation.**

a. The number of Items appraised in the Discovery Sample and, if applicable, in the Full Sample.

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

c. A copy of the statistical software printout(s) estimating how many Items are to be included in the Full Sample, 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. Oh's billing and coding system(s), including the identification, by position description, of the personnel involved in coding and billing.

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

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

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.