

**INTEGRITY AGREEMENT
BETWEEN THE
OFFICE OF INSPECTOR GENERAL
OF THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND
JEAN BENSON, M.D.**

I. PREAMBLE

Jean Benson, M.D. (Dr. Benson) 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 compliance with the statutes, regulations, program requirements, and written directives of Medicare, Medicaid, and all other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)) (Federal health care program requirements) by Dr. Benson, her employees, contractors and agents. This commitment to promote compliance also applies to any entity that Dr. Benson owns or in which Dr. Benson has a control interest, as defined in 42 U.S.C. § 1320a-3(a)(3), including Independent Medical Associates, P.A., and such entity's employees, agents, contractors, and all other individuals responsible for providing, documenting, or preparing claims for the reimbursement of, items or services that are reimbursed by Federal health care programs on behalf of Dr. Benson. Contemporaneously with this Agreement, Dr. Benson 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

A. The date on which the final signatory of this Agreement executes this Agreement shall be known as the "Effective Date." The period of compliance obligations assumed by Dr. Benson under this Agreement shall be five (5) years from the Effective Date of this Agreement. Each one-year period, beginning with the one-year period following the Effective Date, shall be referred to as a "Reporting Period."

B. Sections VII, VIII, IX, X, and XI shall expire no later than 120 days from OIG's receipt of: (1) Dr. Benson's final Annual Report; or (2) any additional materials submitted by Dr. Benson pursuant to OIG's request, whichever is later.

C. The scope of this Agreement shall be governed by the following definitions:

1. "Covered Persons" includes:

a. Dr. Benson;

b. all employees of Dr. Benson, Independent Medical Associates, P.A., and any other entity that Dr. Benson owns or in which Dr. Benson has a control interest, as defined in 42 U.S.C. § 1320a-3(a)(3); and

c. all other persons who provide patient care items or services or who perform billing or coding functions on behalf of Dr. Benson, including but not limited to contractors and agents of Dr. Benson.

III. INTEGRITY OBLIGATIONS

Dr. Benson shall establish and maintain a Compliance Program that includes the following elements:

A. Compliance Contact

Within 30 days after the Effective Date, Dr. Benson shall designate a person to be responsible for compliance activities (Compliance Contact). Dr. Benson shall maintain a Compliance Contact for the term of this Agreement. The Compliance Contact shall be responsible for: (1) developing and implementing policies, procedures, and practices designed to ensure compliance with the requirements set forth in this Agreement and with Federal health care program requirements; (2) monitoring Dr. Benson's day-to-day compliance activities; and (3) meeting all reporting obligations created under this Agreement.

Dr. Benson shall report to OIG, in writing, any changes in the identity or job responsibilities of the Compliance Contact, or any actions or changes that would affect the Compliance Contact's ability to perform the duties necessary to meet the obligations in this Agreement, within 15 days after such change. The name, address, phone number, and a description of any other job responsibilities performed by the Compliance Contact shall be included in the Implementation Report.

B. Posting of Notice

Within the 90 days after the Effective Date, Dr. Benson shall post in a prominent place accessible to all patients and Covered Persons a notice detailing her commitment to comply with all Federal health care program requirements in the conduct of her business.

This notice shall also include the following information: (i) a means (e.g., telephone number or address) by which instances of misconduct may be reported anonymously; (ii) Dr. Benson's commitment to maintain the confidentiality of the report; and (iii) notification that reporting a suspected violation will not result in retribution or retaliation by Dr. Benson. A copy of this notice shall be included in the Implementation Report.

This notice shall also include the OIG Fraud Hotline telephone number (1-800-HHS-TIPS) as a confidential means by which suspected fraud or abuse in the Federal health care programs may be reported.

A copy of this notice shall be included in the Implementation Report.

C. Written Policies and Procedures

Within 90 days after the Effective Date, Dr. Benson shall develop, implement, and distribute written Policies and Procedures to all Covered Persons. In addition, Dr. Benson shall make the promotion of, and adherence to, the written Policies and Procedures an element in evaluating the performance of all employees. The written Policies and Procedures shall, at a minimum, set forth:

1. Dr. Benson's commitment to full compliance with all Federal health care program requirements, including her commitment to prepare and submit accurate claims consistent with such requirements;
2. the expectation that all of Dr. Benson's Covered Persons shall be expected to comply with all Federal health care program requirements and with Dr. Benson's own written Policies and Procedures as implemented pursuant to this Section III.C (including the requirements of this Agreement);
3. the responsibility and requirement that all Covered Persons report suspected violations of any Federal health care program requirements or of Dr. Benson's own Policies and Procedures to the

Compliance Contact and Dr. Benson's commitment to maintain confidentiality and anonymity, as appropriate, and not to retaliate with respect to such disclosures;

4. the possible consequences to both Dr. Benson and Covered Persons of failure to comply with Federal health care program requirements or with Dr. Benson's written Policies and Procedures and the failure to report such noncompliance;

5. Dr. Benson's commitment to remain current with all Federal health care program requirements by obtaining and reviewing program memoranda, newsletters, and any other correspondence from the carrier related to Federal health care program requirements;

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

7. the proper documentation of services and billing information; and

8. the requirements set forth in this Agreement, including but not limited to the requirement to maintain a log of Prescriptions of Schedule II Narcotic Drugs as specified in Section III.E.2.a.

Within 90 days after the Effective Date, each Covered Person shall certify in writing that he or she has received, read, understood, and shall abide by Dr. Benson's written Policies and Procedures. New Covered Persons shall receive and review the written Policies and Procedures and shall complete the required certification within 30 days after becoming a Covered Person or within 90 days after the Effective Date, whichever is later.

At least annually (and more frequently if appropriate), Dr. Benson shall assess and update, as necessary, the Policies and Procedures. Within 30 days after the effective date of any revisions, the relevant portions of any such revised Policies and Procedures shall be distributed to all Covered Persons. Appropriate and knowledgeable staff shall be available to explain the Policies and Procedures.

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 next Annual Report along

with a summary of any change or amendment to each Policy and Procedure required by this Section and the reason for each change.

D. Training and Certification

Within 90 days after the Effective Date and at least once each year thereafter, Dr. Benson and Covered Persons shall receive at least three hours of training from an individual or entity, other than Dr. Benson or another Covered Person. Persons providing the training shall be knowledgeable about the subject area and the training may be received from a variety of sources, including, for example, live, web-based, online, or videotaped programs.

New Covered Persons shall receive the training described above within 30 days after becoming a Covered Person or within 90 days after the Effective Date, whichever is later. The training for new Covered Persons may either be provided internally by a Covered Person who has completed the required annual training or externally by a qualified individual or entity. A new Covered Person shall work under the direct supervision of a Covered Person who has received such training, to the extent that the work relates to the delivery of patient care items or services and/or the preparation or submission of claims for reimbursement from any Federal health care program, until such time as the new Covered Person completes the training.

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

1. the requirements of this Agreement, including but not limited to the requirement to maintain a log of Prescriptions of Schedule II Narcotic Drugs as specified in Section III.E.2.a;
2. an overview of Dr. Benson's compliance program;
3. the accurate coding and submission of claims for services rendered and/or items provided to Federal health care program beneficiaries;
4. applicable reimbursement statutes, regulations, and program requirements and directives;
5. the written Policies and Procedures developed pursuant to Section III.C, above;

6. the policies, procedures, and other requirements applicable to the documentation of medical records;
7. the personal obligation of each individual involved in the coding and claims submission process to ensure that such claims are accurate; and
8. the legal sanctions for the submission of improper claims or violations of Federal health care program requirements.

In addition to these annual training requirements, Dr. Benson shall also personally complete at least 6 Category 1 credit hours of continuing medical education on pain management and/or prescription drug therapy for the first Reporting Period of this Agreement and at least 3 Category 1 credit hours for each subsequent Reporting Period.

Each Covered Person shall annually certify in writing that he or she has received the required training. The certification shall specify the date the training was received. The Compliance Contact shall retain the certifications, along with all training materials. Dr. Benson shall annually review the training, and, where appropriate, update the training to reflect changes in Federal health care program requirements, any issues discovered during the Prescription Review, and any other relevant information.

The training materials shall be provided in the Implementation Report, and to the extent the training is revised, shall also be included in the Annual Reports. The certifications shall be made available to OIG, upon request.

E. Review Procedures

1. General Description.

a. *Engagement of Independent Review Organization.* Within 90 days after the Effective Date, Dr. Benson shall engage an entity (hereinafter Independent Review Organization or IRO), to perform reviews to assess and evaluate the medical necessity of Dr. Benson's Prescriptions of Schedule II Narcotic Drugs (Prescription Review) and certain other obligations pursuant to this Agreement and the Settlement Agreement.

The IRO selected and engaged by Dr. Benson shall have expertise in the prescription of Schedule II Narcotic Drugs and in the general requirements of the Federal health care program(s). The IRO shall

assess, along with Dr. Benson, whether it can perform the review in a professionally independent and/or objective fashion, as appropriate to the nature of the engagement, taking into account any other business relationships or other engagements that may exist. The applicable requirements relating to the IRO are outlined in Appendix A to the Agreement, which is incorporated by reference.

b. *Frequency of Schedule II Narcotic Drug Prescription Review.* The Prescription Reviews shall be performed semiannually during the term of this Agreement and shall cover the first and second halves of the Reporting Period. The IRO shall perform all components of each Prescription Review. If the first two semiannual Prescription Reviews do not uncover any material errors, Dr. Benson may request the frequency of the Prescription Reviews to be amended to annual reviews. The OIG will consider such requests and may, in its sole discretion, amend the frequency of the Prescription Reviews to annual reviews. If the OIG so permits, the OIG shall notify Dr. Benson in writing.

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

2. Schedule II Narcotic Drug Prescription Review. The Prescription Review shall be conducted as described below.

a. *Prescription Review Sample.* Dr. Benson shall maintain a log of Prescriptions of Schedule II Narcotic Drugs ordered by or on behalf of Dr. Benson for a Medicare, Medicaid, or Federal health care program beneficiary for each review period. The IRO shall determine the Prescription Review Population from this log. The IRO shall randomly select and review a sample of 50 Prescriptions of Schedule II Narcotic Drugs from the Prescription Review Population. The Prescriptions of Schedule II Narcotic Drugs shall be reviewed based on the medical records and other supporting documentation available at Dr. Benson's office or under Dr. Benson's control and any applicable clinical, billing, and coding regulations and guidance to determine whether each Prescription was medically necessary for each beneficiary's indications and diagnosis. The applicable definitions, procedures, and reporting requirements are outlined in Appendix B to this Agreement, which is incorporated by reference.

b. *Notification of Identified Prescriptions of Schedule II Narcotic Drugs That Were Not Medically Necessary.* For any Prescription of a Schedule II Narcotic Drug identified in the sample as not medically necessary, Dr. Benson shall notify the payor of such Prescription within 30 days after such identification for the purpose of calculating any Overpayment(s) regarding the Schedule II Narcotic Drugs. If the payor is Medicaid, Dr. Benson shall notify the Medicaid Surveillance Utilization Review Unit, 11 State House Station, 442 Civic Center Drive, Augusta ME 04333, attn: Mark Fecteau. Dr. Benson shall make available to the payor any and all documentation necessary to calculate the Overpayment(s) regarding the Schedule II Narcotic Drugs prescribed by Dr. Benson. In accordance with Section III.H.1, Dr. Benson shall repay any Overpayment(s) regarding the Schedule II Narcotic Drugs to the appropriate payor pursuant to payor refund policies within 30 days after the Overpayment(s) have been quantified by the payor. Dr. Benson shall make available to OIG any and all documentation that reflects the refund of the Overpayment(s) to the payor.

c. *Referral of Findings.* OIG, in its sole discretion, may refer the findings of the Prescription Review (and any related workpapers) to the appropriate Federal health care program payor (e.g., state Medicaid agency) for appropriate follow-up by that payor. In addition, OIG, in its sole discretion, may refer the findings of the Prescription Review (and any related workpapers) received from Dr. Benson to the Federal Drug Enforcement Administration, the Maine Board of Licensure in Medicine, or any other health oversight agency or law enforcement authority for appropriate follow-up by that authority.

3. Prescription Review Report. The IRO shall prepare a report based upon each Prescription Review performed (Prescription Review Report). Information to be included in the Prescription Review Report shall be as described in Appendix B. In addition to Dr. Benson's obligation to provide the Prescription Review Reports in the Annual Report under Section V.B of this Agreement, the IRO shall submit to the OIG a copy of each Prescription Review Report within 30 days of the end of each applicable semiannual review period.

4. Validation Review. In the event OIG has reason to believe that:
(a) the Prescription Review fails to conform to the requirements of this Agreement; or (b) the IRO's findings or Prescription Review results are

inaccurate, OIG may, at its sole discretion, conduct its own review to determine whether the Prescription Review complied with the requirements of the Agreement and/or the findings or Prescription Review results are inaccurate (Validation Review). Dr. Benson shall pay for the reasonable cost of any such review performed by OIG or any of its designated agents so long as it is initiated within one year after Dr. Benson's final submission (as described in Section II) is received by OIG.

Prior to initiating a Validation Review, OIG shall notify Dr. Benson of its intent to do so and provide a written explanation of why OIG believes such a review is necessary. To resolve any concerns raised by OIG, Dr. Benson may request a meeting with OIG to: (a) discuss the results of any Prescription Review submissions or findings; (b) present any additional or relevant information to clarify the results of the Prescription Review to correct the inaccuracy of the Prescription Review; and/or (c) propose alternatives to the proposed Validation Review. Dr. Benson agrees to provide any additional information requested by OIG under this Section in an expedited manner. OIG will attempt in good faith to resolve any Prescription Review issues with Dr. Benson 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 OIG.

5. Independence/Objectivity Certification. The IRO shall include in its report(s) to Dr. Benson a certification or sworn affidavit that it has evaluated its professional independence and/or objectivity, as appropriate to the nature of the engagement, with regard to the Prescription Review and that it has concluded that it is, in fact, independent and/or objective.

F. Ineligible Persons

1. Definitions. For purposes of this Agreement:

a. An "Ineligible Person" shall include an individual or entity who: (i) is currently excluded, debarred, suspended, or otherwise ineligible to participate in the Federal health care programs or in Federal procurement or nonprocurement programs; or (ii) has been convicted of a criminal offense that falls within the ambit of 42 U.S.C. § 1320a-7(a), but has not yet been excluded, debarred, suspended, or otherwise declared ineligible.

b. "Exclusion Lists" include: (i) the HHS/OIG List of Excluded Individuals/Entities (available through the Internet at

<http://oig.hhs.gov>); and (ii) the General Services Administration's List of Parties Excluded from Federal Programs (available through the Internet at <http://www.epls.arnet.gov>).

2. Screening Requirements. Dr. Benson shall ensure that all prospective and current associates, employees, contractors, and agents of Dr. Benson are not Ineligible Persons. To ensure that such individuals and entities are not Ineligible Persons, Dr. Benson shall require such individuals and entities to disclose immediately any debarment, exclusion, suspension, or other event that makes such individual or entity an Ineligible Person. Prior to engaging the services of such individuals and entities, Dr. Benson shall screen such individuals and entities against the Exclusion Lists. In addition, Dr. Benson shall:

- a. Within 90 days after the Effective Date, review her list of individuals and entities identified in Section III.F.2 against the Exclusion Lists; and
- b. Review her list of individuals and entities identified in Section III.F.2 against the Exclusion Lists annually.

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

Nothing in this Section affects the responsibility of (or liability for) Dr. Benson to refrain from billing Federal health care programs for services of the Ineligible Person.

3. Removal Requirement. If Dr. Benson has notice that any individual or entity in one of the positions identified in Section III.F.2 has become an Ineligible Person, Dr. Benson shall remove such individual or entity from responsibility for, or involvement with, Dr. Benson's business operations related to the Federal health care programs and shall remove such individual or entity from any position for which the individual's or entity's compensation or the items or services rendered, ordered, or prescribed by the individual or entity are paid in whole or part, directly or indirectly, by Federal health care programs or otherwise with Federal funds at least until such time as the individual or entity is reinstated into participation in the Federal health care programs.

4. Pending Charges and Proposed Exclusions. If Dr. Benson has notice that an individual identified in Section III.F.2 is charged with a criminal offense that falls within the ambit of 42 U.S.C. § 1320a-7(a), or an individual or entity identified in Section III.F.2 is proposed for exclusion during his, her or its employment, involvement or contract term, Dr. Benson shall take all appropriate actions to ensure that the responsibilities of that individual or entity has not and shall not adversely affect the quality of care rendered to any beneficiary, patient, or resident, or the accuracy of any claims submitted to any Federal health care program.

G. Notification of Government Investigation or Legal Proceedings

Within 30 days after discovery, Dr. Benson shall notify OIG, in writing, of any ongoing investigation or legal proceeding known to Dr. Benson conducted or brought by a governmental entity or its agents involving an allegation that Dr. Benson or any Covered Persons have 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. Benson shall also provide written notice to OIG within 30 days after the resolution of the matter, and shall provide OIG with a description of the findings and/or results of the proceedings, if any.

H. Reporting

1. Overpayments

a. *Definition of Overpayments.* For purposes of this Agreement, an “Overpayment” shall mean the amount of money Dr. Benson has received, or caused to be paid, in excess of the amount due and payable under any Federal health care program requirements.

b. *Reporting of Overpayments.* If, at any time, Dr. Benson identifies or learns of any Overpayment or any furnishing of an item or service to a patient that results in an Overpayment, Dr. Benson shall notify the appropriate payor (e.g., Medicaid Surveillance Utilization Review Unit) within 30 days after identification for the purpose of calculating any Overpayment(s). If the payor is Medicaid, Dr. Benson shall notify the Medicaid Surveillance Utilization Review Unit, 11 State House Station, 442 Civic Center Drive, Augusta, ME 04333, attn: Mark Fecteau. Dr. Benson shall also take remedial steps within 60 days after the identification (or such additional time as may be agreed to by the payor) to correct the

problem, including preventing the underlying problem and the Overpayment from recurring.

If Dr. Benson has received the Overpayment, Dr. Benson shall calculate the amount of the Overpayment and repay the Overpayment to the appropriate payor to the extent that such Overpayment has been quantified. If not yet quantified within 30 days after identification, Dr. Benson shall notify the payor at that time of her efforts to quantify the Overpayment amount along with a schedule of when such work is expected to be completed. Notification and repayment to the payor shall be done in accordance with the payor's policies, and for Medicare contractors shall include in the information contained on the Overpayment Refund Form, provided at Appendix C to this Agreement.

If Dr. Benson learns of an Overpayment(s) but has not actually received the Overpayment(s), Dr. Benson shall make available to the payor any and all documentation necessary to calculate the Overpayment(s). Within 30 days after quantification of the Overpayment by the payor, Dr. Benson shall repay such Overpayment to the appropriate payor. Notification and repayment to the payor shall be done in accordance with the payor's policies.

Notwithstanding the above, notification and repayment of any Overpayment amount that routinely is reconciled or adjusted pursuant to policies and procedures established by the payor should be handled in accordance with such policies and procedures.

2. Reportable Events.

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

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

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

b. *Reporting of Reportable Event.* If Dr. Benson determines (after a reasonable opportunity to conduct an appropriate review or investigation of the allegations) through any means that there is a Reportable Event, Dr. Benson shall notify OIG, in writing, within 30 days after making the determination that the Reportable Event exists. The report to OIG shall include the following information:

i. If the Reportable Event results in an Overpayment, the report to 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) by which the Overpayment was repaid/refunded;

ii. a complete description of the Reportable Event, including the relevant facts, persons involved, and legal and Federal health care program authorities implicated;

iii. a description of Dr. Benson's actions taken to correct the Reportable Event; and

iv. any further steps Dr. Benson plans to take to address the Reportable Event and prevent it from recurring.

I. Third Party Billing

1. Current Contract with Third Party Biller. If Dr. Benson presently contracts with a third party billing company to submit claims to the Federal health care programs, Dr. Benson represents that she does not have an ownership or control interest (as defined in 42 U.S.C. § 1320a-3(a)(3)) in the third party billing company and is not employed by, and does not act as a consultant to, the third party billing company. If Dr. Benson intends to obtain an ownership or control interest (as defined in 42 U.S.C. § 1320a-3(a)(3)) in, or become employed by, or become a consultant to, any third party billing company during the term of this Agreement, Dr. Benson shall notify OIG 30 days prior to any such proposed involvement.

Within 90 days after the Effective Date, Dr. Benson shall obtain (and provide to OIG in the Implementation Report) a certification from the third party billing company that the company: (i) is presently in compliance with all Federal health care program requirements as they relate to the submission of claims to Federal health care programs, (ii) has a policy of not employing any person who is excluded, debarred, suspended or otherwise ineligible to participate in Medicare or other Federal health care programs to perform any duties related directly or indirectly to the preparation or submission of claims to Federal health care programs; (iii) 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. Benson contracts with a new third party billing company during the term of this Agreement, Dr. Benson shall, within 30 days of entering into such contract, obtain and send to OIG the certification described in this Section III.I.1.

IV. NEW BUSINESS UNITS OR LOCATIONS

In the event that, after the Effective Date, Dr. Benson changes locations or sells, closes, purchases, or establishes a new business unit or location related to the furnishing of items or services that may be reimbursed by Federal health care programs, Dr. Benson shall notify OIG of this fact as soon as possible, but no later than 30 days after the date of change of location, sale, closure, purchase, or establishment. This notification shall include the address of the new business unit or location, phone number, fax number, Medicare Provider number, provider identification number, and/or supplier number, and the corresponding contractor's name and address that issued each number. Each new business unit or location and all Covered Persons at each new business unit or location shall be subject to the applicable requirements in this Agreement.

Prior to Dr. Benson becoming an employee or contractor with another party related to the furnishing of items or services that may be reimbursed by Federal health care programs, Dr. Benson shall notify that party of this Agreement. This notification shall include a copy of the Agreement, a statement indicating the remaining term of the Agreement, and a summary of Dr. Benson's obligations under the Agreement. In addition, Dr. Benson shall notify OIG of such relationship in her next Annual Report.

V. REPORTS

A. Implementation Report

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

1. the Compliance Contact's name, address, and phone number, a description of any other job responsibilities performed by the Compliance Contact, and the date the Compliance Contact was appointed;
2. a copy of the notice Dr. Benson posted in her offices as required by Section III.B, a description of where the notice is posted, and the date the notice was posted;
3. a copy of the written Policies and Procedures required by Section III.C of this Agreement and the date these Policies and Procedures were implemented and distributed;
4. a copy of all training materials used for the training session(s) required by Section III.D, a description of the training, including a summary of the topics covered, the length of each session, and a schedule of when the training session(s) were held;
5. the name and qualifications of the IRO, a summary/description of all engagements between Dr. Benson and the IRO, including, but not limited to, any outside financial audits, compliance program engagements, or reimbursement consulting, and the proposed start and completion dates of the first Prescription Review.
6. a copy of the IRO's engagement letter, including the length of the engagement;
7. a certification from the IRO regarding its professional independence and/or objectivity with respect to Dr. Benson;
8. a description of Dr. Benson's process to screen Covered Persons to determine if they are ineligible;
9. a summary of personnel actions (other than hiring) taken pursuant to Section III.F, the name, title and responsibilities of any person who is

determined to be an Ineligible Person under Section III.F, and the actions taken in response to the obligations set forth in Section III.F;

10. a copy of the certification from the third party billing company required by Section III.I of the Agreement;

11. a list of all of Dr. Benson'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 number(s), provider identification number(s), and/or supplier number(s), and the name and address of each contractor to which Dr. Benson currently submits claims;

12. if Dr. Benson is or becomes an employee or contractor with another party related to the furnishing of items or services that may be reimbursed by Federal health care programs, Dr. Benson shall inform OIG of the name, location, relationship, and its responsibilities with respect Dr. Benson's employment or contract;

13. a certification by the Compliance Contact that:

a. the written Policies and Procedures required by Section III.C of this Agreement have been developed, are being implemented, and have been distributed to all Covered Persons; and that all Covered Persons have executed the written Policies and Procedures certification in accordance with the timeframe required by Section III.C of this Agreement;

b. all Covered Persons have completed the applicable training required by Section III.D of this Agreement; and that all Covered Persons have executed the applicable training certification(s) in accordance with the timeframe required by Section III.D of this Agreement;

c. all associates, employees, contractors, and agents that were hired or engaged since the execution of the Agreement were screened against the Exclusion Lists and asked to disclose if they are excluded, debarred, suspended, or are otherwise considered an Ineligible Person, prior to entering into their relationship with Dr. Benson, as required by Section III.F of this Agreement; and

d. all current associates, employees, contractors, and agents of Dr. Benson were screened against the Exclusion Lists within 90 days

after the Effective Date of this Agreement, as required by Section III.F of this Agreement and the date(s) of the screening.

14. a certification signed by Dr. Benson certifying (a) to the best of her knowledge, except as otherwise described in the Implementation Report, she is in compliance with all of the requirements of this Agreement and (b) she has reviewed the Implementation Report and has made a reasonable inquiry regarding its content and believes that the information is accurate and truthful.

B. Annual Reports

Dr. Benson shall submit to OIG Annual Reports with respect to the status of, and findings regarding, Dr. Benson's compliance activities for each of the five (5) Reporting Periods (Annual Report).

Each Annual Report shall, at a minimum, include:

1. any change in the name, address, phone number, or job responsibilities of Dr. Benson's Compliance Contact;
2. any changes to the posted notice and the reason for such changes;
3. a copy of any new compliance-related Policies and Procedures;
4. a summary of any changes or amendments to the written Policies and Procedures required by Section III.C and the reason(s) for such changes (e.g., change in contractor policies);
5. a copy of all training materials used for the training session(s) required by Section III.D (to the extent they have not already been provided as part of the Implementation Report); a description of the training, including a summary of the topics covered; the length of each session; and a schedule of when the training session(s) was held;
6. a complete copy of all reports prepared pursuant to the IRO's Prescription Review, required by Section III.E and Appendix B, and a complete copy of the logs of Prescriptions of Schedule II Narcotic Drugs required by Section III.E.2.a of this Agreement;
7. if applicable, a certification by Dr. Benson stating that she does not currently and has not submitted any cost reports to any Federal health care programs since this Agreement was executed;

8. Dr. Benson's response and corrective action plan(s) related to any issues raised or recommendations made by the IRO, as a result of the Review(s) performed pursuant to Section III.E and Appendix B;
9. a summary/description of all engagements between Dr. Benson and the IRO, including, but not limited to, any compliance program engagements or consulting engagements, if different from what was submitted as part of the Implementation Report;
10. a certification from the IRO regarding its professional independence and/or objectivity to Dr. Benson;
11. a description of Dr. Benson's process to screen Covered Persons to determine if they are ineligible (to the extent it has changed from the Implementation Report);
12. a summary of personnel actions (other than hiring) taken pursuant to Section III.F; the name, titles and responsibilities of any person who is determined to be an Ineligible Person under Section III.F; and Dr. Benson's actions taken in response to the obligations set forth in Section III.F;
13. 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;
14. a summary of Reportable Events (as defined in Section III.H) identified during the Reporting Period and the status of any corrective and preventative action relating to all such Reportable Events;
15. a report of the aggregate Overpayments that have been returned to the Federal health care programs. Overpayment amounts shall be broken down into the following categories: Medicare, Medicaid, and other Federal health care programs;
16. a copy of the certification from the third party billing company required by Section III.I of the Agreement, if applicable;
17. a description of all changes to the most recently provided list of Dr. Benson's locations (including addresses) as required by Section IV. Include the corresponding phone numbers, fax numbers, each location's

Medicare Provider Number(s), provider identification number(s), and/or supplier number(s), and the name and address of the contractor that issued each number;

18. if Dr. Benson became an employee or contractor with another party related to the furnishing of items or services that may be reimbursed by Federal health care programs, Dr. Benson shall inform OIG of the name, location, relationship, and its responsibilities with respect to Dr. Benson's employment or contract;

19. A certification, where appropriate, by the Compliance Contact that certifies that:

a. the written Policies and Procedures have been reviewed during the Reporting Period, as required by Section III.C of this Agreement, and that all Covered Persons have executed the written Policies and Procedures certification in accordance with the timeframe required by Section III.C of this Agreement;

b. all Covered Persons have completed the applicable training required by Section III.D of this Agreement and that all Covered Persons have executed the applicable training certification(s) in accordance with the timeframe required by Section III.D of this Agreement;

c. all associates, employees, contractors, and agents that were hired, engaged or otherwise involved with Dr. Benson during the Reporting Period have been screened against the Exclusion Lists and asked to disclose if they are excluded, debarred, suspended, or are otherwise considered an Ineligible Person, prior to entering into their relationship with Dr. Benson, as required by Section III.F of this Agreement; and

d. all associates, employees, contractors, and agents (employed, engaged or otherwise involved with Dr. Benson for the entire Reporting Period) were screened against the Exclusion Lists during the Reporting Period, in accordance with Section III.F of this Agreement and the date(s) they were screened.

20. a certification signed by Dr. Benson certifying that (a) she has completed the Category 1 credit hours of continuing medical education on pain management and/or prescription drug therapy during the Reporting Period as required by Section III.D of this Agreement; (b) to the best of her

knowledge, except as otherwise described in the applicable Report, she is in compliance with all of the requirements of this Agreement; and (c) she has reviewed the Annual Report and has made a reasonable inquiry regarding its content and believes that the information is accurate and truthful;

The first Annual Report shall be received by OIG no later than 60 days after the end of the first Reporting Period. Subsequent Annual Reports shall be received by OIG no later than the anniversary date of the due date of the first Annual Report.

C. Designation of Information

Dr. Benson shall clearly identify any portions of her submissions that she believes are trade secrets, or information that is commercial or financial and privileged or confidential, and therefore potentially exempt from disclosure under the Freedom of Information Act (FOIA), 5 U.S.C. § 552. Dr. Benson shall refrain from identifying any information as exempt from disclosure if that information does not meet the criteria for exemption from disclosure under FOIA.

VI. NOTIFICATIONS AND SUBMISSION OF REPORTS

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

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

Dr. Benson: Barbara Dunakin
 Independent Medical Associates, P.A.
 78 Ridgewood Drive
 Bangor, ME 04401
 Telephone: (207) 947-0768 / (207) 947-3805 ext. 5
 Facsimile: (207) 945-9705

Unless otherwise specified, all notifications and Reports required by this Agreement shall be made by certified mail, overnight mail, hand delivery, or other means, provided that there is proof that such notification was received. For

purposes of this requirement, internal facsimile confirmation sheets do not constitute proof of receipt.

VII. OIG INSPECTION, AUDIT, AND REVIEW RIGHTS

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

VIII. DOCUMENT AND RECORD RETENTION

Dr. Benson shall maintain for inspection all documents and records relating to reimbursement from the Federal health care programs, or to compliance with this Agreement, for six (6) years (or longer if otherwise required by law).

IX. DISCLOSURES

Consistent with HHS's FOIA procedures, set forth in 45 C.F.R. Part 5, OIG shall make a reasonable effort to notify Dr. Benson prior to any release by OIG of information submitted by Dr. Benson pursuant to her obligations under this Agreement and identified upon submission by Dr. Benson as trade secrets, or information that is commercial or financial and privileged or confidential, under the FOIA rules. With respect to such releases, Dr. Benson shall have the rights set forth at 45 C.F.R. § 5.65(d).

X. BREACH AND DEFAULT PROVISIONS

Dr. Benson is expected to fully and timely comply with all of her Agreement obligations.

A. Stipulated Penalties for Failure to Comply with Certain Obligations

As a contractual remedy, Dr. Benson and OIG hereby agree that failure to comply with certain obligations set forth in this Agreement (unless a timely written request for an extension has been requested and approved in accordance with Section B below) 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 \$750 (which shall begin to accrue on the day after the date the obligation became due) for each day Dr. Benson fails to:
 - a. have a Compliance Contact in accordance with the requirements of Section III.A;
 - b. establish and/or post a notice in accordance with the requirements of Section III.B;
 - c. establish, implement, maintain, distribute and/or update the written Policies and Procedures in accordance with the requirements of Section III.C;
 - d. establish and implement a training program in accordance with the requirements of Section III.D.
 - e. obtain a certification from the third party biller, send the third party biller certification to OIG in accordance with the requirements of Section III.I, or notify OIG within 30 days prior to Dr. Benson obtaining an ownership or control interest (as defined in 42 U.S.C. § 1320a-3(a)(3)) in, or becoming employed by, or becoming a consultant to, any third party billing company;
 - f. engage an IRO in accordance with the requirements of Section III.E.1.a and Appendix A.
 - g. submit the IRO's Prescription Review Reports and prescription logs in accordance with the requirements of Section V.B and Appendix B;
 - h. obtain and/or maintain the following documentation: Policies and Procedures certifications in accordance with the requirements of Section III.C, training certification(s) in accordance with the

requirements of Section III.D, and/or documentation of screening and disclosure requirements in accordance with the requirements of Section III.F.2.

i. screen current or prospective associates, employees, contractors or agents in accordance with the requirements of Section III.F; or require associates, employees, contractors or agents to disclose if they are debarred, excluded, suspended or are otherwise considered an Ineligible Person in accordance with the requirements of Section III.F; or

j. notify OIG of a Government investigation or legal proceeding, in accordance with the requirements of Section III.G.

2. 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. Benson fails to submit the Implementation Report or the Annual Reports to OIG in accordance with the requirements of Section V by the deadlines for submission.

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

4. A Stipulated Penalty of \$5,000 for each false certification submitted by or on behalf of Dr. Benson as part of her Implementation Report, Annual Reports, additional documentation to a Report (as requested by OIG), or as otherwise required by this Agreement.

5. A Stipulated Penalty of \$750 for each day Dr. Benson fails to comply fully and adequately with any obligation of this Agreement. OIG shall provide notice (Notice) to Dr. Benson stating the specific grounds for its determination that Dr. Benson has failed to comply fully and adequately with the Agreement obligation(s) at issue and steps Dr. Benson shall take to comply with the Agreement. (This Stipulated Penalty shall begin to accrue 10 days after the date Dr. Benson receives this Notice from OIG of the failure to comply.) A Stipulated Penalty as described in this Subsection shall not be demanded for any violation for which OIG has sought a Stipulated Penalty under Subsections 1-4 of this Section.

B. Timely Written Requests for Extensions

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

2. Response to Demand Letter. Within 10 days of the receipt of the Demand Letter, Dr. Benson shall either: (a) cure the breach to OIG's satisfaction and pay the applicable Stipulated Penalties; or (b) send 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. Benson elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until Dr. Benson 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. Benson have 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. Benson to report a Reportable Event, take corrective action and make the appropriate refunds, as required in Section III.H;

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 engage and use an IRO in accordance with Section III.E.

2. Notice of Material Breach and Intent to Exclude. The parties agree that a material breach of this Agreement by Dr. Benson constitutes an independent basis for Dr. Benson’s exclusion from participation in the Federal health care programs. Upon a determination by OIG that Dr. Benson has materially breached this Agreement and that exclusion is the appropriate remedy, OIG shall notify Dr. Benson of: (a) Dr. Benson’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. Benson 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. Benson is in compliance with the obligations of the Agreement cited by 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. Benson has begun to take action to cure the material breach; (ii) Dr. Benson is pursuing such action with due diligence; and (iii) Dr. Benson 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. Benson fails to satisfy the requirements of Section X.D.3, OIG may exclude Dr. Benson from participation in the Federal health care programs. OIG shall notify Dr. Benson in writing of its determination to exclude Dr. Benson (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 Dr. Benson's receipt 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. After the end of the period of exclusion, Dr. Benson may apply for reinstatement, by submitting a written request for reinstatement in accordance with the provisions at 42 C.F.R. §§ 1001.3001-.3004.

E. Dispute Resolution

1. Review Rights. Upon OIG's delivery to Dr. Benson 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. Benson 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 after the receipt of the Demand Letter and the request for a hearing involving exclusion shall be made within 25 days after receipt of the Exclusion Letter.

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. Benson was in full and timely compliance with the obligations of this Agreement for which OIG demands payment; and (b) the period of noncompliance. Dr. Benson shall have the burden of proving their full and timely compliance and the steps taken to cure the noncompliance, if any. OIG shall not have the right to appeal to the DAB an adverse ALJ decision related to Stipulated Penalties. If the ALJ agrees with OIG with regard to a finding of a breach of this Agreement and orders Dr. Benson to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable 20 days after the ALJ issues such a decision unless Dr. Benson 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. Benson 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. Benson had begun to take action to cure the material breach within that period; (ii) Dr. Benson has pursued and is pursuing such action with due diligence; and (iii) Dr. Benson provided to OIG within that period a reasonable timetable for curing the material breach and Dr. Benson 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. Benson, only after a DAB decision in favor of OIG. Dr. Benson's election of her contractual right to appeal to the DAB shall not abrogate OIG's authority to exclude Dr. Benson 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. Benson 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. Benson shall waive her right to any notice of such an exclusion if a decision upholding the exclusion is rendered by the ALJ or DAB. If the DAB finds in favor of Dr. Benson, Dr. Benson shall be reinstated effective on the date of the original exclusion.

4. Finality of Decision. The review by an ALJ or DAB provided for above shall not be considered to be an appeal right arising under any statutes or regulations. Consequently, the parties to this Agreement agree that the DAB's decision (or the ALJ's decision if not appealed) shall be considered final for all purposes under this Agreement.

XI. EFFECTIVE AND BINDING AGREEMENT

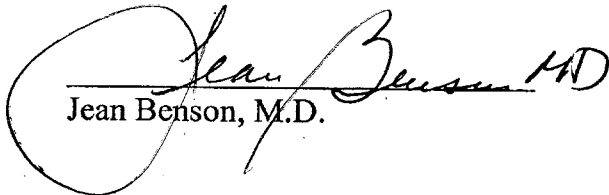
Consistent with the provisions in the Settlement Agreement pursuant to which this Agreement is entered, and into which this Agreement is incorporated, Dr. Benson and OIG agree as follows:

- A. This Agreement shall be binding on the successors, assigns, and transferees of Dr. Benson;
- B. This Agreement shall become final and binding on the date the final signature is obtained on the Agreement;
- C. Any modifications to this Agreement shall be made with the prior written consent of the parties to this Agreement;
- D. OIG may agree to a suspension of Dr. Benson's obligations under this Agreement in the event of Dr. Benson's cessation of participation in Federal health care programs. If Dr. Benson withdraws from participation in Federal health care programs and is relieved of her Agreement obligations by OIG, Dr. Benson shall notify OIG 30 days in advance of Dr. Benson's intent to reapply as a participating provider or supplier with any Federal health care program. Upon receipt of such notification, OIG shall evaluate whether the Agreement shall be reactivated or modified.
- E. All requirements and remedies set forth in this Agreement are in addition to, and do not effect, (1) Dr. Benson's responsibility to follow all applicable Federal health care program requirements or (2) the Government's right to impose appropriate remedies for failure to follow applicable program requirements.

F. The undersigned signatories for Dr. Benson represent and warrant that they are authorized to execute this Agreement. The undersigned OIG signatory represents that he is signing this Agreement in his official capacity and that he is authorized to execute this Agreement.

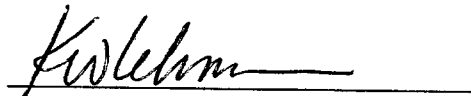
IN WITNESS WHEREOF, the parties hereto affix their signatures:

JEAN BENSON, M.D.



Jean Benson, M.D.

Date 7/26/05



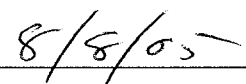
Kenneth Lehman, Esq.
Counsel for Jean Benson, M.D.

Date 8/1/2005

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



Lewis Morris
Chief Counsel to the Inspector General
Office of Counsel to the Inspector General
Office of Inspector General
U. S. Department of Health and Human Services



Date

APPENDIX A INDEPENDENT REVIEW ORGANIZATION

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

A. IRO Engagement.

Dr. Benson shall engage an IRO that possesses the qualifications set forth in Paragraph B, below, to perform the responsibilities in Paragraph C, below. The IRO shall conduct the review in a professionally independent and/or objective fashion, as set forth in Paragraph D. Within 30 days after OIG receives written notice of the identity of the selected IRO, OIG will notify Dr. Benson if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, Dr. Benson may continue to engage the IRO.

If Dr. Benson engages a new IRO during the term of the CIA, this IRO shall also meet the requirements of this Appendix. If a new IRO is engaged, Dr. Benson shall submit the information identified in Section V.A.5 to OIG within 30 days of engagement of the IRO. Within 30 days after OIG receives written notice of the identity of the selected IRO, OIG will notify Dr. Benson if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, Dr. Benson may continue to engage the IRO.

B. IRO Qualifications.

The IRO shall:

1. assign individuals to conduct the Prescription Review engagement who have expertise in the Prescription of Schedule II Narcotic Drugs and in the general requirements of the Federal health care program(s) from which Dr. Benson seeks reimbursement;
2. assign individuals to design and select the Prescription Review sample who are knowledgeable about the appropriate statistical sampling techniques; and
3. have sufficient staff and resources to conduct the reviews required by the CIA on a timely basis.

C. IRO Responsibilities.

The IRO shall:

1. perform each Prescription Review in accordance with the specific requirements of the CIA;
2. follow all applicable Medicare, Medicaid, or other Federal health care programs rules and reimbursement guidelines in making assessments in the Prescription Review;
3. if in doubt of the application of a particular Medicare, Medicaid, or other Federal health care programs policy or regulation, request clarification from the appropriate authority (e.g., fiscal intermediary or carrier);
4. respond to all OIG inquiries in a prompt, objective, and factual manner; and
5. prepare timely, clear, well-written reports that include all the information required by Appendix B.

D. IRO Independence/Objectivity.

The IRO must perform the Prescription Review in a professionally independent and/or objective fashion, as appropriate to the nature of the engagement, taking into account any other business relationships or engagements that may exist between the IRO and Dr. Benson.

E. IRO Removal/Termination.

1. *Provider.* If Dr. Benson terminates her IRO during the course of the engagement, Dr. Benson must submit a notice explaining its reasons to OIG no later than 30 days after termination. Dr. Benson must engage a new IRO in accordance with Paragraph A of this Appendix.

2. *OIG Removal of IRO.* In the event OIG has reason to believe that the IRO does not possess the qualifications described in Paragraph B, is not independent and/or objective as set forth in Paragraph D, or has failed to carry out its responsibilities as described in Paragraph C, OIG may, at its sole discretion, require Dr. Benson to engage a new IRO in accordance with Paragraph A of this Appendix.

Prior to requiring Dr. Benson to engage a new IRO, OIG shall notify Dr. Benson of its intent to do so and provide a written explanation of why OIG believes such a step is necessary. To resolve any concerns raised by OIG, Dr. Benson may request a meeting

with OIG to discuss any aspect of the IRO's qualifications, independence or performance of its responsibilities and to present additional information regarding these matters. Dr. Benson shall provide any additional information as may be requested by OIG under this Paragraph in an expedited manner. OIG will attempt in good faith to resolve any differences regarding the IRO with Dr. Benson prior to requiring Dr. Benson to terminate the IRO. However, the final determination as to whether or not to require Dr. Benson to engage a new IRO shall be made at the sole discretion of OIG.

APPENDIX B
PRESCRIPTION REVIEW PROTOCOL

A. Schedule II Narcotic Drug Prescription Review.

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

- a. Schedule II Narcotic Drug: All narcotic drugs, as such term is defined in the Controlled Substances Act of 1970, 21 U.S.C. § 802(17), that are listed under Schedule II of the Controlled Substances Act of 1970, 21 U.S.C. § 812.
- b. Prescription: A written direction for the preparation, compounding, and administration of a medicine.
- c. Population: All Prescriptions of Schedule II Narcotic Drugs that have been ordered by or on behalf of Dr. Benson for a Medicare, Medicaid, or any other Federal health care program beneficiary during the review period of the Prescription Review. The Population shall be determined from the log of Prescriptions of Schedule II Narcotic Drugs described in Section III.E.2.a of the Agreement.
- d. Error Rate: The percentage of Prescriptions of Schedule II Narcotic Drugs identified in the sample as not medically necessary. The Error Rate shall be calculated by dividing the number of Prescriptions of Schedule II Narcotic Drugs identified in the sample as not medically necessary by the total number of Prescriptions of Schedule II Narcotic Drugs reviewed in the sample.

2. *Other Requirements.*

- a. Schedule II Narcotic Drug Prescription without Supporting Documentation. For the purpose of appraising a Prescription of a Schedule II Narcotic Drug included in the Prescription Review, any Prescription of a Schedule II Narcotic Drug for which Dr. Benson cannot produce documentation sufficient to support the Prescription shall be considered to be not medically necessary and shall be deemed an error. Replacement sampling for Prescriptions of Schedule II Narcotic Drugs with missing documentation is not permitted.

b. Use of First Samples Drawn. For the purpose of the sample discussed in this Appendix, the Prescriptions of Schedule II Narcotic Drugs selected in each first sample (or first sample for each strata, if applicable) shall be used (i.e., it is not permissible to generate more than one list of random samples and then select one for use).

B. Prescription Review Report. The following information shall be included in the Prescription Review Report.

1. *Prescription Review Methodology*.

a. Prescription Review Objective. A clear statement of the objective intended to be achieved by the Prescription Review.

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

c. Review Protocol. A narrative description of how the Prescription Review was conducted and what was evaluated.

d. Review Period. The period of time covered by the Prescription Review.

e. Source of Data. A description of the specific documentation relied upon by the IRO when performing the Prescription Review (e.g., medical records, physician orders, laboratory tests, and any clinical, billing, or coding regulations or guidance).

2. *Statistical Sampling Documentation*.

a. The number of Prescriptions of Schedule II Narcotic Drugs appraised.

b. A description of how the sample was selected from the Prescription Review Population, including a description or identification of the statistical sampling software package used to select the sample and a copy of the printout of random numbers generated by the "Random Numbers" function of the statistical sampling software used by the IRO.

3. *Prescription Review Findings.*

a. Narrative Results.

i. A narrative explanation of the IRO's findings and supporting rationale (including reasons for errors, patterns noted, etc.) regarding the Prescription Review, including the results of the sample.

b. Quantitative Results.

i. Total number of instances in which the IRO determined that the Prescriptions of Schedule II Narcotic Drugs were not medically necessary.

ii. The Error Rate in the sample.

iii. A spreadsheet of the Prescription Review results that includes the following information for each Prescription appraised: beneficiary name, Federal health care program under which beneficiary sought reimbursement, beneficiary health insurance number, name of the Schedule II Narcotic Drug prescribed to the beneficiary, quantity of the Prescription of the Schedule II Narcotic Drug, and date of prescription.

4. *Systems Review.* Observations, findings, and recommendations to prevent further medically unnecessary Prescription(s) and 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 Prescription Review; and (2) performed the Prescription Review.

OVERPAYMENT REFUND

TO BE COMPLETED BY MEDICARE CONTRACTOR

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

TO BE COMPLETED BY PROVIDER/PHYSICIAN/SUPPLIER

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

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

REFUND INFORMATION

For each Claim, provide the following:

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

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

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

For Institutional Facilities Only:

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

For OIG Reporting Requirements:

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

Reason Codes:

- | | | |
|---|---|---|
| <p><u>Billing/Clerical Error</u></p> <ul style="list-style-type: none"> 01 - Corrected Date of Service 02 - Duplicate 03 - Corrected CPT Code 04 - Not Our Patient(s) 05 - Modifier Added/Removed 06 - Billed in Error 07 - Corrected CPT Code | <p><u>MSP/Other Payer Involvement</u></p> <ul style="list-style-type: none"> 08 - MSP Group Health Plan Insurance 09 - MSP No Fault Insurance 10 - MSP Liability Insurance 11 - MSP, Workers Comp.(Including Black Lung 12 - Veterans Administration | <p><u>Miscellaneous</u></p> <ul style="list-style-type: none"> 13 - Insufficient Documentation 14 - Patient Enrolled in an HMO 15 - Services Not Rendered 16 - Medical Necessity 17 - Other (Please Specify) |
|---|---|---|