INTEGRITY AGREEMENT
BETWEEN THE
OFFICE OF INSPECTOR GENERAL
OF THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND
DONALD E. BERMAN, M.D. AND DONALD E. BERMAN, M.D., P.C.

I. PREAMBLE

Donald E. Berman, M.D., on behalf of himself and his medical practice, Donald E. Berman, M.D., Professional Corporation, (collectively referred to as "Berman") hereby agrees to enter into this Integrity Agreement ("Agreement") with the Office of Inspector General ("OIG") of the United States Department of Health and Human Services ("HHS") to provide for the establishment of certain integrity measures to ensure compliance with the requirements of the federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)) by Berman, Berman's employees and agents, any entity in which Berman is an owner or has a control interest (as defined in 42 U.S.C. § 1320a-3(a)(3)), and all third parties with whom Berman may choose to engage to act as billing or coding consultants for purposes of claiming reimbursement from the federal health care programs. Contemporaneously with this Agreement, Berman is entering into a Stipulation and Order of Settlement and Dismissal with the United States. This Agreement is incorporated by reference into the Stipulation and Order of Settlement and Dismissal.

II. TERM OF THE AGREEMENT

Except as otherwise provided in this Agreement, the period of compliance obligations assumed by Berman under this Agreement shall be five (5) years from the effective date of this Agreement. The effective date of this Agreement shall be August 1, 1999 (the "effective date"). In the event that Berman is excluded from participation in the federal health care programs (including an exclusion under 42 U.S.C. § 1320a-7(a)) at any time prior to the effective date of this Agreement or during the term of this Agreement, Berman shall be released from any further obligations under this Agreement as may exist at the time of Berman's exclusion. If, however, Berman is reinstated as a participating provider of the federal health care programs during what would have been the term of this Agreement, Berman shall be required to fulfill the obligations herein agreed to for the remainder of the term of this Agreement.

III. INTEGRITY OBLIGATIONS

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

A. COMPLIANCE CONTACT

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

B. POSTING OF NOTICE

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

C. WRITTEN POLICIES AND PROCEDURES

Berman agrees to develop and implement written policies and procedures within forty-five (45) days of the effective date of this Agreement, which written policies and procedures shall address the following:

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

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

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

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

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

D. TRAINING AND CERTIFICATION

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

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

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

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

1. Berman's obligations under this Agreement;

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

3. The written policies and procedures developed pursuant to subsection C, above;

Berman and each employee and agent shall date and sign a certification indicating attendance of the training session and further attesting to an understanding of the provisions in the policies and procedures and all applicable federal health care program standards addressed in training. These certifications will be maintained by Berman and shall be made available for inspection by OIG or its duly authorized representatives. At least one copy of the training materials or a detailed description of the topics covered during the training session shall be kept with the certifications.

E. INDEPENDENT REVIEWS

On at least an annual basis and for the duration of this Agreement, Berman agrees to contract with an independent third-party reviewer (e.g., a health care billing auditor or a consultant) (hereinafter the "independent reviewer") to undertake a review of a statistically valid sample of the claims submitted by Berman and his agents and/or employees to the federal health care programs. The purpose of this review is determine whether the claims are in compliance with the appropriate billing requirements. This review will be conducted by an independent and appropriately trained person or entity with knowledge of federal health care program statutes, regulations, requirements, and reimbursement policies and procedures. These reviews shall cover, at a minimum, the preceding one (1) year period and shall seek to determine that the claims submitted to the federal health care programs are medically necessary and covered services under applicable program guidelines and that the claims are appropriately coded and billed. At the conclusion of each review, the independent reviewer shall prepare a report describing the review's parameters, methodologies and procedures, as well as

presenting the review findings and the reviewer's conclusions and recommendations. A copy of this report shall be included in Berman's Annual Reports to OIG.

If any of these reviews uncovers claims processing and/or billing policies, procedures or practices that result in material deficiencies, Berman shall notify the entity in charge of processing the claim for reimbursement (such as the Medicare carrier or other payor), within fifteen (15) days of discovering the deficiency and take remedial steps within thirty (30) days of discovering the deficiency (or such additional time as may be agreed to by the payor) to correct the problem, and prevent the deficiency from recurring.

Contemporaneous with Berman's notification to the payor as provided above, Berman shall notify OIG of: (1) all of the information provided to the payor in returning the overpayment; (2) the name and the address of the payor to which the overpayment was sent; (3) Berman's findings concerning the material deficiency; (4) Berman's actions to correct such material deficiency; and (5) any further steps Berman plans to take to address such material deficiency and prevent it and similar billing deficiencies from recurring.

For purposes of this Agreement, a "material deficiency" shall mean anything that involves: (i) a substantial overpayment or improper payment relating to the federal health care programs; (ii) conduct or policies that clearly violate the federal health care program statutes, regulations or directives issued by the Health Care Financing Administration ("HCFA") and/or its agents; or (iii) serious quality of care implications for federal health care program patients. A material deficiency may be the result of an isolated event or a series of occurrences.

If Berman learns of any overpayment (regardless of its size and regardless of whether it results from a material deficiency) received from a Federal health care program, Berman shall notify the appropriate payor, make appropriate refunds and take any steps necessary to prevent any recurrence.

IV. SELF-DISCLOSURE OF PROBABLE VIOLATIONS

During the term of this Agreement, Berman agrees to report to OIG any reliable evidence of actions or omissions by Berman and/or his employees and agents (acting within the scope of employment or agency) that Berman believes may constitute a probable violation of any state or federal criminal, civil or administrative statute, regulation, or rule governing a federal health care program. Berman must make the

required disclosure no later than thirty (30) calendar days after becoming aware of the existence of the probable violation.

Any disclosures made pursuant to this paragraph shall contain a certification by Berman that the matter at issue has been fully investigated and that appropriate corrective actions have been taken to ensure compliance with all state and federal civil, criminal, and administrative statutes, regulations and rules governing all federal health care programs. Nothing in this paragraph waives OIG's right to enforce any and all statutes and regulations governing any federal health care program, subject to the release provisions of the Stipulation and Order of Settlement and Dismissal into which this Agreement is incorporated by reference.

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 Berman's books, records, and other documents and supporting materials in his possession or under his control for the purpose of verifying and evaluating: (i) Berman's compliance with the terms of this Agreement; and (ii) Berman's compliance with the requirements of the federal health care programs. OIG, HCFA, or the appropriate federal health care program contractor may conduct unannounced on-site visits at any time to review patient medical records and other related documentation for the purpose of verifying and evaluating Berman's compliance with the statutory and regulatory requirements of the federal health care programs.

VI. REPORTS

To assist OIG in its monitoring of Berman's compliance with the applicable federal health care program standards and the obligations in this Agreement, Berman shall be required pursuant to this Agreement to submit an Implementation Report and Annual Reports as set forth below.

A. IMPLEMENTATION REPORT

Within sixty (60) days of the effective date of this Agreement, Berman shall provide the OIG with a written report demonstrating that he has complied with the Program's requirements. This report, known as the "Implementation Report," shall include:

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

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

3. A copy of the written policies and procedures required by section III.C. of this Agreement.

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

B. ANNUAL REPORTS

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

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

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

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

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

VII. NOTIFICATIONS AND SUBMISSION OF REPORTS

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

ATTN: Civil Recoveries Branch - Compliance Unit
Office of Counsel to the Inspector General
Office of Inspector General
U.S. Department of Health and Human Services
330 Independence Avenue, SW
Cohen Building, Room 5527
Washington, DC 20201
Ph. 202.619.2078
Fax 202.205.0604

All correspondence to Berman shall be sent to:

Maryann Cossano &
Donald E. Berman, M.D.
301 Titusville Road
Poughkeepsie, NY 12603
Ph. 914.473.5353
Fax 914.485.3578

VIII. BREACH AND DEFAULT PROVISIONS

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

A. REMEDIES FOR MATERIAL BREACH OF THIS AGREEMENT

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

(1) cure the alleged material breach; or

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

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

B. DISPUTE RESOLUTION

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

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, including, but not limited to, the obligations addressed in section VI.A and VI.B of this Agreement; or (iii) a failure to retain and use an independent reviewer for the purposes described in section III.E.

IX. DISCLOSURES

Subject to HHS's Freedom of Information Act ("FOIA") procedures and definitions set forth in 45 C.F.R. Part 5, OIG shall make reasonable efforts to notify Berman prior to any release by OIG of information submitted by Berman pursuant to its obligations under this Agreement and identified upon submission by Berman as: (i) trade secrets; or (ii) commercial or financial information that is privileged or confidential under applicable FOIA requirements. Berman will make a good faith effort to designate as trade secrets, commercial or financial information that is privileged or confidential only materials that meet recognized criteria for exemption from disclosure under FOIA.

X. EFFECTIVE AND BINDING AGREEMENT

Consistent with the provisions in the Stipulation and Order of Settlement and Dismissal pursuant to which this Agreement is reached, and into which this Agreement is incorporated, Berman and OIG agree as follows:

1. this Agreement shall be binding on the successors, assigns and transferees of Berman's Professional Corporation, who employ, contract with, or otherwise retain Berman for the purpose of rendering services for which reimbursement is sought from the federal health care programs, and any person or entity that otherwise employs or contracts with Berman for the purpose of rendering services for which reimbursement is sought from the federal health care programs.

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:

FOR: DONALD E. BERMAN, M.D. AND DONALD E. BERMAN, M.D., P.C.

Donald E. Berman, M.D. Date

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

Lewis Morris

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

July 14, 1999
Date

IN WITNESS WHEREOF, the parties hereto affix their signatures:

FOR: DONALD E. BERMAN, M.D. AND DONALD E. BERMAN, M.D., P.C.

Donald E. Berman, M.D. 7/14/99
Date

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

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

Date