

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

**I. PREAMBLE**

Willis M. Madden, M.D. (Madden) hereby enters into this Integrity Agreement (IA) 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, and written directives of Medicare, Medicaid, and all other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)) (Federal health care program requirements). This Agreement applies to Madden and any entity that Madden owns or in which Madden has a control interest, as defined in 42 U.S.C. § 1320a-3(a)(3), and Madden's and any such entity's Covered Persons as defined in Section II.C. Contemporaneously with this Agreement, Madden is entering into a Settlement Agreement with the OIG, and this Agreement is incorporated by reference into the Settlement Agreement.

**II. TERM AND SCOPE OF THE IA**

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 Madden under this Agreement shall be five 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 after OIG's receipt of: (1) Madden's final annual report; or (2) any additional materials submitted by Madden pursuant to OIG's request, whichever is later.

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

1. "Covered Persons" includes:
  - a. Madden;
  - b. all officers, directors, associates, and employees of Madden; and
  - c. all contractors, subcontractors, agents, and other persons who provide patient care items or patient care services or who perform billing or coding functions on behalf of Madden.
2. "Relevant Covered Persons" includes Covered Persons involved in the delivery of patient care items or services and/or in the preparation or submission of claims for reimbursement from any Federal health care program.
3. "Cataract Surgery" includes any surgery performed by Madden on a patient's cataract that is reimbursable by Medicare, Medicaid, or other Federal health care programs.

### **III. INTEGRITY OBLIGATIONS**

Madden shall establish and maintain a Compliance Program that includes the following elements:

#### **A. Compliance Contact**

Within 30 days after the Effective Date, Madden shall designate a person to be responsible for compliance activities (Compliance Contact). Madden shall maintain a Compliance Contact for the term of this IA. 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 IA and with Federal health care program requirements; (2) monitoring Madden's day-to-day compliance activities; (3) meeting all reporting obligations created under this IA; and (4) responding to questions and concerns from Covered Persons and the OIG regarding compliance with the integrity provisions herein.

Madden 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 IA, 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, Madden shall post in a prominent place accessible to all patients and Covered Persons a notice detailing his commitment to comply with all Federal health care program requirements in the conduct of his business.

This notice shall include the following information: (i) a means (e.g., telephone number or address) by which billing concerns and other issues may be reported anonymously; (ii) Madden's commitment to maintain the confidentiality of the report; and (iii) notification that reporting concerns and issues will not result in retribution or retaliation by Madden.

This notice shall also include the HHS 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, Madden shall develop, implement, and distribute written Policies and Procedures to all Covered Persons. In addition, Madden 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. Madden's commitment to full compliance with all Federal health care program requirements, including his commitment to prepare and submit accurate claims consistent with such requirements;
2. the expectation that all of Madden's Covered Persons shall be expected to comply with all Federal health care program requirements and with Madden'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 Madden's own Policies and Procedures to the Compliance Contact and Madden's

commitment to maintain confidentiality and anonymity, as appropriate, and not to retaliate with respect to such disclosures;

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

5. Madden'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 medical record documentation of medical records for patients with cataracts, including documentation of refraction with best-corrected visual acuity and documentation of functional disability in cataract patients;

8. appropriate preoperative and postoperative examination of cataract surgery patients;

9. the proper procedure for assessing the medical necessity of cataract surgery; and

10. the proper procedure for completing the Preoperative and Postoperative Cataract Surgery Examination Templates for use in connection with all cataract surgery procedures.

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 Madden'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), Madden 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 Education.

1. General Training. Within 90 days after the Effective Date, Madden shall provide at least two hours of General Training to each Covered Person. This training, at a minimum, shall cover the following topics:

- a. The requirements of Madden's IA;
- b. An overview of Madden's compliance program. In particular, the General Training shall include discussion on the Code of Conduct's requirement that all Covered Persons are expected:
  - (i) to comply with all Federal health care program requirements and with Madden's own Policies and Procedures; and
  - (ii) to report to the Compliance Contact or other appropriate individual designated by Madden suspected violations of any Federal health care program requirements or of Madden's own Policies and Procedures; and
- c. The written Policies and Procedures developed pursuant to Section III.C, above.

New Covered Persons shall receive the General Training described above within 30 days after becoming a Covered Person or within 90 days after the Effective Date, whichever is later. After receiving the initial General Training, described above, each Covered Person shall receive at least one hour of General Training in each subsequent Reporting Period.

2. Specific Training. Within 90 days after the Effective Date, each Relevant Covered Person shall receive at least four hours of Specific Training in addition to the General Training required above in a manner relevant to the individual's job responsibilities. The Specific Training shall be provided by an individual or entity other than Madden or another Covered Person, and may be

received from a variety of sources (e.g., CME classes, hospitals, associations, Medicare contractors). This Specific Training shall include a discussion of the Policies and Procedures set forth in Section III.C, including but not limited to:

- a. Appropriate documentation of medical records;
- b. Appropriate preoperative and postoperative examination of cataract surgery patients, including documentation of refraction with best-corrected visual acuity and documentation of functional disability in cataract patients;
- c. The legal sanctions for the submission of improper claims or violations of the Federal health care program requirements;
- d. Examples of proper and improper medical record documentation for patients with cataracts;
- e. Examples of proper and improper techniques for performing preoperative and postoperative examination of cataract surgery patients; and
- f. the proper procedure for completing the Preoperative and Postoperative Cataract Surgery Examination Templates for use in connection with all cataract surgery procedures.

New Relevant Covered Persons shall receive this training within 30 days after the beginning of their employment or becoming Relevant Covered Persons, or within 120 days after the Effective Date, whichever is later. A Madden employee who has completed the Specific Training shall review a new Relevant Covered Person's work, to the extent that the work relates to the delivery of patient care items or services, until such time as the new Relevant Covered Person completes his or her Specific Training.

After receiving the initial Specific Training described in this Section, each Relevant Covered Person shall receive at least two hours of Specific Training in each subsequent Reporting Period.

3. Certification. Each individual who is required to receive training shall certify in writing, or in electronic form if the training is computerized, that he or she has received the required training. The certification shall specify the type of training received and the date received. The Compliance Contact shall retain the certifications along with all training materials. 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.

4. Qualifications of Trainer. Persons providing the General and Specific Training shall be knowledgeable about the subject area. Persons providing the Specific Training shall not be Covered Persons or Relevant Covered Persons.

5. Update of Training. Madden 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 engagement of the IRO, the Clinical Quality Consultant, the Cataract Surgery Procedures Review, the Preoperative and Postoperative Cataract Surgery Examination Templates Review, and any other relevant information.

6. Computer-based Training. Madden may provide the training required under this IA through appropriate computer-based training approaches. If Madden chooses to provide computer-based training, he shall make available appropriately qualified and knowledgeable staff or trainers to answer questions or provide additional information to the individuals receiving such training.

E. Preoperative and Postoperative Cataract Surgery Examination Templates.

1. Engagement of a Clinical Quality Consultant. Within 30 days after the Effective Date, Madden shall engage an entity or person (hereinafter "Clinical Quality Consultant") to develop Preoperative and Postoperative Cataract Surgery Examination Templates (Templates) that identify the examinations that Madden should provide in connection with cataract surgery procedures. The Clinical Quality Consultant shall have expertise in ophthalmology, cataract surgery, and professionally recognized standards of health care for preoperative and postoperative care provided in connection with cataract surgery procedures, including but not limited to the established practice guidelines and the generally accepted standards of medical practice described by the American Academy of Ophthalmology.

The Clinical Quality Consultant shall be responsible for developing Preoperative and Postoperative Cataract Surgery Examination Templates. Each Template shall include all necessary components of cataract surgery examinations in accordance with professionally recognized standards of health care, including but not limited to the standards of medical practice described by the American Academy of Ophthalmology, and shall be accompanied by a completed sample Template.

The Clinical Quality consultant shall provide Madden with completed sample Templates to demonstrate the proper method for completing the Templates.

Within 30 days after OIG receives written notice of the identity of the selected Clinical Quality Consultant and a completed sample of the Templates, OIG will notify Madden if the Clinical Quality Consultant or the Templates are unacceptable. Absent notification from OIG that the Clinical Quality Consultant or the Templates are unacceptable, Madden shall continue to complete and use the Templates during the term of the Agreement. The engagement of the Clinical Quality Consultant shall be for the term of the IA. If Madden terminates the Clinical Quality Consultant during the course of the engagement, Madden must submit a notice explaining his reasons to OIG no later than 30 days after termination and Madden must engage a new Clinical Quality Consultant in accordance with this Paragraph III.E.1.

2. Madden Template Obligations. Within 60 days after the Effective Date, Madden shall implement the requirement to complete and use the Preoperative and Postoperative Cataract Surgery Examination Templates developed by the Clinical Quality Consultant in connection with all cataract surgeries. Madden must use and complete the Preoperative and Postoperative Cataract Surgery Examinations Templates for each cataract surgery he provides during the term of the IA in a manner that comports with the completed sample Templates and professionally recognized standards of health care, including but not limited to the standards of medical practice described by the American Academy of Ophthalmology. Madden also shall consult the Clinical Quality Consultant at the beginning of each Reporting Period and modify the Templates, if necessary, to ensure that the Templates reflect the most recent developments in professionally recognized standards of health care, including by not limited to the standards of medical practice described by the American Academy of Ophthalmology. Madden shall notify the OIG within 30 days of modifying the Templates.

#### F. Review Procedures.

1. Engagement of Independent Review Organization. Within 90 days after the Effective Date, Madden shall engage an entity or person (hereinafter "Independent Review Organization" or "IRO") to perform reviews to assist Madden in assessing and evaluating Madden's compliance with his Medicare obligations to provide care only to the extent medically necessary, that is of a quality which meets professionally recognized standards of health care, and is supported by evidence of medical necessity.



The IRO shall perform all components of each review. The IRO shall assess, along with Madden, whether it can perform the reviews in a professionally independent and 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 this Agreement, which is incorporated by reference. The IRO and Madden shall retain and make available to OIG, upon request, all work papers, supporting documentation, correspondence, and draft reports (those exchanged between the IRO and Madden) related to the reviews.

Within 30 days after OIG receives written notice of the identity of the selected IRO, OIG will notify Madden if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, Madden may continue to engage the IRO. The engagement of the IRO shall be for the term of the IA. If Madden terminates the IRO during the course of the engagement, Madden must submit a notice explaining his reasons to OIG no later than 30 days after termination and Madden must engage a new IRO in accordance with this Paragraph III.F.1.

2. Cataract Surgery Procedures Review. Madden shall engage an IRO to evaluate and analyze: (1) the medical necessity of the cataract surgery procedures provided by Madden; (2) the quality of preoperative and postoperative care provided in connection with cataract surgery procedures provided by Madden; and (3) the medical record documentation for cataract surgery procedures provided by Madden (Cataract Surgery Procedures Review). The procedures shall be reviewed based on the supporting documentation available to Madden or under Madden's control and applicable regulations and guidance to determine whether the procedure was medically necessary, supported by documentation of medical necessity, and of a quality that meets professionally recognized standards of health care, including but not limited to the established practice guidelines and generally accepted standards of medical practice described by the American Academy of Ophthalmology.

The Cataract Surgery Procedures Review shall be performed annually and shall cover each of the Reporting Periods. The IRO engaged by Madden shall have expertise in ophthalmology, cataract surgery, the professionally recognized standards of health care for preoperative and postoperative care provided in connection with cataract surgery procedures; the general requirements of the Federal health care program(s) from which Madden seeks reimbursement; and the established practice guidelines and generally accepted standards of medical practice described by the American Academy of Ophthalmology.

The IRO shall prepare a report based upon the Cataract Surgery Procedures Review performed (Cataract Surgery Procedures Review Report). Information to be included in the Cataract Surgery Procedures Review Report is described in Appendix B.

3. Preoperative and Postoperative Cataract Surgery Examination Templates Review. Madden shall engage an IRO to conduct the Preoperative and Postoperative Cataract Surgery Examination Templates Review using the Templates developed by the Clinical Quality Consultant on all cataract patients.

The IRO shall evaluate and analyze Madden's use and completion of the Preoperative and Postoperative Cataract Surgery Examination Templates. The Preoperative and Postoperative Cataract Surgery Examination Templates Review shall be performed annually and shall cover each of the Reporting Periods. The IRO engaged by Madden shall have expertise in ophthalmology, cataract surgery, the professionally recognized standards of health care for preoperative and postoperative care provided in connection with cataract surgery procedures, and the general requirements of the Federal health care program(s) from which Madden seeks reimbursement.

The IRO shall prepare a report based upon the Preoperative and Postoperative Cataract Surgery Examination Templates Review performed (Preoperative and Postoperative Cataract Surgery Examination Templates Review Report). Information to be included in the Preoperative and Postoperative Cataract Surgery Examination Templates Report is described in Appendix C.

4. Validation Review. In the event OIG has reason to believe that: (a) Madden's Cataract Surgery Procedures Review or Preoperative and Postoperative Cataract Surgery Examination Templates Review fails to conform to the requirements of this IA; or (b) the IRO's findings or Cataract Surgery Procedures Review or Preoperative and Postoperative Cataract Surgery Examination Templates Review results are inaccurate, OIG may, at its sole discretion, conduct its own review to determine whether Cataract Surgery Procedures Review or Preoperative and Postoperative Cataract Surgery Examination Templates Review complied with the requirements of the IA and/or the findings or Cataract Surgery Procedures Review or Preoperative and Postoperative Cataract Surgery Examination Templates Review results are inaccurate (Validation Review). Madden shall pay for the reasonable cost of any such review performed by OIG or any of its designated agents. Any Validation Review of Reports submitted as part of Madden's final Annual Report must be initiated no later than one year after Madden's final submission (as described in Section II) is received by OIG.

Prior to initiating a Validation Review, OIG shall notify Madden 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, Madden may request a meeting with OIG to: (a) discuss the results of any Cataract Surgery Procedures Review or Preoperative and Postoperative Cataract Surgery Examination Templates Review submissions or findings; (b) present any additional information to clarify the results of the Cataract Surgery Procedures Review or Preoperative and Postoperative Cataract Surgery Examination Templates Review or to correct the inaccuracy of the Cataract Surgery Procedures Review or Preoperative and Postoperative Cataract Surgery Examination Templates Review; and/or (c) propose alternatives to the proposed Validation Review. Madden agrees to provide any additional information as may be requested by OIG under this Section in an expedited manner. OIG will attempt in good faith to resolve any Cataract Surgery Procedures Review or Preoperative and Postoperative Cataract Surgery Examination Templates Review issues with Madden 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 Madden a certification or sworn affidavit that it has evaluated its professional independence and objectivity, as appropriate to the nature of the engagement, with regard to the Cataract Surgery Procedures Review or Preoperative and Postoperative Cataract Surgery Examination Templates Review and that it has concluded that it is, in fact, independent and/or objective.

G. Ineligible Persons.

1. *Definitions.* For purposes of this IA:

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.gov>).

c. "Screened Persons" includes prospective and current owners, officers, directors, employees, contractors, and agents of Madden.

2. Screening Requirements. Madden shall ensure that all Screened Persons are not Ineligible Persons, by implementing the following screening requirements.

a. Madden shall screen all Screened Persons against the Exclusion Lists prior to engaging their services and, as part of the hiring or contracting process, shall require such persons to disclose whether they are an Ineligible Person.

b. Madden shall screen all Screened Persons against the Exclusion Lists within 90 days after the Effective Date and on an annual basis thereafter.

c. Madden shall implement a policy requiring all Screened Persons to disclose immediately any debarment, exclusion, suspension, or other event that makes that person an Ineligible Person.

Nothing in this Section affects the responsibility of (or liability for) Madden to refrain from billing Federal health care programs for items or services furnished, ordered, or prescribed by an Ineligible Person.

3. Removal Requirement. If Madden has actual notice that a Screened Person has become an Ineligible Person, Madden shall remove such person from responsibility for, or involvement with, Madden's business operations related to the Federal health care programs and shall remove such person from any position for which the person's compensation or the items or services furnished, ordered, or prescribed by the person are paid in whole or part, directly or

indirectly, by Federal health care programs or otherwise with Federal funds at least until such time as the person is reinstated into participation in the Federal health care programs.

4. Pending Charges and Proposed Exclusions. If Madden has actual notice that a Screened Person is charged with a criminal offense that falls within the ambit of 42 U.S.C. §§ 1320a-7(a), 1320a-7(b)(1)-(3), or is proposed for exclusion during his or her employment or contract term, or, in the case of a physician, during the term of the physician's medical staff privileges, Madden shall take all appropriate actions to ensure that the responsibilities of that person have 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.

H. Notification of Government Investigation or Legal Proceedings.

Within 30 days after discovery, Madden shall notify OIG, in writing, of any ongoing investigation or legal proceeding known to Madden conducted or brought by a governmental entity or its agents involving an allegation that Madden has committed a crime or has engaged in fraudulent activities. This notification shall include a description of the allegation, the identity of the investigating or prosecuting agency, and the status of such investigation or legal proceeding. Madden 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 investigation or proceedings, if any.

I. Reporting.

1. Overpayments.

a. Definition of Overpayments. For purposes of this IA, an "Overpayment" shall mean the amount of money Madden has received in excess of the amount due and payable under any Federal health care program requirements.

b. Reporting of Overpayments. If, at any time, Madden identifies or learns of any Overpayment, Madden shall notify the Federal health care program payor (e.g., Medicare fiscal intermediary or carrier) within 30 days after identification of the Overpayment and take remedial steps within 60 days after 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.

Also, within 30 days after identification of the Overpayment, Madden shall repay the Overpayment to the appropriate payor to the extent such Overpayment has been quantified. If not yet quantified, within 30 days after identification, Madden shall notify the payor of his 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 the information contained on the Overpayment Refund Form, provided as Appendix D to this IA. 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 IA, 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; or
- iii. a violation of the obligation to provide items or services of a quality that meets professionally recognized standards of health care where such violation has occurred in one or more instances and presents an imminent danger to the health, safety, or well-being of a Federal health care program beneficiary or places the beneficiary unnecessarily in high-risk situations.

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

b. Reporting of Reportable Events. If Madden determines (after a reasonable opportunity to conduct an appropriate review or investigation of the allegations) through any means that there is a Reportable Event, Madden 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.J.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 Madden's actions taken to correct the Reportable Event; and

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

## J. Third Party Billing

1. Current Contract with Third Party Biller. If Madden presently contracts with a third party billing company to submit claims to the Federal health care programs, Madden represents that it does not have an board membership 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 Madden intends to obtain an board membership 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, Madden shall notify OIG 30 days prior to any such proposed involvement.

Within 90 days after the Effective Date, Madden 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 Madden contracts with a new third party billing company during the term of this Agreement, Madden shall, within 30 days of entering into such contract, obtain and send to OIG the certification described in this Section III.J.1.

2. Future Contract with Third Party Biller. If, at any time during the term of this Agreement, Madden contracts with a third party billing company to submit claims to the Federal health care programs, at least 30 days prior to executing the contract, Madden shall submit a certification indicating whether it has an board membership or control interest (as defined in 42 U.S.C. § 1320a – 3(a)(3)) in the third party billing company and whether it is employed by or acts as a consultant to the third party billing company.

Within 30 days after Madden contracts with the third party billing company, Madden shall obtain 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; and (iii) provides the required training in accordance with Section III.D for those employees involved in the preparation and submission of claims to Federal health care programs.

If Madden contracts with a new third party billing company during the term of this Agreement, Madden shall, within 30 days of entering into such contract, obtain and send to OIG the certification described in this Section III.J.2.



#### **IV. NEW BUSINESS UNITS OR LOCATIONS**

In the event that, after the Effective Date, Madden 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, Madden 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 Madden 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, Madden 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 Madden's obligations under the Agreement. In addition, Madden shall notify OIG of such relationship in the next Annual Report.

#### **V. IMPLEMENTATION AND ANNUAL REPORTS**

A. Implementation Report. Within 120 days after the Effective Date, Madden shall submit a written report to OIG summarizing the status of his implementation of the requirements of this IA (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 Madden posted in his office 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 and the date these Policies and Procedures were implemented and distributed;

4. the following information regarding each type of training required by Section III.D:

- a. a description of such training, including a summary of the topics covered, the length of sessions and a schedule of training sessions;
- b. the number of individuals required to be trained, percentage of individuals actually trained, and an explanation of any exceptions.

A copy of all training materials and the documentation supporting this information shall be available to OIG, upon request.

5. the following information regarding the Clinical Quality Consultant: (a) identity, address, and phone number; (b) a copy of the engagement letter; (c) summary and description of any and all current and prior engagements and agreements between Madden and the Clinical Quality Consultant; and (d) completed samples of the Templates the Clinical Quality Consultant developed for the Preoperative and Postoperative Cataract Surgery Examination Templates Review;

6. for each cataract surgery performed by Madden at least 30 days after the Effective Date, a copy of the Preoperative and Postoperative Examination Template Madden completed for that cataract surgery;

7. the following information regarding the IRO: (a) identity, address, and phone number; (b) a copy of the engagement letter; (c) summary and description of any and all current and prior engagements and agreements between Madden and the IRO; and (d) the proposed start and completion dates of the Cataract Surgery Procedures Review or Preoperative and Postoperative Cataract Surgery Examination Templates Review;

8. a certification from the IRO regarding his/her professional independence and/or objectivity with respect to Madden;

9. a description of Madden's process to screen Screened Persons to determine if they are ineligible;

10. a summary of personnel actions (other than hiring) taken pursuant to Section III.G, the name, title and responsibilities of any person who is determined to be an Ineligible Person under Section III.G, and the actions taken in response to the obligations set forth in Section III.G;

11. a copy of the certification from the third party billing company required by Section III.J;

12. a list of all Madden'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 Madden currently submits claims;

13. if Madden 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, Madden shall inform OIG of the name, location, relationship, and its responsibilities with respect Madden's employment or contract;

14. a certification by the Compliance Contact that:

a. he or she has reviewed the IA in its entirety, understands the requirements described within, and maintains a copy for reference;

b. the written Policies and Procedures required by Section III.C 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;

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

d. all Screened Persons 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 Madden, as required by Section III.G; and

e. all Screened Persons of Madden were screened against the Exclusion Lists within 90 days after the Effective Date, as required by Section III.G and the date(s) of the screening.

13. a certification signed by Madden certifying (a) to the best of his knowledge, except as otherwise described in the Implementation Report, Madden is in compliance with all of the requirements of this Agreement and (b) Madden 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**

Madden shall submit to OIG Annual Reports with respect to the status of, and findings regarding, Madden's compliance activities for each of the five 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 Madden'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. for each cataract surgery performed by Madden during the Reporting Period, a copy of the Preoperative and Postoperative Template Madden completed for that cataract surgery;
7. if applicable, samples of the modified Templates as modified by the Clinical Quality Consultant to reflect new professionally recognized standards of health care, including but not limited to the standards of medical practice as described by the American Academy of Ophthalmology;

8. a complete copy of all reports prepared pursuant to the IRO's Cataract Surgery Review and Preoperative and Postoperative Cataract Surgery Examination Review required by Section III.F (and, if applicable for the first Annual Report, a copy of the certification described in Section III.F.5);

9. Madden'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.F;

10. a summary/description of all engagements between Madden and the IRO and the Clinical Quality Consultant, including, but not limited to, any outside financial audits, compliance program engagements, or reimbursement consulting, if different from what was submitted as part of the Implementation Report;

11. a certification from the IRO regarding its professional independence and/or objectivity to Madden;

12. a description of Madden's process to screen Screened Persons to determine if they are ineligible (to the extent it has changed from the Implementation Report);

13. a summary of personnel actions/other than hiring taken pursuant to Section III.G; the name, titles and responsibilities of any person who is determined to be an Ineligible Person under Section III.G; and Madden's actions taken in response to the obligations set forth in Section III.G;

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

15. a summary of Reportable Events (as defined in Section III.I) identified during the Reporting Period and the status of any corrective and preventative action relating to all such Reportable Events;

16. 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;

17. a copy of the certification from the third party billing company required by Section III.J, if applicable;

18. a description of all changes to the most recently provided list of Madden'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;

19. if Madden 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, Madden shall inform OIG of the name, location, relationship, and his responsibilities with respect Madden's employment or contract;

20. 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, and that all Covered Persons have executed the written Policies and Procedures certification in accordance with the timeframe required by Section III.C;

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

c. all Screened Persons 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 Madden, as required by Section III.G; and

d. all Screened Persons were screened against the Exclusion Lists during the Reporting Period, in accordance with Section III.G and the date(s) they were screened.

21. a certification signed by Madden certifying that (a) to the best of his knowledge, except as otherwise described in the applicable Report, Madden is in compliance with all of the requirements of this Agreement; and (b) Madden 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**

Madden shall clearly identify any portions of his submissions that he 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. Madden 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

Madden: Willis M. Madden, M.D.  
2719A South Crater Road  
Petersburg VA 23803  
Telephone: (804) 733-2177  
Facsimile: (804) 733-6483

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 Madden's books, records, and other documents and supporting materials and/or conduct on-site reviews of any of Madden's locations for the purpose of verifying and evaluating: (a) Madden's compliance with the terms of this Agreement; and (b) Madden's compliance with the requirements of the Federal health care programs in which he participates. The documentation described above shall be made available by Madden 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 Madden's employees, contractors, or agents who consent to be interviewed at the individual's place of business during normal business hours or at such other place and time as may be mutually agreed upon between the individual and OIG. Madden shall assist OIG or its duly authorized representative(s) in contacting and arranging interviews with such individuals upon OIG's request. Madden's employees may elect to be interviewed with or without a representative of Madden present.

## **VIII. DOCUMENT AND RECORD RETENTION**

Madden shall maintain for inspection all documents and records relating to reimbursement from the Federal health care programs, or to compliance with this Agreement, for six years (or longer if otherwise required 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 Madden prior to any release by OIG of information submitted by Madden pursuant to his obligations under this Agreement and identified upon submission by Madden as trade secrets, or information that is commercial or financial and privileged or confidential, under the FOIA rules. With respect to such releases, Madden shall have the rights set forth at 45 C.F.R. § 5.65(d).



**X. BREACH AND DEFAULT PROVISIONS**

Madden is expected to fully and timely comply with all of his Agreement obligations.

**A. Stipulated Penalties for Failure to Comply with Certain Obligations**

As a contractual remedy, Madden 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 Madden 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.J, or notify OIG within 30 days prior to Madden 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. submit the IRO’s annual Cataract Surgery Procedures Review or Preoperative and Postoperative Cataract Surgery Examination Templates Review in accordance with the requirements of Section III.E and Appendices B and C;

g. 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.G.2.

h. screen Screened Persons in accordance with the requirements of Section III.G; or require Screened Persons to disclose if they are debarred, excluded, suspended or are otherwise considered an Ineligible Person in accordance with the requirements of Section III.G; or

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

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 Madden 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 Madden fails to grant access to the information or documentation as required in Section VII. (This Stipulated Penalty shall begin to accrue on the date Madden fails to grant access.)

4. A Stipulated Penalty of \$5,000 for each false certification submitted by or on behalf of Madden as part of his 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 Madden fails to comply fully and adequately with any obligation of this Agreement. OIG shall provide notice (Notice) to Madden stating the specific grounds for its determination that Madden has failed to comply fully and adequately with the Agreement obligation(s) at issue and steps the Madden shall take to comply with the Agreement. (This Stipulated Penalty shall begin to accrue 10 days after the date Madden 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**

Madden 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 Madden 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 Madden 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 Madden 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 Madden of: (a) Madden's failure to comply; and (b) OIG's exercise of his 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, Madden 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 Madden elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until Madden 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 Madden has materially breached this Agreement, which decision shall be made at OIG's discretion and shall be governed by the provisions in Section X.D, below.

**D. Exclusion for Material Breach of this Agreement**

1. Definition of Material Breach. A material breach of this Agreement means:

- a. a failure by Madden to report a Reportable Event, take corrective action and make the appropriate refunds, as required in Section III.I;
- 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;
- d. a failure to engage and use a Clinical Quality Consultant in accordance with Section III.E;
- e. a failure to engage and use an IRO in accordance with Section III.F;
- f. a failure by Madden to implement the Preoperative and Postoperative Cataract Surgery Examination Templates in accordance with Section III.E; and
- g. a failure by Madden to complete any corrective action identified by the IRO.

2. Notice of Material Breach and Intent to Exclude. The parties agree that a material breach of this Agreement by Madden constitutes an independent basis for Madden's exclusion from participation in the Federal health care programs. Upon a determination by OIG that Madden has materially breached this Agreement and that exclusion is the appropriate remedy, OIG shall notify Madden of: (a) Madden's material breach; and (b) OIG's intent to exercise his 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. Madden 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. Madden 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) Madden has begun to take action to cure the material breach; (ii) Madden is pursuing such action with due diligence; and (iii) Madden has provided to OIG a reasonable timetable for curing the material breach.

4. Exclusion Letter. If at the conclusion of the 30-day period, Madden fails to satisfy the requirements of Section X.D.3, OIG may exclude Madden from participation in the Federal health care programs. OIG shall notify Madden in writing of its determination to exclude Madden (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 Madden’s receipt of the Exclusion Letter. The exclusion shall have national effect and shall also apply to all other Federal procurement and nonprocurement programs. Reinstatement to program participation is not automatic. After the end of the period of exclusion, Madden 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 Madden 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, Madden 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 Madden was in full and timely compliance with the obligations of this Agreement for which OIG demands payment; and (b) the period of noncompliance. Madden shall have the burden of proving his 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 Madden to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable 20 days after the ALJ issues such a decision unless Madden 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 Madden 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. Madden had begun to take action to cure the material breach within that period; ii. Madden has pursued and is pursuing such action with due diligence; and iii. Madden provided to OIG within that period a reasonable timetable for curing the material breach and Madden 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 Madden, only after a DAB decision in favor of OIG. Madden's election of his contractual right to appeal to the DAB shall not abrogate OIG's authority to exclude Madden 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 Madden 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. Madden shall waive his 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 Madden, Madden 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 IA is incorporated, Madden and OIG agree as follows:

A. This IA shall be binding on the successors, assigns, and transferees of Madden;

B. This IA shall become final and binding on the date the final signature is obtained on the IA;

C. Any modifications to this IA shall be made with the prior written consent of the parties to this IA;

D. OIG may agree to a suspension of Madden's obligations under this IA in the event of Madden's cessation of participation in Federal health care programs. If Madden withdraws from participation in Federal health care programs and is relieved of his IA obligations by OIG, Madden shall notify OIG 30 days in advance of Madden'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 IA shall be reactivated or modified.

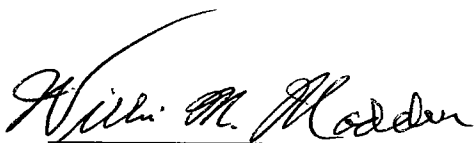
E. All requirements and remedies set forth in this IA are in addition to, and do not effect, (1) Madden's responsibility to follow all applicable Federal health care program requirements or (2) the Government's right to impose appropriate remedies for failure to follow applicable program requirements.

F. The undersigned Madden signatory represents and warrants that he is authorized to execute this IA. The undersigned OIG signatory represents that he is signing this IA in his official capacity and that he is authorized to execute this IA.

G. Respondent's Knowledge of Agreement. Madden represents that this IA is freely and voluntarily entered into without any degree of duress or compulsion whatsoever, and that Madden understands his right to advice of counsel concerning this IA.

IN WITNESS WHEREOF, the parties hereto affix their signatures:

**MADDEN**

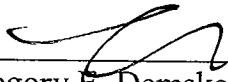


Willis M. Madden, M.D.  
2719A South Crater Road  
Petersburg VA 23803  
Telephone: (804) 733-2177  
Facsimile: (804) 733-6483

02/26/2007  
Date



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



\_\_\_\_\_  
Gregory E. Demske  
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

8/1/07

\_\_\_\_\_  
Date

## APPENDIX A INDEPENDENT REVIEW ORGANIZATION

This Appendix contains the requirements relating to the Independent Review Organization (IRO) required by Section III.F of the IA.

### A. IRO Engagement.

Madden 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 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 Madden if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, Madden may continue to engage the IRO.

If Madden engages a new IRO during the term of the IA, this IRO shall also meet the requirements of this Appendix. If a new IRO is engaged, Madden shall submit the information identified in Section V.B.7 to OIG within 30 days of engagement of the IR. Within 30 days after OIG receives written notice of the identity of the selected IRO, OIG will notify Madden if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, Madden may continue to engage the IRO.

### B. IRO Qualifications.

The IRO shall:

1. assign individuals to conduct the Cataract Surgery Procedures Review and Preoperative and Postoperative Cataract Surgery Examination Templates Review engagements who have expertise in ophthalmology, cataract surgery, and professionally recognized standards of health care for preoperative and postoperative care provided in connection with cataract surgery procedures, including but not limited to the established practice guidelines and the generally accepted standards of medical practice described by the American Academy of Ophthalmology, and the general requirements of the Federal health care program(s) from which Madden seeks reimbursement; and
2. have sufficient staff and resources to conduct the reviews required by the IA on a timely basis.

C. IRO Responsibilities.

The IRO shall:

1. perform each Cataract Surgery Procedures Review and Preoperative and Postoperative Cataract Surgery Examination Templates Review in accordance with the specific requirements of the IA;
2. follow all applicable Medicare, Medicaid, or other Federal health care program rules and reimbursement guidelines in making assessments in the Cataract Surgery Procedures Review;
3. if in doubt of the application of a particular Medicare, Medicaid, or other Federal health care program 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 and Appendix C.

D. IRO Independence and Objectivity.

The IRO must perform the Cataract Surgery Procedures Review and Preoperative and Postoperative Cataract Surgery Examination Templates Review in a professionally independent and 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 Madden.

E. IRO Removal/Termination.

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

Prior to requiring Madden to engage a new IRO, OIG shall notify Madden 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, Madden 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. Madden 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 Madden prior to requiring Madden to terminate the IRO. However, the final determination as to whether or not to require Madden to engage a new IRO shall be made at the sole discretion of OIG.

**APPENDIX B**  
**CATARACT SURGERY PROCEDURES REVIEW**

This Appendix contains the requirements relating to the Cataract Surgery Procedures Review required by Section III.F.3 of the IA.

A. Cataract Surgery Procedures Review.

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

a. Cataract Surgery Procedure: Any surgery performed by Madden on a patient's cataract that is reimbursable by Medicare, Medicaid, or other Federal health care programs.

b. Population: For each Reporting Period, the Population shall be defined as all Cataract Surgery Procedures for which Madden has received reimbursement from Medicare, Medicaid, or other Federal health care programs during the relevant 12-month Reporting Period.

c. Error: Any Cataract Surgery Procedure which the IRO determines was not medically necessary, supported by documentation of medical necessity, or of a quality that meets professionally recognized standards of health care, including but not limited to the established practice guidelines and generally accepted standards of medical practice described by the American Academy of Ophthalmology.

B. Cataract Surgery Procedures Review Report. The following information shall be included in the Cataract Surgery Procedures Review Report.

1. *Cataract Surgery Procedures Review Methodology.*

a. Unit for Review. A description of the Cataract Surgery Procedures as that term is utilized for the Cataract Surgery Procedures Review.

b. Cataract Surgery Procedures Review Population. A description of the Population subject to the Cataract Surgery Procedures Review.

c. Cataract Surgery Procedures Review Objective. A clear statement of the objective intended to be achieved by the Cataract Surgery Procedures Review.

d. Source of Data. A description of the specific documentation relied upon by the IRO when performing the Cataract Surgery Procedures Review (e.g., medical records, local medical review policies (including title and policy number), CMS program memoranda (including title and issuance number), Medicare carrier or intermediary manual or bulletins (including issue and date), other policies, regulations, or directives).

e. Review Protocol. A narrative description of how the Cataract Surgery Procedures Review was conducted and what was evaluated.

2. *Cataract Surgery Procedures Review Findings.*

a. A narrative explanation of the IRO's findings and supporting rationale (including reasons for errors, patterns noted, etc.) regarding the Cataract Surgery Procedures Review.

b. Total number and percentage of instances in which the IRO determined that the Cataract Surgery Procedures was not medically necessary, supported by documentation of medical necessity, or of a quality that meets professionally recognized standards of health care, including but not limited to the established practice guidelines and generally accepted standards of medical practice described by the American Academy of Ophthalmology.

c. A spreadsheet of the Cataract Surgery Procedure Review results that includes the following information for each Cataract Surgery Procedure appraised: (i) type of Cataract Surgery Procedure performed; (ii) whether the Cataract Surgery Procedure was medically necessary, supported by documentation of medical necessity, and of a quality that meets professionally recognized standards of health care; (iii) the reason for the finding that the Cataract Surgery Procedure was or was not medically necessary, supported by documentation of medical necessity, or of a quality that meets professionally recognized standards of health care; (iv) the beneficiary name; (v) beneficiary health insurance claim number; (vi) date of service; (vii) procedure code submitted; (viii) Federal health care program billed; and (ix) amount reimbursed.

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

5. *Credentials.* The names and credentials of the individuals who: (1) designed the review methodology utilized for the Cataract Surgery Procedures Review; and (2) performed the Cataract Surgery Procedures Review.

**APPENDIX C**  
**PREOPERATIVE AND POSTOPERATIVE CATARACT SURGERY**  
**EXAMINATION TEMPLATES REVIEW**

This Appendix contains the requirements relating to the Preoperative and Postoperative Cataract Surgery Examination Templates Review required by Section III.F.2 of the IA.

A. Preoperative and Postoperative Cataract Surgery Examination Templates Review.

1. *Definitions.* For the purposes of the Preoperative and Postoperative Cataract Surgery Examination Templates Review, the following definitions shall be used:

a. Cataract Surgery: Any surgery performed by Madden on a patient's cataract that is reimbursable by Medicare, Medicaid, or other Federal health care programs.

b. Preoperative Cataract Surgery Examination: An examination of the patient that takes place within the three months prior to cataract surgery.

c. Postoperative Cataract Surgery Examination: An examination of a patient that takes place within 48 hours after cataract surgery.

d. Population: For each Reporting Period, the Population shall be defined as all Preoperative and Postoperative Cataract Surgery Examinations for which Madden has received reimbursement from Medicare, Medicaid, or other Federal health care programs during the relevant 12-month Reporting Period.

c. Error: Any instance in which the IRO determines that Madden did not fully complete the Preoperative and Postoperative Cataract Surgery Examination Templates in accordance with professionally recognized standards of health care, including but not limited to the established practice guidelines and generally accepted standards of medical practice described by the American Academy of Ophthalmology.



B. Preoperative and Postoperative Cataract Surgery Examination Templates Review Report. The following information shall be included in the Preoperative and Postoperative Cataract Surgery Examination Templates Report.

1. *Preoperative and Postoperative Cataract Surgery Examination Templates Review Methodology.*

a. Unit for Review. A description of the Preoperative and Postoperative Cataract Surgery Examinations as those terms are utilized for the Preoperative and Postoperative Cataract Surgery Examination Templates Review.

b. Preoperative and Postoperative Cataract Surgery Examination Population. A description of the Population subject to the Preoperative and Postoperative Cataract Surgery Examination Templates Review.

c. Preoperative and Postoperative Cataract Surgery Examination Template Review Objective. A clear statement of the objective intended to be achieved by the Preoperative and Postoperative Cataract Surgery Examination Templates Review.

d. Source of Data. A description of the specific documentation relied upon by the IRO when performing the Preoperative and Postoperative Cataract Surgery Examination Templates Review (e.g., medical records, local medical review policies (including title and policy number), CMS program memoranda (including title and issuance number), Medicare carrier or intermediary manual or bulletins (including issue and date), other policies, regulations, or directives).

e. Review Protocol. A narrative description of how the Preoperative and Postoperative Cataract Surgery Examination Templates Review was conducted and what was evaluated.

2. *Preoperative and Postoperative Cataract Surgery Examination Templates Review Findings.*

a. A narrative explanation of the IRO's findings and supporting rationale (including reasons for errors, patterns noted, etc.) regarding the Preoperative and Postoperative Cataract Surgery Examination Templates Review.

b. Total number and percentage of instances in which the IRO determined that Madden did not fully complete the Preoperative and Postoperative Cataract Surgery Examination Templates in accordance with professionally recognized standards of health care, including but not limited to the established practice guidelines and generally accepted standards of medical practice described by the American Academy of Ophthalmology.

c. A spreadsheet of the Preoperative and Postoperative Cataract Surgery Examination Templates Review results that includes: (i) type of Cataract Surgery Procedure performed; (ii) whether the Preoperative and Postoperative Cataract Surgery Examination Templates were used; (iii) whether the Preoperative and Postoperative Cataract Surgery Examination Templates were fully completed in accordance with professionally recognized standards of health care; (iv) whether the Preoperative and Postoperative Cataract Surgery Examination Templates were completed contemporaneously with the provision of the preoperative and postoperative examination service; (v) the reason for the finding that the Preoperative or Postoperative Cataract Surgery Examination Template was or was not used, completed contemporaneously with the provision of the preoperative and postoperative examination service, or fully completed in accordance with professionally recognized standards of health care; (vi) the beneficiary name; (vii) beneficiary health insurance claim number; (viii) date of service; (ix) procedure code submitted; (x) Federal health care program billed; and (xi) amount reimbursed.

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

5. *Credentials.* The names and credentials of the individuals who: (1) designed the review methodology utilized for the Preoperative and Postoperative Cataract Surgery Examination Templates Review; and (2) performed the Preoperative and Postoperative Cataract Surgery Examination Templates 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><br/>                 01 - Corrected Date of Service<br/>                 02 - Duplicate<br/>                 03 - Corrected CPT Code<br/>                 04 - Not Our Patient(s)<br/>                 05 - Modifier Added/Removed<br/>                 06 - Billed in Error<br/>                 07 - Corrected CPT Code</p> | <p><u>MSP/Other Payer Involvement</u><br/>                 08 - MSP Group Health Plan Insurance<br/>                 09 - MSP No Fault Insurance<br/>                 10 - MSP Liability Insurance<br/>                 11 - MSP, Workers Comp.(Including Black Lung<br/>                 12 - Veterans Administration</p> | <p><u>Miscellaneous</u><br/>                 13 - Insufficient Documentation<br/>                 14 - Patient Enrolled in an HMO<br/>                 15 - Services Not Rendered<br/>                 16 - Medical Necessity<br/>                 17 - Other (Please Specify)</p> |
|--|--|--|