

INTEGRITY AGREEMENT
BETWEEN THE
OFFICE OF INSPECTOR GENERAL
OF THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND
KEE SHUM, M.D. AND LI SHUM

I. PREAMBLE

Kee Shum, M.D. (Dr. Shum) and Mrs. Li Shum (Mrs. Shum) (collectively, the Shums) hereby enter 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, program requirements, and written directives of Medicare, Medicaid, and all other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)) (Federal health care program requirements). This IA applies to Dr. Shum and Mrs. Shum, any entity in which the Shums, collectively or individually, have an ownership or control interest at any time during the term of the IA, as defined in 42 U.S.C. § 1320a-3(a)(3), and any other Covered Persons as defined in Section II.C. Contemporaneously with this IA, the Shums are entering into a Settlement Agreement with the United States. Unless otherwise expressly stated, all provisions in this IA apply with equal force and effect to Dr. Shum and Mrs. Shum.

II. TERM AND SCOPE OF THE IA

A. The date on which the final signatory of this IA executes this IA shall be known as the Effective Date. The period of compliance obligations assumed by the Shums under this IA shall be 5 years from the Effective Date. 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, IX, X, and XI shall expire no later than 120 days from OIG's receipt of: (1) Dr. Shum's final Annual Report; or (2) any additional materials submitted by the Shums pursuant to OIG's request, whichever is later.

C. The term "Covered Persons" includes:

1. Dr. Shum, Mrs. Shum and all associates and employees of Dr. Shum's medical practice;

2. all contractors, agents, and other persons who provide patient care items or services or who perform billing or coding functions on behalf of Dr. Shum's medical practice; and

3. all employees of any entity in which either Dr. Shum or Mrs. Shum has an ownership or control interest at any time during the term of this IA (as defined in 42 U.S.C. §1320a-3(a)(3)) and any contractors, agents, or other persons who provide patient care items or services or who perform billing or coding functions on behalf of such entity.

III. INTEGRITY OBLIGATIONS

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

A. Compliance Contact. Within 30 days after the Effective Date, Dr. Shum shall designate a Covered Person to be responsible for compliance activities (Compliance Contact). Dr. Shum shall maintain a Compliance Contact for the term of this IA. The Compliance Contact shall be responsible for: (1) monitoring Dr. Shum's and Mrs. Shum's day-to-day compliance activities; (2) meeting all reporting obligations created under this IA; and (3) responding to questions and concerns from Covered Persons and the OIG regarding compliance with the IA.

Dr. Shum 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, phone number, and a description of any other job responsibilities performed by the Compliance Contact shall be included in the Implementation Report.

B. Posting of Notice. Within the 90 days after the Effective Date, Dr. Shum 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) Dr. Shum'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 Dr. Shum.

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. Billing and Claims Submission and Medical Record Documentation Procedures. Within 90 days after the Effective Date, Dr. Shum shall implement and distribute to all Covered Persons written procedures and requirements for (i) preparing and submitting claims to Federal health care programs on behalf of Dr. Shum, including claims for drugs; (ii) the proper documentation of medical records and billing information for services furnished on behalf of Dr. Shum; and (iii) the order, purchase, and receipt of drugs, including, but not limited to, procedures and requirements intended to ensure compliance with all United States Food and Drug Administration (FDA), Food, Drug and Cosmetic Act (FDCA), and Federal health care program requirements governing the ordering, purchasing, receiving, and prescribing of oncology related drugs obtained from foreign countries. 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 these procedures. New Covered Persons shall receive and review the written procedures and shall complete the required certification within 30 days after becoming a Covered Person or within 90 days after the Effective Date, whichever is later.

At least annually (and more frequently if appropriate), Dr. Shum shall assess and update, as necessary, these billing and claims submission, medical record documentation, and ordering procedures. Within 30 days after the effective date of any revisions, any such revised procedures shall be distributed to all Covered Persons.

Copies of the written billing and claims submission, medical record documentation and ordering procedures shall be included in the Implementation Report. Copies of any such procedures that are subsequently revised shall be included in the next Annual Report along with a summary of any change or amendment to the procedures required by this Section and the reason for each change.

D. Training and Certification.

1. *Training.* Within 90 days after the Effective Date and during each subsequent Reporting Period, all Covered Persons shall receive at least three hours of training from an individual or entity, other than Dr. Shum, Mrs. Shum or another Covered

Person. Training may be received from a variety of sources (e.g., CME classes, hospitals, associations, Medicare contractors). In the event Dr. Shum currently contracts with a third party billing company, the employees of any such third party billing company that submits claims to the Federal health care programs on behalf of Dr. Shum shall not be considered Covered Persons for purposes of these training and certification requirements, provided that neither Dr. Shum nor Mrs. Shum has any ownership or control interest (as defined in 42 U.S.C. § 1320a-3(a)(3)) in the third party billing company and the third party billing company provides the certification required by Section III.I.

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

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

- a. the requirements of this IA;
- b. the accurate coding and submission of claims for services rendered and/or items provided to Federal health care program beneficiaries;
- c. applicable reimbursement statutes, regulations, and program requirements and directives;
- d. the policies, procedures, and other requirements applicable to the documentation of medical records;
- e. the personal obligation of each individual involved in the coding and claims submission process to ensure that such claims are accurate;
- f. the legal sanctions for the submission of improper claims or violations of the Federal health care program requirements;
- g. examples of proper and improper coding and claims submission practices; and

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- h. the policies, procedures, and other requirements applicable to the ordering, purchasing, receipt and billing of drugs, including, but not limited to, FDA, FDCA, and Federal health care program requirements governing the ordering, purchasing, receipt, and billing of oncology related drugs obtained from foreign countries.

2. *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. Dr. Shum shall retain the certifications along with all training materials. The certifications and the training materials shall be made available to OIG, upon request.

3. *Qualifications of Trainer(s).* Persons providing the training shall be knowledgeable about the subject.

4. *Update of Training.* The training required by this section shall be updated as necessary to reflect changes in Federal health care program or FDA requirements and any other relevant information.

5. *Computer Based Training.* Dr. Shum may provide the training required under this IA through appropriate computer-based training approaches. If Dr. Shum 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. Review and Document Retention Procedures

1. *Review Procedures and Reporting.* Within 90 days following the Effective Date of this IA, Dr. Shum and Mrs. Shum shall assess the internal procedures used by Dr. Shum's medical practice relating to the ordering, purchasing, receipt and billing of drugs, including drugs obtained from foreign countries. If necessary, Dr. Shum and Mrs. Shum shall establish and implement, or revise, internal procedures so they are designed to prevent the billing of drugs to patients, Federal health care programs or third party insurers that were obtained in violation of FDA, FDCA, Federal health care program or other requirements. Any such procedures established or revised shall be implemented and distributed in accordance with the requirements of Section III.C.

As part of each Annual Report, Dr. Shum shall describe the procedures used by his medical practice to order, purchase, or receive drugs and the procedures used to bill for drugs. In addition, Dr. Shum shall provide the following information and documents:

- a. The entity or individual who provided each type of drug ordered, purchased, received or prescribed by Dr. Shum and the total volume of the drug so ordered, purchased, received or prescribed; and
- b. A certification by Dr. Shum that he did not bill any drug to any patient, Federal health care program, or third party insurer in violation of any FDA, FDCA, or Federal health care program requirement.

2. *Validation Review.* In the event the OIG has reason to believe that: (a) Dr. Shum's or Mrs. Shum's ordering, purchasing, or receipt of drugs or billing to Federal health care programs, patients or third party insurers for drugs fail to conform to the requirements of this IA; or (b) the information or certification provided in accordance with Section III.E.1. is inaccurate, the OIG may, at its sole discretion, conduct its own review to determine whether Dr. Shum's or Mrs. Shum's ordering, purchasing, or receipt of or billing for drugs complies with the requirements of the IA or whether the information or certification provided pursuant to Section III.E.1. is inaccurate (Validation Review). Prior to initiating such a Validation Review, the OIG shall notify the Shums of its intent to do so and provide a written explanation of why the OIG believes such a Validation Review is necessary. The OIG will attempt in good faith to resolve any issues relating to the Validation Review with the Shums prior to conducting the Validation Review.

However, the final determination as to whether or not to proceed with a Validation Review shall be made at the sole discretion of the OIG. The Shums agree to pay for the reasonable cost of any such Validation Review performed by the OIG or any of its designated agents so long as it is initiated before one year after the final Annual Report is received by the OIG.

F. 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://www.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>)

2. *Screening Requirements.* Dr. Shum shall not hire, employ or engage as a Covered Person any Ineligible Person. Dr. Shum shall ensure that all Covered Persons are not Ineligible Persons, by implementing the following screening requirements.

- a. Dr. Shum shall screen all Covered Persons against the Exclusion Lists prior to engaging their services and, as part of the hiring or contracting process, shall require Covered Persons to disclose whether they are Ineligible Persons.

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

c. Dr. Shum shall require all Covered Persons to immediately disclose any debarment, exclusion, suspension, or other event that makes that Covered Person an Ineligible Person.

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

Nothing in this Section affects the responsibility of (or liability for) Dr. Shum or Mrs. Shum to refrain from billing Federal health care programs for items or services furnished, ordered, or prescribed by an Ineligible Person. Dr. Shum and Mrs. Shum understand that items or services furnished by excluded persons are not payable by Federal health care programs and that Dr. Shum or Mrs. Shum may be liable for overpayments and/or criminal, civil, and administrative sanctions for employing or contracting with an excluded person regardless of whether Dr. Shum or Mrs. Shum, as applicable, meets the requirements of Section III.F.

3. *Removal Requirement.* If Dr. Shum has actual notice that a Covered Person has become an Ineligible Person, Dr. Shum shall remove such Covered Person from responsibility for, or involvement with, Dr. Shum's business operations related to the Federal health care programs and shall remove such Covered Person from any position for which the Covered Person's compensation or the items or services rendered, ordered, or prescribed by the Covered 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 Covered Person is reinstated into participation in the Federal health care programs.

4. *Pending Charges and Proposed Exclusions.* If Dr. Shum has actual notice that a Covered Person is charged with a criminal offense that falls within the scope of 42 U.S.C. §§ 1320a-7(a), 1320a-7(b)(1)-(3), or is proposed for exclusion during the Covered Person's employment or contract term, Dr. Shum shall take all appropriate actions to ensure that the responsibilities of that Covered 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.

G. Notification of Government Investigation or Legal Proceedings. Within 30 days after discovery, Dr. Shum or Mrs. Shum, as applicable, shall notify OIG, in writing, of any ongoing investigation or legal proceeding known to Dr. Shum or Mrs. Shum conducted or brought by a governmental entity or its agents involving an allegation that Dr. Shum or Mrs. Shum have committed a crime or have engaged in fraudulent activities. This notification shall include a description of the allegation, the identity of the investigating or prosecuting agency, and the status of such investigation or legal proceeding. Dr. Shum or Mrs. Shum shall also provide written notice to OIG within 30 days after the resolution of the matter, and shall provide OIG with a description of the findings and/or results of the proceedings, if any.

H. Reporting.

1. *Overpayments.*

a. *Definition of Overpayments.* For purposes of this IA, an "Overpayment" shall mean the amount of money Dr. Shum 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, Dr. Shum identifies or learns of any Overpayment, Dr. Shum shall notify the 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, Dr. Shum 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, Dr. Shum shall notify the payor at that time of his efforts to quantify the Overpayment amount and provide 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 A 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. the filing of a bankruptcy petition by Dr. Shum.

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

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

- i. If the Reportable Event results in an Overpayment, the report to OIG shall be made at the same time as the notification to the payor required in Section III.H.1, and shall include all of the information on the Overpayment Refund Form, as well as:

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

(B) the date of the check and identification number (or electronic transaction number) by which the Overpayment was repaid/refunded;

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

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

iv. any further steps Dr. Shum or Mrs. Shum plan to take to address the Reportable Event and prevent it from recurring.

If the Reportable Event involves the filing of a bankruptcy petition, the report to the OIG shall include documentation of the filing and a description of any Federal health care program authorities implicated.

I. Third Party Billing. If, prior to the Effective Date or at any time during the term of this IA, Dr. Shum contracts with a third party billing company to submit claims to the Federal health care programs on behalf of Dr. Shum, Dr. Shum must certify to OIG that he and Mrs. Shum do not have an ownership or control interest (as defined in 42 U.S.C. § 1320a-3(a)(3)) in the third party billing company and are not employed by, and do not act as a consultant to, the third party billing company. Such certification must be included in the Implementation Report and each Annual Report (as applicable) submitted to OIG.

Dr. Shum also shall obtain and provide to OIG in the Implementation Report and each Annual Report (as applicable) a certification from any third party billing company that the company: (i) 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; (ii) screens its prospective and current employees against the HHS/OIG List of Excluded Individuals/Entities and the General Services Administration's List of Parties Excluded from Federal Programs; and (iii) provides training in the applicable requirements of the Federal health care programs to those employees involved in the preparation and submission of claims to Federal health care programs.

IV. CHANGES TO BUSINESS UNITS OR LOCATIONS; NEW EMPLOYMENT OR CONTRACTUAL ARRANGEMENT

A. Change or Closure of Unit or Location. In the event that, after the Effective Date, Dr. Shum changes locations or closes a business unit or location related to the furnishing of items or services that may be reimbursed by Federal health care programs, Dr. Shum shall notify OIG of this fact as soon as possible, but no later than 30 days after the date of change or closure of the location.

B. Purchase or Establishment of New Unit or Location. In the event that, after the Effective Date, Dr. Shum purchases or establishes a new business unit or location related to the furnishing of items or services that may be reimbursed by Federal health care programs, Dr. Shum shall notify OIG at least 30 days prior to such purchase or the operation of the new business unit or location. 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 name and address of the contractor 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 of this IA.

C. Sale of Unit or Location. In the event that, after the Effective Date, Dr. Shum proposes to sell any or all of his business units or locations that are subject to this IA, Dr. Shum shall notify OIG of the proposed sale at least 30 days prior to the sale of such business unit or location. This notification shall include a description of the business unit or location to be sold, a brief description of the terms of the sale, and the name and contact information of the prospective purchaser. This IA shall be binding on the purchaser of such business unit or location, unless otherwise determined and agreed to in writing by OIG.

D. New Employment or Contractual Arrangement. Prior to Dr. Shum or Mrs. Shum becoming an employee or contractor with another party related to the furnishing of items or services that may be reimbursed by Federal health care programs, Dr. Shum or Mrs. Shum shall notify that party of this IA. This notification shall include a copy of the IA, a statement indicating the remaining term of the IA, and a summary of the Shums' respective obligations under the IA. In addition, Dr. Shum shall notify OIG of such relationship(s) in his next Annual Report.

V. IMPLEMENTATION AND ANNUAL REPORTS

A. Implementation Report. Within 120 days after the Effective Date, Dr. Shum 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 name, phone number, and a description of any other job responsibilities performed by the Compliance Contact, and the date the Compliance Contact was appointed;
2. a copy of the notice Dr. Shum 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 procedures required by Section III.C;
4. a description of the training provided in accordance with the requirements of Section III.D, including a summary of the topics covered, the length of each session, and a schedule of when the training session(s) were held;
5. the information required by Section III;
6. a certification by Dr. Shum that all prospective and current Covered Persons are being screened against the Exclusion Lists, as required by section III.F;
7. the name, title, and responsibilities of any person who is determined to be an Ineligible Person under Section III.F, the actions taken in response to the screening and removal obligations set forth in Section III.F, and the actions taken to identify, quantify, and repay any overpayments to Federal health care programs relating to items or services furnished, ordered, or prescribed by such Ineligible Person;
8. a copy of any certifications from Dr. Shum or Mrs. Shum and any third party billing company required by Section III.I (if applicable);
9. a list of all of Dr. Shum'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 Medicare contractor to which Dr. Shum currently submits claims;

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

11. a certification by Dr. Shum, Mrs. Shum and 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) to the best of his or her knowledge, except as otherwise described in the Implementation Report, Dr. Shum and Mrs. Shum are in compliance with all of the requirements of this IA; and (c) he or she has reviewed the Implementation Report and has made a reasonable inquiry regarding its content and believes that the information is accurate and truthful.

B. Annual Reports. Dr. Shum shall submit to OIG Annual Reports with respect to the status of, and findings regarding, Dr. Shum's and Mrs. Shum's compliance activities for each of the 5 Reporting Periods (Annual Report). Each Annual Report shall, at a minimum, include:

1. any change in the name, phone number, or job responsibilities of the Compliance Contact;
2. any changes to the posted notice and the reason for such changes;
3. a copy of any new or revised procedures required by Section III.C and the reason(s) for any revisions (e.g., change in contractor policies, etc.);
4. a description of the training provided in accordance with the requirements of Section III.D, including a summary of the topics covered; the length of each session; and a schedule of when the training session(s) was held;
5. a complete copy of all certificates and information required pursuant to Section III.E;
6. a certification by Dr. Shum that all prospective and current Covered Persons are being screened against the Exclusion Lists, as required by section III.F;
7. the name, title, and responsibilities of any person who is determined to be an Ineligible Person under Section III.F, the actions taken in response to the screening

and removal obligations set forth in Section III.F, and the actions taken to identify, quantify, and repay any overpayments to Federal health care programs relating to items or services furnished, ordered, or prescribed by such Ineligible Person;

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

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

10. 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;

11. a copy of any certifications from Dr. Shum, Mrs. Shum and any third party billing company required by Section III.I (if applicable);

12. a description of all changes to the most recently provided list of Dr. Shum's locations (including addresses) as required by Section V.A.9; 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 Medicare contractor to which Dr. Shum currently submits claims;

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

14. a certification signed by Dr. Shum, Mrs. Shum and the Compliance Contact certifying that: (a) he or she has reviewed the IA in its entirety, understands the requirements described within, and maintains a copy for reference; (b) to the best of his or her knowledge, except as otherwise described in the Annual Report, the Shums are in compliance with all of the requirements of this IA; and (c) he or she has reviewed the Annual Report and has made a reasonable inquiry regarding its content and believes that

the information is accurate and truthful.

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

C. Designation of Information. The Shums shall clearly identify any portions of their submissions that either 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. The Shums 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 IA shall be submitted to the following entities:

For the 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

For the Shums:

Kee Y. Shum, M.D. and Mrs. Li Shum
136-25 Maple Avenue, Suite 205
Flushing, New York 11355
TEL: (718) 463-2245 --FAX: (718) 463-2290

Unless otherwise specified, all notifications and reports required by this IA 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. Upon request by OIG, the Shums may be required to provide OIG with an electronic copy of each notification or report required by this IA in searchable portable document format (pdf), either instead of or in addition to, a paper copy.

VII. OIG INSPECTION, AUDIT, AND REVIEW RIGHTS

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

VIII. DOCUMENT AND RECORD RETENTION

Dr. Shum and Mrs. Shum shall maintain for inspection all documents and records relating to reimbursement from the Federal health care programs, or to compliance with this IA, for six years (or longer if otherwise required by law) from the Effective Date, including, but not limited to, documents reflecting the order, purchase and receipt of drugs by Dr. Shum's medical practice.

IX. DISCLOSURES

Consistent with HHS's FOIA procedures, set forth in 45 C.F.R. Part 5, OIG shall make a reasonable effort to notify Dr. Shum and Mrs. Shum prior to any release by OIG of information submitted by Dr. Shum or Mrs. Shum pursuant to their obligations under this IA and identified upon submission by Dr. Shum or Mrs. Shum as trade secrets, or information that is commercial or financial and privileged or confidential, under the

FOIA rules. With respect to such releases, Dr. Shum and Mrs. Shum shall have the rights set forth at 45 C.F.R. § 5.65(d).

X. BREACH AND DEFAULT PROVISIONS

Dr. Shum and Mrs. Shum are expected to fully and timely comply with all of their IA obligations.

A. Stipulated Penalties for Failure to Comply with Certain Obligations. As a contractual remedy, the Shums and OIG hereby agree that failure to comply with certain obligations set forth in this IA (unless a timely written request for an extension has been submitted and approved in accordance with Section B below) may lead to the imposition of the following monetary penalties (hereinafter referred to as “Stipulated Penalties”) in accordance with the following provisions.

1. A Stipulated Penalty of \$750 (which shall begin to accrue on the day after the date the obligation became due) for each day Dr. Shum or Mrs. Shum, as applicable, fail to:

- a. designate 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. implement, distribute, or update the procedures required by Section III.C;
- d. establish and implement a training program in accordance with the requirements of Section III.D;
- e. obtain and/or maintain the following documentation: written procedures certifications in accordance with the requirements of Section III.C, training certification(s) in accordance with the requirements of Section III.D, and/or documentation of screening and disclosure requirements in accordance with the requirements of Section III.F;
- f. screen Covered Persons in accordance with the requirements of

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

g. notify OIG of a government investigation or legal proceeding, in accordance with the requirements of Section III.G; or

h. provide to OIG the certifications required by Section III.I relating to any third party biller engaged by Dr. Shum during the term of the IA;

i. provide to OIG in each Annual Report the information required by Section III.E.1.a relating to drug orders; or

j. provide to OIG the certification required by Section III.E.1.b relating to compliance with applicable requirements governing the billing of drugs.

2. A Stipulated Penalty of \$1,000 (which shall begin to accrue on the day after the date the obligation became due) for each day Dr. Shum fails to submit the Implementation Report or the Annual Reports to OIG in accordance with the requirements of Section V by the deadlines for submission.

3. A Stipulated Penalty of \$750 for each day Dr. Shum or Mrs. Shum, as applicable, fail to grant access as required in Section VII. (This Stipulated Penalty shall begin to accrue on the date Dr. Shum or Mrs. Shum fail to grant access.)

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

5. A Stipulated Penalty of \$750 for each day Dr. Shum or Mrs. Shum, as applicable, fail to comply fully and adequately with any obligation of this IA. OIG shall provide notice to the Shums stating the specific grounds for its determination that the Shums have failed to comply fully and adequately with the IA obligation(s) at issue and steps the Shums shall take to comply with the IA. (This Stipulated Penalty shall begin to accrue 10 days after the date the Shums receive 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. The Shums 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 IA. 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 the Shums fail 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 the Shums receive 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 the Shums have failed to comply with any of the obligations described in Section X.A and after determining that Stipulated Penalties are appropriate, OIG shall notify the Shums of: (a) the Shums' failure to comply; and (b) OIG's intent to exercise its contractual right to demand payment of the Stipulated Penalties (this notification is referred to as the "Demand Letter").

2. *Response to Demand Letter.* Within 10 days of the receipt of the Demand Letter, the Shums 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 the Shums elect to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until the Shums cure, 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 IA and shall be grounds for exclusion under Section X.D.

3. *Form of Payment.* Payment of the Stipulated Penalties shall be made by certified or cashier's check, payable to: "Secretary of the Department of Health and Human Services," and submitted to OIG at the address set forth in Section VI.

4. *Independence from Material Breach Determination.* Except as set forth in Section X.D.1.c, these provisions for payment of Stipulated Penalties shall not affect or otherwise set a standard for OIG's decision that Dr. Shum or Mrs. Shum have materially breached this IA, 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 IA.

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

- a. a failure by the Shums to report a Reportable Event, take corrective action and make the appropriate refunds, as required in Section III.H;
- b. a repeated or flagrant violation of the obligations under this IA, including, but not limited to, the obligations addressed in Section X.A; or
- c. a failure to respond to a Demand Letter concerning the payment of Stipulated Penalties in accordance with Section X.C.

2. *Notice of Material Breach and Intent to Exclude.* The parties agree that a material breach of this IA by the Shums constitutes an independent basis for the Shums' exclusion from participation in the Federal health care programs. Upon a determination by OIG that the Shums have materially breached this IA and that exclusion is the appropriate remedy, OIG shall notify the Shums of: (a) the Shums' material breach; and (b) OIG's intent to exercise its contractual right to impose exclusion (this notification is hereinafter referred to as the "Notice of Material Breach and Intent to Exclude").

3. *Opportunity to Cure.* The Shums 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. the Shums are in compliance with the obligations of the IA 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) the Shums have begun to take action to cure the material breach; (ii) the Shums are pursuing such action with due diligence; and (iii) the Shums have provided to OIG a reasonable timetable for curing the material breach.

4. *Exclusion Letter.* If, at the conclusion of the 30-day period, the Shums fail to satisfy the requirements of Section X.D.3, OIG may exclude the Shums from participation in the Federal health care programs. OIG shall notify the Shums in writing of its determination to exclude the Shums (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 the Shums' 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. At the end of the period of exclusion, the Shums 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 the Shums of its Demand Letter or of its Exclusion Letter, and as an agreed-upon contractual remedy for the resolution of disputes arising under this IA, the Shums 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 IA. 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 IA shall be: (a) whether the Shums were in full and timely compliance with the obligations of this IA for which OIG

demands payment; and (b) the period of noncompliance. The Shums shall have the burden of proving their full and timely compliance and the steps taken to cure the noncompliance, if any. OIG shall not have the right to appeal to the DAB an adverse ALJ decision related to Stipulated Penalties. If the ALJ agrees with OIG with regard to a finding of a breach of this IA and orders the Shums to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable 20 days after the ALJ issues such a decision unless the Shums 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 IA shall be:

- a. whether the Shums were in material breach of this IA;
- 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) the Shums had begun to take action to cure the material breach within that period; (ii) the Shums have pursued and are pursuing such action with due diligence; and (iii) the Shums have provided to OIG within that period a reasonable timetable for curing the material breach and the Shums have 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 the Shums, only after a DAB decision in favor of OIG. The Shums' election of their contractual right to appeal to the DAB shall not abrogate OIG's authority to exclude the Shums 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 the Shums 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. The Shums shall waive their 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 the Shums, the Shums shall be

reinstated effective 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 IA agree that the DAB's decision (or the ALJ's decision if not appealed) shall be considered final for all purposes under this IA.

XI. EFFECTIVE AND BINDING AGREEMENT

The Shums and OIG agree as follows:

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

B. This IA constitutes the complete agreement between the parties and may not be amended except by prior written consent of the parties to this IA.

C. This IA shall be binding on the successors, assigns, and transferees of the Shums.

D. OIG may agree to a suspension of the Shums' obligations under this IA in the event of the Shums' cessation of participation in Federal health care programs. If the Shums cease to participate in Federal health care programs and are relieved of their IA obligations by OIG, the Shums shall notify OIG 30 days in advance of the Shums' 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) the Shums' responsibility to follow all applicable Federal health care program requirements or (2) the Government's right to impose appropriate remedies for failure to follow applicable program requirements.

F. The undersigned signatories, Dr. Shum and Mrs. Shum, represent and warrant that they are 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. This IA may be executed in counterparts, each of which constitutes an original

and all of which constitute one and the same IA. Facsimiles of signatures shall constitute acceptable, binding signatures for purposes of this IA.

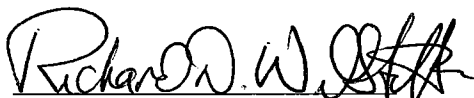
FOR KEE SHUM, M.D.



Kee Shum, M.D.
136-25 Maple Avenue
Flushing, New York 11355

4-15-08

Date



Richard D. Willstatter, Esq.
Green & Willstatter
Counsel for Dr. Kee Shum
200 Mamaroneck Avenue
Suite 605
White Plains, New York 10601

4-15-08

Date

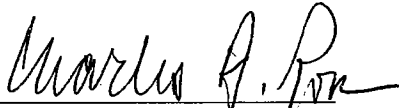
FOR LI SHUM



Li Shum
136-25 Maple Avenue
Flushing, New York 11355

4/15/08

Date



Charles A. Ross, Esq.
Charles A. Ross & Associates, LLC
Counsel for Mrs. Li Shum
Trinity Centre, Suite 1401
111 Broadway
New York, New York 10006

4-15-08

Date

**ON BEHALF OF THE 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

4/23/08
Date

APPENDIX A

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:

Billing/Clerical Error	MSP/Other Payer Involvement	Miscellaneous
01 - Corrected Date of Service	08 - MSP Group Health Plan Insurance	13 - Insufficient Documentation
02 - Duplicate	09 - MSP No Fault Insurance	14 - Patient Enrolled in an HMO
03 - Corrected CPT Code	10 - MSP Liability Insurance	15 - Services Not Rendered
04 - Not Our Patient(s)	11 - MSP, Workers Comp.(Including Black Lung	16 - Medical Necessity
05 - Modifier Added/Removed	12 - Veterans Administration	17 - Other (Please Specify)
06 - Billed in Error		
07 - Corrected CPT Code		