

Exhibit A

**INTEGRITY AGREEMENT
BETWEEN THE
OFFICE OF INSPECTOR GENERAL
OF THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND
INLAND EMPIRE LITHOTRIPSY, LLC**

I. PREAMBLE

Inland Empire Lithotripsy, LLC (“Inland”) hereby enters into this Integrity Agreement with the Office of Inspector General (“OIG”) of the United States Department of Health and Human Services (“HHS”) to promote compliance with the statutes, regulations, program requirements, and written directives of Medicare, Medicaid, and all other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)) (“Federal health care program requirements”) by Inland. This commitment to promote compliance applies to all managers, member physicians, employees, and agents of Inland (collectively “Covered Persons”). Contemporaneously with this Integrity Agreement, Inland is entering into a Settlement Agreement with the OIG and this Integrity Agreement is incorporated by reference into the Settlement Agreement.

II. TERM OF THE AGREEMENT

Except as otherwise provided, the period of compliance obligations assumed by Inland under this Integrity Agreement shall be three years from the effective date of this Integrity Agreement. The effective date of this Integrity Agreement shall be the date on which the final signatory of this Integrity Agreement executes this agreement (“Effective Date”).

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

III. INTEGRITY OBLIGATIONS

Inland shall establish a Compliance Program that, at minimum, includes the following elements:

Integrity Agreement:
Inland Empire Lithotripsy, LLC

A. Compliance Officer

Inland shall designate a person to be the Compliance Officer for purposes of developing and implementing policies, procedures, and practices designed to ensure compliance with the obligations herein and with Federal health care program requirements. In addition, the Compliance Contact is responsible for responding to questions and concerns from Covered Persons and the OIG regarding compliance with the Integrity Agreement obligations, and for certifying certain items in the Annual Reports. The name and phone number of the Compliance Officer shall be reported to the OIG within 30 days of the Effective Date. In the event a new Compliance Officer is appointed during the term of this Integrity Agreement, Inland shall notify the OIG, in writing, within 30 days of such a change.

B. Posting of Notice

Within the first 30 days following the Effective Date, Inland shall post in a prominent place accessible to all patients and Covered Persons a notice detailing its commitment to comply with all Federal health care program requirements in the conduct of its business. This notice shall include a means (i.e., telephone number, address, etc.) by which instances of misconduct may be reported anonymously. A copy of this notice shall be provided to the OIG within 30 days of the Effective Date. An example of a notice is attached as Attachment 1.

C. Written Policies and Procedures

Within 120 days of the Effective Date, Inland shall develop, implement, and make available to all Covered Persons written policies that address the following (hereafter “Policies and Procedures”):

1. Inland’s commitment to operate its business in full compliance with all Federal health care program requirements, and the commitment of Inland to remain current with all applicable Federal health care program requirements.
2. Inland’s requirement that all Covered Persons shall be expected to comply with Inland’s own Policies and Procedures as implemented pursuant to this Section III.C (including the requirements of this Integrity Agreement).

3. The requirement that all of Inland's Covered Persons shall be expected to report to the Compliance Officer suspected violations of any Federal health care program requirements or Inland's own Policies and Procedures. Any Covered Person who makes an inquiry regarding compliance with Federal health care program requirements shall be able to do so without risk of retaliation or other adverse effect.

4. The requirement that Inland shall ensure that no managers, members, employees, contractors or agents of Inland are Ineligible Persons. For purposes of this Integrity Agreement, an "Ineligible Person" shall be any individual or entity who: (i) is currently excluded, debarred, 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, or otherwise declared ineligible. To ensure that such individuals are not Ineligible Persons, Inland shall check all prospective managers, members, employees, and agents prior to engaging their services against the HHS/OIG List of Excluded Individuals/Entities (available through the Internet at <http://oig.hhs.gov>) and the General Services Administration's List of Parties Excluded from Federal Programs (available through the Internet at <http://epls.arnet.gov>). In addition to prospective checks, Inland shall conduct annual checks of all managers, members, employees, and agents against each exclusion list.

5. The requirement that Inland review its business relationships for compliance with all Federal health care program requirements relating to 42 U.S.C. § 1320a-7b(b) (the "Anti-Kickback Statute") and 42 U.S.C. § 1395nn (the "Stark Law"), and the regulations and other guidance documents related to these statutes. Inland shall also ensure that it has policies and procedures requiring compliance with the provisions of Section III.E below.

At least annually (and more frequently if appropriate), Inland shall assess and update as necessary the Policies and Procedures. Within 45 days of the effective date of any revisions, the relevant portions of any such revised Policies and Procedures shall be made available to all individuals whose membership or job functions are related to those Policies and Procedures.

Within 120 days of the Effective Date and annually thereafter, each Covered Person shall certify in writing that he or she has read, understood, and shall abide by Inland's Policies and Procedures. New Covered Persons shall review the Policies and Procedures and shall complete the required certification within 30 days after becoming a Covered Person or within 120 days of the Effective Date of the Integrity Agreement, whichever is later.

Copies of the written policies and procedures shall be included in the first Annual Report. Copies of any written policies and procedures that are subsequently revised shall be included in the next subsequent Annual Report.

D. Training and Certification

Within 120 days following the Effective Date and at least once each year thereafter, all Covered Persons except those specified herein shall receive at least two hours of training. Physician members who are retired from the active practice of medicine and have surrendered their provider numbers; physician members who are not providing services to any Federal health care program beneficiaries; and those physician members who do not reside or practice medicine in the States of Washington or Idaho, and who complete annual certifications using the form at Attachment 2, need not receive training. The training shall be conducted by individuals with expertise in the relevant subject areas, e.g., the Anti-Kickback Statute and the Stark Law and may be received from a variety of sources (i.e., CME classes, hospitals, associations, carriers).

New Covered Persons shall receive the training described above within 45 days after becoming a Covered Person or within 120 days of the Effective Date, whichever is later. The training for New Covered Persons may either be provided internally by Covered Persons who have completed the required annual training or externally by a qualified individual or entity. Until they have received the requisite training, such New Covered Persons shall work under the direct supervision of a Covered Person who has received such training.

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

1. The legal sanctions and consequences for improper contracting or financial arrangements;

2. Examples of violations of the Anti-Kickback Statute and the Stark Law; and

3. A review of Inland's contracting Policies and Procedures related to Arrangements, as defined in Section III.E. below, and the personal obligation of each individual involved in the development or maintenance of Arrangements to know applicable legal requirements and Inland's Policies and Procedures.

Each Covered Person required to receive training shall annually certify in writing that he or she has received the required training. The certification shall specify the type of training received and the date received. Each Covered Person who is not required to receive training shall annually certify to that effect using the form appended to this Integrity Agreement as Attachment 2. Inland shall retain the certifications, along with the training course materials. The training course materials shall be provided in the Annual Report.

5. Contractual Compliance with the Anti-Kickback Statute and the Stark Law.

This Section III.E. shall apply to every arrangement or transaction that:

(1) (a) involves, directly or indirectly, the offer, payment, solicitation, or receipt of anything of value; and (b) is between Inland and any actual or potential source of health care business or referrals to Inland or any actual or potential recipient of health care business or referrals from Inland. The term "source" shall mean any physician, hospital, contractor, vendor, or agent and the term "health care business or referrals" shall be read to include referring, recommending, arranging for, ordering, leasing, or purchasing of any good, facility, item, or service for which payment may be made in whole or in part by a Federal health care program.

(2) is between Inland and a physician (or a physician's immediate family member (as defined at 42 C.F.R. § 411.351)) who makes a referral (as defined at 42 U.S.C. § 1395nn(h)(5)) to Inland for designated health services (as defined at 42 U.S.C. § 1395nn(h)(6)),

The arrangements and transactions described above, and the written versions thereof, are collectively referred to as “Arrangements.” The party(ies) to an Arrangement other than Inland shall be referred to herein as a “Contracting Party.”

Within 120 days after the Effective Date, Inland shall create procedures reasonably designed to ensure that each Arrangement does not violate the Anti-Kickback Statute and/or would not cause Inland or its members to violate the Stark Law, and shall implement procedures to evaluate all existing Arrangements, to the extent not already so evaluated, to determine whether such Arrangements violate the Anti-Kickback Statute and/or would cause Inland or its members to violate the Stark Law. Inland shall summarize all Arrangements in the form provided at Attachment 3. Inland shall update the summary at Attachment 3 annually and shall submit the summary with each Annual Report. Inland, at its option, may choose to submit Attachment 3 (and related documentation) to the OIG earlier than its submission with the Annual Report. However, to the extent that the early submission does not fully reflect all Arrangements, Inland shall ensure that an updated Attachment 3 is submitted with the next subsequent Annual Report.

Prior to entering into new Arrangements or renewing existing Arrangements, Inland shall evaluate all Arrangements for compliance with the Anti-Kickback Statute and determine if they would cause Inland or its members to violate the Stark Law, and the regulations related to these statutes. Inland shall also ensure that the Arrangements comply with the following requirements:

1. The Arrangement shall be set forth in writing and signed by Inland and the Contracting Party(ies);
2. The Arrangement shall include a provision that all individuals who meet the definition of Covered Persons shall comply with Inland’s compliance program, including the training related to the Anti-Kickback Statute and the Stark Law. Additionally, Inland shall provide each Contracting Party with a copy of its notice of compliance and its Stark and Anti-Kickback related policies and procedures;
3. Inland shall certify and shall require the Contracting Party(ies) to certify, at the time of signing the Arrangement and upon contract renewal, that the Arrangement is not intended to generate referrals for

services or supplies for which payment may be made in whole or in part under any Federal health care program; and

4. Inland shall require the Contracting Party(ies) to certify, at the time of signing the Arrangement, that the Contracting Party(ies) shall comply with Inland's compliance program and with the Anti-Kickback Statute and the Stark Law.

Inland shall retain and make available to OIG, upon request, copies of all written agreements relating to the Arrangements subject to this Section III.E. and, to the extent available, all nonprivileged communications related to the Arrangements and the actual performance of the duties under the Arrangements. Nothing in this Integrity Agreement, or any other communication or report made pursuant to this Integrity Agreement, shall constitute a waiver by Inland of its attorney-client, attorney work-product, or other applicable privileges. Notwithstanding that fact, the existence of any such privilege shall not be used by Inland to avoid its obligations to comply with the provisions of this Integrity Agreement.

F. Notification of Government Investigations or Legal Proceedings

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

G. Notification of Change in Membership

Within 30 days of any change in the composition of its membership, Inland shall notify the OIG, in writing, of the nature and reasons for the change. This notification shall include an identification of any individual(s) who divested his or her membership interest (voluntarily or involuntarily), acquired a membership interest in Inland, or increased or decreased his or her membership interest; the terms under which the membership interest was acquired or divested, or increased or decreased; the reasons for the divestiture, acquisition, increase or decrease; and contact information for any divesting member.

IV. ANNUAL REPORTS

Inland shall submit to the OIG Annual Reports with respect to the status of and findings regarding Inland's compliance activities for each of the three one-year periods beginning on the Effective Date. (The one-year period covered by each Annual Report shall be referred to as "the Reporting Period"). The first Annual Report shall be received by the OIG no later than 90 days after the end of the first Reporting Period. Subsequent Annual Reports shall be received by the OIG no later than the anniversary date of the due date of the first Annual Report.

Each Annual Report shall include:

1. For the first Annual Report, a copy of the written Policies and Procedures required by Section III.C. If revisions are made to the written Policies and Procedures developed pursuant to Section III.C after the submission of the first Annual Report, the next subsequent Annual Report shall include a copy of any Policies and Procedures that were revised;
2. A certification signed by the Compliance Officer attesting that the Policies and Procedures are being implemented and have been made available to all Covered Persons, and that all Covered Persons have executed the annual Policies and Procedures certification required by Section III.C;
3. A schedule, topic outline and copies of the training materials for the training programs attended in accordance with Section III.D of this Integrity Agreement and a certification by the Compliance Officer attesting that all Covered Persons who are so required have completed the initial training required by Section III.D and have executed the required certifications;
4. A certification signed by the Compliance Officer certifying that he or she is maintaining written certifications from all Covered Persons required to receive training that they received training pursuant to the requirements set forth in Section III.D of this Integrity Agreement;
5. Copies of the required certifications from those Covered Persons not

required to receive training, as set forth in Section III.D. and Attachment 2;

6. The summary of all Arrangements entered into by Inland required by Section III.E. and set forth on Attachment 3 of this Integrity Agreement;
7. A summary describing any ongoing investigation or legal proceeding required to have been reported pursuant to Section III.F. 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;
8. A summary of all changes in Inland's membership that occurred during the Reporting Period consistent with Section III.G;
9. A certification signed by the Compliance Officer certifying that all managers, members, employees, and agents are being screened against the HHS/OIG List of Excluded Individuals/Entities and the General Services Administration's List of Parties Excluded from Federal Programs; and
10. A certification signed by the Compliance Officer certifying that he or she has reviewed the Annual Report; he or she has made a reasonable inquiry regarding its content and believes that, upon such inquiry, the information is accurate and truthful.

V. NOTIFICATIONS AND SUBMISSION OF REPORTS

Unless otherwise stated subsequent to the execution of this Integrity Agreement, all notifications and reports required under the terms of this Integrity Agreement shall be submitted to the following:

OIG: Administrative and Civil Remedies Branch - Compliance Unit
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, S.W.
Washington, DC 20201
Ph. (202) 619-2078
Fax (202) 205-0604

Inland Empire Lithotripsy, LLC:

C. Frederick Hollon, M.D.
235 East Rowan, Suite 202
Spokane, WA 99207
Ph. (509) 483-6449
Fax. (509) 483-3122

Unless otherwise specified, all notifications and reports required by this Integrity Agreement may 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.

VI. OIG INSPECTION, AUDIT AND REVIEW RIGHTS

In addition to any other rights the OIG may have by statute, regulation, or contract, the OIG or its duly authorized representative(s) may examine or request copies of Inland's books, contracts, records, and other documents and supporting materials and/or conduct on-site reviews of any of Inland's locations for the purpose of verifying and evaluating: (a) Inland's compliance with the terms of this Integrity Agreement; and (b) Inland's compliance with the requirements of the Federal health care programs in which it participates. The documentation described above shall be made available by Inland to the OIG or its duly authorized representative(s) at all reasonable times for inspection, audit or reproduction. Furthermore, for purposes of this provision, the OIG or its duly authorized representative(s) may interview any of Inland's employees, members, 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 the OIG. Inland shall assist the OIG or its duly authorized representative(s) in contacting and arranging interviews with such individuals upon the OIG's request. Inland's members or employees may elect to be interviewed with or

without a representative of Inland present.

VII. DOCUMENT AND RECORD RETENTION

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

VIII. DISCLOSURES

Consistent with HHS's FOIA procedures, set forth in 45 C.F.R. Part 5, the OIG shall make a reasonable effort to notify Inland prior to any release by OIG of information submitted by Inland pursuant to its obligations under this Integrity Agreement and identified upon submission by Inland as trade secrets, or information that is commercial or financial and privileged or confidential, under the FOIA rules. With respect to such releases, Inland shall have the rights set forth at 45 C.F.R. § 5.65(d). Inland shall refrain from identifying any information as exempt from release if that information does not meet the criteria for exemption from disclosure under FOIA.

IX. BREACH AND DEFAULT PROVISIONS

Full and timely compliance by Inland is expected throughout the duration of this Integrity Agreement with respect to all of the obligations herein agreed to by Inland.

A. Stipulated Penalties for Failure to Comply with Certain Obligations

As a contractual remedy, Inland and OIG hereby agree that failure to comply with certain obligations set forth in this Integrity Agreement 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 \$1,000 (which shall begin to accrue on the day after the date the obligation became due) for each day Inland fails to:
 - a. have in place a Compliance Officer as required in Section III.A;
 - b. post the notice required in Section III.B;
 - c. implement and make available the Policies and Procedures required

in Section III.C;

- d. require that Covered Persons attend the training required by Section III.D of the Integrity Agreement within the time frames required in that Section;
- e. implement and follow procedures as required by Section III.E. that are designed to ensure that each Arrangement does not violate the Anti-Kickback Statute or cause Inland or its members to violate the Stark Law;
- 6. notify the OIG of any changes in membership as required by Section III.G., or
- g. meet any of the deadlines for the submission of the Annual Reports to OIG.

2. A Stipulated Penalty of \$750 (which shall begin to accrue on the date the failure to comply began) for each day Inland has an owner, officer, director, member, employee, contractor or agent an Ineligible Person and that person: (i) has responsibility for, or involvement with, Inland's business operations related to the Federal health care programs; or (ii) is in a position for which the person's salary or the items or services rendered, 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 (the Stipulated Penalty described in this paragraph shall not be demanded for any time period during which Inland can demonstrate that Inland did not discover the person's exclusion or other ineligibility after making a reasonable inquiry (as described in Section III.C.4) as to the status of the person).

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

4. A Stipulated Penalty of \$5,000 for each false certification submitted by or on behalf of Inland as part of any Annual Report, additional documentation to a report (as requested by the OIG), or otherwise required by this Integrity Agreement.

5. A Stipulated Penalty of \$750 for each day Inland fails to comply fully and adequately with any other obligation of this Integrity Agreement. In its notice to Inland, the OIG shall state the specific grounds for its determination that Inland has failed to comply fully and adequately with the Integrity Agreement obligation(s) at issue and

steps Inland shall take to comply with the Integrity Agreement. (This Stipulated Penalty shall begin to accrue 10 days after the date Inland receives notice from the OIG of the failure to comply.) A Stipulated Penalty as described in this paragraph shall not be demanded for any violation for which the OIG has sought a Stipulated Penalty under Paragraphs 1-4 of this Section.

B. Timely Written Requests for Extensions

Inland 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 Integrity Agreement. Notwithstanding any other provision in this Section, if the 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 Inland fails to meet the revised deadline set by the OIG. Notwithstanding any other provision in this Section, if the 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 Inland receives the 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 the 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 Inland has failed to comply with any of the obligations described in Section IX.A and after determining that Stipulated Penalties are appropriate, the OIG shall notify Inland of: (a) Inland's failure to comply; and (b) the OIG's exercise of its contractual right to demand payment of the Stipulated Penalties (this notification is hereinafter referred to as the "Demand Letter").

2. *Response to Demand Letter.* Within 10 days of the receipt of the Demand Letter, Inland shall respond by either: (a) curing the breach to the OIG's satisfaction and paying the applicable Stipulated Penalties; or (b) sending in writing to the OIG a request for a hearing before an HHS administrative law judge ("ALJ") to dispute the OIG's determination of noncompliance, pursuant to the agreed upon provisions set forth below in Section IX.E. In the event Inland elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until cures, to the OIG's satisfaction, the alleged breach in dispute. Failure to respond to the Demand Letter in one of these two

matters within the allowed time period shall be considered a material breach of this Integrity Agreement and shall be grounds for exclusion under Section IX.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 the OIG at the address set forth in Section V.

4. *Independence from Material Breach Determination.* Except as set forth in Section IX.D.1.c, these provisions for payment of Stipulated Penalties shall not affect or otherwise set a standard for the OIG's decision that Inland has materially breached this Integrity Agreement, which decision shall be made at the OIG's discretion and shall be governed by the provisions in Section IX.D, below.

D. Exclusion for Material Breach of this Agreement

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

- a. a repeated or flagrant violation of the obligations under this Integrity Agreement, including, but not limited to, the obligations addressed in Section IX.A;
- b. a failure to respond to a Demand Letter concerning the payment of Stipulated Penalties in accordance with Section IX.C; or
- c. a failure to conduct the review of Arrangements in accordance with Section III.E. of this Integrity Agreement.

2. *Notice of Material Breach and Intent to Exclude.* The parties agree that a material breach of this Integrity Agreement by Inland constitutes an independent basis for Inland's exclusion from participation in the Federal health care programs. Upon a determination by the OIG that Inland has materially breached this Integrity Agreement and that exclusion shall be imposed, the OIG shall notify Inland of: (a) Inland's material breach; and (b) the 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.* Inland shall have 30 days from the date of receipt of the Notice of Material Breach and Intent to Exclude to demonstrate to the OIG's

satisfaction that:

- a. Inland is in compliance with the obligations of the Integrity Agreement cited by the 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) Inland has begun to take action to cure the material breach; (ii) Inland is pursuing such action with due diligence; and (iii) Inland has provided to the OIG a reasonable timetable for curing the material breach.

4. *Exclusion Letter.* If at the conclusion of the 30-day period, Inland fails to satisfy the requirements of Section IX.D.3, the OIG may exclude Inland from participation in the Federal health care programs. The OIG shall notify Inland in writing of its determination to exclude Inland (this letter shall be referred to hereinafter as the “Exclusion Letter”). Subject to the Dispute Resolution provisions in Section IX.E, below, the exclusion shall go into effect 30 days after the date of the Exclusion Letter. The exclusion shall have national effect and shall also apply to all other Federal procurement and non-procurement programs. Reinstatement to program participation is not automatic. If at the end of the period of exclusion, Inland wishes to apply for reinstatement, Inland shall submit 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 the OIG's delivery to Inland of its Demand Letter or of its Exclusion Letter, and as an agreed-upon contractual remedy for the resolution of disputes arising under this Integrity Agreement, Inland 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 Integrity Agreement. Specifically, the 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 of the receipt of the Demand Letter and the request for a hearing involving exclusion shall be made within 25 days of 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 Integrity Agreement shall be: (a) whether Inland was in full and timely compliance with the obligations of this Integrity Agreement for which the OIG demands payment; and (b) the period of noncompliance. Inland shall have the burden of proving its full and timely compliance and the steps taken to cure the noncompliance, if any. The OIG shall not have the right to appeal to the DAB an adverse ALJ decision related to Stipulated Penalties. If the ALJ agrees with the OIG with regard to a finding of a breach of this Integrity Agreement and orders Inland to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable 20 days after the ALJ issues such a decision unless Inland 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 the 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 Integrity Agreement shall be:

- a. whether Inland was in material breach of this Integrity 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) Inland had begun to take action to cure the material breach within that period;

(ii) Inland has pursued and is pursuing such action with due diligence; and

(iii) Inland provided to the OIG within that period a reasonable timetable for curing the material breach and Inland has followed the timetable.

For purposes of the exclusion herein, exclusion shall take effect only after an ALJ decision favorable to the OIG, or, if the ALJ rules for Inland, only after a DAB decision in favor of the OIG. Inland's election of its contractual right to appeal to the DAB shall not abrogate the OIG's authority to exclude Inland upon the issuance of an ALJ's decision in favor of the OIG. If the ALJ sustains the determination of the OIG and determines that exclusion is authorized, such exclusion shall take effect 20 days after the ALJ issues such a decision, notwithstanding that Inland may request review of the ALJ decision by the DAB. If the DAB finds in favor of the OIG after an ALJ decision adverse to the OIG, the exclusion shall take effect 20 days after the DAB decision. Inland shall waive its 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 Inland, Inland shall be reinstated effective on the date of the original exclusion.

X. EFFECTIVE AND BINDING AGREEMENT

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

- A. This Integrity Agreement shall be binding on Inland and the OIG and their respective successors, assigns and transferees;
- B. This Integrity Agreement shall become final and binding on the date the final signature is obtained on the Integrity Agreement;

3. Any modifications to this Integrity Agreement shall be made with the prior written consent of the parties to this Integrity Agreement;
4. The undersigned Inland signatories represent and warrant that they are authorized to execute this Integrity Agreement. The undersigned OIG signatory represents that he is signing this Integrity Agreement in his official capacity and that he is authorized to execute this Integrity Agreement.

IN WITNESS WHEREOF, the parties hereto affix their signatures:

Inland Empire Lithotripsy, LLC

FOR Inland Empire Lithotripsy, LLC


C. Frederick Hollon, M.D.

1/30/03
Date

As to form:


Thomas L. Mills, Esq.
Gordon A. Coffee, Esq.
Marion K. Goldberg, Esq.
Counsel for Inland Empire Lithotripsy, LLC

1/30/03
Date

**Integrity Agreement:
Inland Empire Lithotripsy, LLC**

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

1/31/03
Date



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

NOTICE

Inland Empire Lithotripsy, LLC (“Inland”), wholly owned by urologists, is committed to complying with all ethical, professional, and Federal health care program requirements in the operation of its business.

If you wish to be treated at a facility not owned by your urologist, please contact the undersigned.

Anyone who has information or concerns about any possible violations of law or ethical treatment should contact the Compliance Officer at *(123) 456-7890* or via email at *[insert address]*. Reporting may also be made anonymously by sending correspondence to:

Name of Compliance Contact
Inland Empire Lithotripsy, LLC
Address
Phone Number
Fax Number

Attachment 2

CERTIFICATION

I, _____ [insert name], [Social Security Number _____ /date of birth _____], hereby certify that I did not receive training as required by Section III.D. of the Integrity Agreement entered between the Office of Inspector General (OIG) and Inland Empire Lithotripsy, LLC for the following reason(s) [check all that apply]:

- During the Reporting Period, I have been retired from the active practice of medicine and I have surrendered my Medicare and Medicaid provider numbers;
- During the Reporting Period, I have not provided services to any Federal health care program beneficiaries; and/or
- During the Reporting Period, I have not resided or practiced medicine in the States of Washington or Idaho.

I also certify that I shall notify the OIG, at the address listed below, at least twenty (20) days prior to any change in the status of any of the factors listed above.

Administrative and Civil Remedies Branch
Office of Counsel to the Inspector General
Office of Inspector General
U.S. Department of Health and Human Services
330 Independence Avenue, S.W.
Cohen Building, Room 5527
Washington, D.C. 20201

I hereby declare under penalty of perjury and the laws of the United States that the foregoing is true and correct.

Signature

Date

[Name - Typed or Printed]

