CORPORATE INTEGRITY AGREEMENT
BETWEEN THE
OFFICE OF INSPECTOR GENERAL
OF THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND
UROCOR, INC.

I. PREAMBLE

UroCor, Inc.("Urocor") hereby enters into this Corporate Integrity Agreement ("CIA") with the Office of Inspector General ("OIG") of the United States Department of Health and Human Services ("HHS") to promote compliance by its officers, directors, employees and any third parties, including contractors and agents (whether individual persons or entities), engaged to bill/submit reimbursement claims or that are responsible for the provision, marketing or documentation of items or services reimbursable by Federal health care programs, or in the preparation of claims, reports or other requests for reimbursement for such items or services ("Covered Persons") with the statutes, regulations and written directives of Medicare, Medicaid and all other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f))("Federal health care program requirements"). Contemporaneously with this CIA, UroCor is entering into a Settlement Agreement with the United States, and this CIA is incorporated by reference into the Settlement Agreement.

Prior to the execution of this CIA, UroCor voluntarily established a compliance program (hereinafter the "Compliance Plan" or the "Program") formally adopted by a Board of Directors' resolution in November 1998. As represented by UroCor in this CIA, the Compliance Plan provides for policies and procedures aimed at ensuring that its participation in the Federal health care programs conforms with Federal Health Care Program requirements. Therefore, pursuant to this CIA, UroCor hereby agrees to maintain in full operation the Compliance Plan for the term of this CIA. The Compliance Plan may be modified by UroCor as appropriate, but at a minimum, it shall comply with the integrity obligations set forth in this CIA.

II. TERM OF THE CIA

The period of the compliance obligations assumed by UroCor under this CIA shall be 5 years from the effective date of this CIA (unless otherwise specified). The effective date of this CIA shall be the date on which the final signatory of this CIA executes this CIA.

Sections VII, VIII, IX, X and XI shall remain in effect until OIG has completed its review of the final annual report and any additional materials submitted by UroCor pursuant to OIG's request.

III. CORPORATE INTEGRITY OBLIGATIONS

UroCor hereby agrees to maintain a Compliance Program that includes the following elements:

A. Compliance Officer and Committee.

1. *Compliance Officer.* For the duration of this CIA, UroCor shall continue to maintain an individual to serve as its Compliance Officer. The Compliance Officer shall be responsible for developing and implementing policies, procedures, and practices designed to ensure compliance with the requirements set forth in this CIA and with Federal health care program requirements. The Compliance Officer shall be a member of senior management of UroCor, shall make periodic (at least quarterly) reports regarding compliance matters directly to the Board of Directors of UroCor, and shall be authorized to report on such matters to the Board of Directors at any time. The Compliance Officer shall be responsible for monitoring the day-to-day compliance activities engaged in by UroCor as well as for any reporting obligations created under this CIA.

Any substantive changes in the identity or position description of the Compliance Officer, or any actions or changes that would affect the Compliance Officer's ability to perform the duties necessary to meet the obligations in this CIA, must be reported to OIG, in writing, within 30 days of such a change.

2. *Compliance Committee.* For the duration of this CIA, UroCor shall continue to maintain a Compliance Committee. The Compliance Committee shall, at a minimum, include the Compliance Officer and any other members of senior management

necessary to meet the requirements of this CIA (e.g., senior executives of each major department, such as billing, clinical, human resources, audit, and operations). The Compliance Officer shall chair the Compliance Committee and the Committee shall support the Compliance Officer in fulfilling his/her responsibilities (e.g., shall assist in the analysis of the organization's risk areas and shall oversee monitoring of internal and external audits and investigations).

Any substantive changes in the composition of the Compliance Committee, or any actions or changes that would affect the Compliance Committee's ability to perform the duties necessary to meet the obligations in this CIA, must be reported to OIG, in writing, within 30 days of such a change.

B. Written Standards.

1. *Code of Conduct.* UroCor represents its Program includes an "Ethics Policy" and "Standards of Conduct." For the duration of this CIA, UroCor shall continue to maintain its Ethics Policy and Standards of Conduct or similar code however denominated (hereinafter referred to as "Code of Conduct") and, to the extent necessary, shall amend the Program and/or Code of Conduct within 90 days of the effective date of this CIA to ensure that the Code of Conduct meets the following requirements. UroCor shall make the promotion of, and adherence to, the Code of Conduct an element in evaluating the performance of all employees. The Code of Conduct shall, at a minimum, set forth:

a. UroCor's commitment to full compliance with all Federal health care program requirements, including its commitment to prepare and submit accurate claims consistent with such requirements;

b. UroCor's requirement that all of its Covered Persons shall be expected to comply with all Federal health care program requirements and with UroCor's own Policies and Procedures as implemented pursuant to section III.B (including the requirements of this CIA);

c. the requirement that all of UroCor's Covered Persons shall be expected to report to the Compliance Officer or other individual designated by UroCor or the Confidential Disclosure Program suspected violations of any Federal health care program

requirements or of UroCor's own Policies and Procedures related thereto;

d. the possible consequences to both UroCor and Covered Persons of failure to comply with all Federal health care program requirements and with UroCor's own Policies and Procedures or of failure to report such non-compliance; and

e. the right of all individuals to use the Disclosure Program described in section III.E, and UroCor's commitment to maintain confidentiality, as appropriate, and non-retaliation with respect to disclosures.

To the extent not already distributed, the Code of Conduct shall be distributed to all Covered Persons within 90 days of the effective date of this CIA. Within 90 days of the effective date of the CIA, each Covered Person shall certify, in writing, that he or she has received, read, understood, and will abide by UroCor's Code of Conduct. New Covered Persons shall receive the Code of Conduct and shall complete the required certification within two weeks after becoming a Covered Person or within 90 days of the effective date of the CIA, whichever is later.

UroCor shall annually review the Code of Conduct to determine if revisions are appropriate and shall make any necessary revisions based on such a review. Any such revised Code of Conduct of Conduct shall be distributed within 45 days of finalizing such changes. Covered Persons shall certify that they have received, read, understood and will abide by the revised Code of Conduct within 30 days of the distribution of such revisions.

2. *Policies and Procedures*. Within 120 days of the effective date of this CIA, UroCor shall review and, where appropriate, revise or develop written policies and procedures to address the specific obligations identified below regarding the operation of UroCor's compliance program and its compliance with Federal health care program requirements. At a minimum, the Policies and Procedures shall address:

a. Code of Conduct: the subjects relating to the Code of Conduct identified in section III.B.1;

b. Laboratory Services. UroCor shall have policies and procedures designed to ensure adherence to relevant Federal health care program requirements

relating to the provision of and reimbursement for clinical laboratory services. At a minimum, such policies and procedures shall address the following issues in the manner prescribed below:

(1) Medical Necessity. UroCor shall (i) ensure that it does not engage in any conduct or activities that cause the submission of claims to Federal health care programs for laboratory tests and/or services that lack medical necessity; (ii) design and implement internal controls designed to prevent UroCor from receiving reimbursement for medically unnecessary tests; and (iii) communicate to physicians that claims submitted for service will only be paid if the services are covered, reasonable and medically necessary for the beneficiary, given his or her clinical condition;

(2) Test Ordering Procedure and Forms. UroCor shall ensure that all requisition forms (including computer-based ordering forms) are constructed to minimize the risk of any improper influence on the independence of the medical necessity decision by the physician or other authorized individual with regard to each test that UroCor bills for;

(3) Panels. UroCor shall ensure that to the extent it permits physicians to order tests by panels, UroCor fully discloses the contents of its panels on its test ordering forms or other test ordering system and gives physicians the option of ordering each test in a panel individually. If UroCor permits tests to be ordered as panels, procedures shall be in place to assure that the tests that compose the panels are properly billed to Federal health care programs.

(4) Billing. UroCor shall ensure that each claim submitted for payment to Federal health care programs reflects services that have been ordered pursuant to a valid order from the ordering physician or other authorized individual and have been performed.

(a) *CPT/HCPCS Codes*. UroCor shall ensure that the CPT/HCPCS codes used to bill services accurately describe the service that was ordered and performed.

(b) *ICD-9 Codes*. UroCor shall request physicians or other authorized individuals to submit diagnostic information as documentation of the medical necessity of the service. UroCor shall encourage ordering

physicians and other persons authorized to order tests to submit diagnoses in ICD-9 code format. UroCor shall ensure that when diagnoses received in non-ICD-9 format are translated into ICD-9 code format, such translations will be performed by persons with appropriate technical expertise.

(5) OIG Fraud Alert Compliance. UroCor shall ensure that it does not engage in improper practices identified in the OIG Fraud Alert for clinical laboratories published by the HHS/OIG in October 1994, regarding the provision of phlebotomy services to physicians. See 59 F.R. 65372 (December 19, 1994).

c. Kickbacks and Self-Referrals

(1) Generally. UroCor shall refrain from offering or paying anything of value (i.e., remuneration) to physicians or other referral sources in violation of the anti-kickback statute (codified at 42 U.S.C. § 1320a-7b(b)), the federal physician self referral prohibition (also known as the "Stark Statute" and codified at 42 U.S.C. § 1395nn), or other applicable statutes, regulations, and program requirements relating to payments to and from referral sources.

(2) Sales and Marketing. UroCor shall have policies and procedures designed to ensure that its sales and marketing practices and information are clear, accurate, informative and non-deceptive, and are designed to ensure that physicians and other individuals authorized to order tests, items, or services provided by UroCor understand the services offered by UroCor and the services that will be provided when tests, items or services are ordered. UroCor shall ensure that its marketing materials and sales tactics are not designed for the purpose of generating orders for unnecessary tests or services. UroCor shall not establish a commission structure that causes its sales staff to illegally influence a physician's judgment regarding the medical necessity of services offered by UroCor.

Within 120 days of the effective date of the CIA, the relevant portions of the Policies and Procedures shall be distributed to all individuals whose job functions are related to those Policies and Procedures. Appropriate and knowledgeable staff should be available to explain the Policies and Procedures.

At least annually (and more frequently if appropriate), UroCor 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

distributed to all individuals whose job functions are related to those Policies and Procedures.

C. Training and Education.

1. *General Training.* Within 120 days of the effective date of this CIA, UroCor shall provide at least two hours of general training to each Covered Person. This training, at a minimum, shall explain UroCor's:

a. CIA requirements; and

b. Compliance Program (including the Code of Conduct and the Policies and Procedures as they pertain to general compliance issues).

New Covered Persons shall receive the general training described above within 30 days of becoming a Covered Person or within 120 days after the effective date of this CIA, whichever is later. After receiving the initial training described above, each Covered Person shall receive at least one hour of general training annually.

2. *Specialized Training for Billing Personnel.* Within 120 days of the effective date of this CIA, each Covered Person who is involved in the the preparation or submission of claims for reimbursement from any Federal health care program (hereinafter referred to as "Relevant Covered Persons") shall receive at least 3 hours of specialized training in addition to the general training required above. This training shall cover relevant Federal health care program requirements and applicable policies and procedures. Specifically, the training shall address: :

a. the submission of accurate bills for services rendered to Federal health care program beneficiaries;

b. the personal obligation of each individual involved in the billing process to ensure that such billings are accurate;

c. applicable reimbursement statutes, regulations, and program requirements and directives;

d. the legal sanctions for improper billings; and

e. examples of proper and improper billing practices.

3. *Specialized Training for Sales and Marketing Personnel.* Within 120 days of the effective date of the CIA, each Covered Person who is involved in the sales or marketing of items and services furnished to beneficiaries of any Federal health care program (hereinafter referred to as "Relevant Covered Persons") shall receive 3 hours of specialized training in addition to the general compliance training described above. This training shall cover relevant Federal health care program requirements and applicable policies and procedures as well as other relevant regulatory matters relating to illegal kickbacks and prohibitions on physician self-referral arrangements.

Persons providing the training described in paragraph (2) and (3) above must be knowledgeable about the subject area.

New Relevant Covered Persons shall receive the applicable training described in paragraph (2) and (3) within 30 days of the beginning of their employment or becoming Relevant Covered Persons or within 120 days of the effective date of this CIA, whichever is later. A UroCor employee who has completed the applicable specialized training shall generally review a new Relevant Covered Person's work, to the extent that the work relates to the preparation or submission of claims or the sales or marketing of items or services for reimbursement from any Federal health care program, until such time as the new Relevant Covered Person completes applicable training

After receiving the initial training described in this section, every Relevant Covered Person shall receive at least 2 hours of applicable specialized training annually.

Any General or Specialized Training that has been provided to applicable Covered Persons within 6 months prior to the effective date of this CIA that meets the requirements of Paragraph C1, C2, or C3, respectively, shall be deemed to meet the initial training obligations required by the applicable Paragraph.

3. *Certification.* Each individual who is required to attend training shall 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. The Compliance Officer (or his or her designee) shall retain the certifications, along with all course materials. These shall be made available to OIG, upon request.

D. Review Procedures.

1. *General Description.*

a. Retention of Independent Review Organization. Within 120 days of the effective date of this CIA, UroCor shall retain an entity (or entities), such as an accounting, auditing or consulting firm (hereinafter "Independent Review Organization" or "IRO"), to perform review engagements to assist UroCor in assessing and evaluating its billing and coding practices and its compliance obligations pursuant to this CIA and the Settlement Agreement. Each Independent Review Organization retained by UroCor shall have expertise in the billing, coding, reporting and other requirements of the particular section of the health care industry pertaining to this CIA and in the general requirements of the Federal health care program(s) from which UroCor seeks reimbursement. Each IRO shall assess, along with UroCor, whether it can perform the IRO engagements in a professionally independent fashion taking into account any other business relationships or other engagements that may exist.

b. Types of Engagements. The Independent Review Organization(s) shall conduct two separate engagements. One engagement shall address UroCor's billing and coding to the Federal health care programs ("Billing Engagement"). The second engagement shall address UroCor's compliance with the obligations assumed under this CIA and the Settlement Agreement ("Compliance Engagement").

c. Frequency of Billing and Compliance Engagements. The Billing Engagement shall be performed annually (or as further qualified below regarding the "Systems Review") and shall cover each of the one-year periods beginning with the first day of the month immediately following the effective date of this CIA. The IRO(s) shall perform all components of each annual Billing Engagement. The Compliance Engagement shall be performed by the IRO for the first one-year period beginning with the effective date of this CIA.

d. Retention of Records. The IRO and UroCor shall retain and make available to the OIG, upon request, all work papers, supporting documentation, correspondence, and draft reports (those exchanged between the IRO and UroCor) related to the engagements.

2. *Billing Engagement.* The Billing Engagement shall be composed of two separate reviews, a "Claims Review" and a "Systems Review." The Claims Review and corresponding Claims Review Report are discussed in detail in Appendix A to this CIA, which is incorporated by reference.

a. Claims Review. The IRO shall perform a Claims Review to identify any overpayments through an appraisal of Paid Claims submitted by UroCor to the Medicare program. The Claims Review shall be performed in accordance with the procedures set forth in Appendix A to this CIA.

b. Claims Review Report. The IRO shall prepare a report based upon each Claims Review performed ("Claims Review Report"). The Claims Review Report shall be created in accordance with the procedures set forth in Appendix A to this CIA.

c. Systems Review. The IRO shall review UroCor's billing and coding systems and/or operations (the "Systems Review") for the first one-year period following the effective date of the CIA. Thereafter, the Systems Review shall be performed for any subsequent one-year period, only to the extent that there have been changes to the billing and coding systems and/or operations in that year; however, the OIG in its discretion may require that an additional Systems Review be performed in any subsequent one-year period in the event that the OIG determines that a prior Systems Review Report indicates significant weaknesses in UroCor's billing systems and/or operations. The Systems Review shall consist of a thorough review of the following:

i. UroCor's billing systems and/or operations relating to claims submitted to all Federal health care programs (including, but not limited to, the operation of the billing

system, safeguards to ensure proper claim submission and billing, and procedures to correct inaccurate billing);

ii. UroCor's coding systems and/or operations relating to claims submitted to all Federal health care programs (including, but not limited to, the process by which claims are coded, safeguards to ensure proper coding, and procedures to correct inaccurate coding).

d. Systems Review Report. The IRO shall prepare a report based upon each Systems Review performed ("Systems Review Report"). The Systems Review Report shall include the IRO's findings and supporting rationale regarding:

i. the strengths and weaknesses in UroCor's billing systems and/or operations;

ii. the strengths and weaknesses in UroCor's coding systems and/or operations; and

iii. any recommendations the IRO may have to improve any of these systems, operations, and processes.

3. *Compliance Engagement.*

a. Compliance Review. The IRO shall conduct a review of UroCor's compliance activities ("Compliance Review"). The Compliance Review shall consist of a review of UroCor's adherence to the obligations set forth in sections I through VIII of this CIA, and a review of UroCor's compliance with certain provisions of the Settlement Agreement.

i. CIA Obligations Review. The IRO shall assess and evaluate UroCor's compliance with the obligations set forth in sections I through VIII of this CIA.

ii. Unallowable Costs Review. To the extent applicable, the IRO shall determine whether UroCor has complied with its

obligation not to charge to, or otherwise seek payment from, Federal or State payors for unallowable costs (as defined in the Settlement Agreement) and its obligation to identify to applicable Federal or State payors any unallowable costs included in payments previously sought from the United States, or any State Medicaid program. This unallowable cost analysis shall include, but not be limited to, payments sought in any cost reports, cost statements, information reports, or payment requests already submitted by UroCor or any of its subsidiaries, and to request, and agree, that such cost reports, cost statements, information reports or payment requests, even if already settled, be adjusted to account for the effect of the inclusion of the unallowable costs. In making this determination, the IRO may need to review cost reports and/or financial statements from the year in which of the Settlement Agreement was executed, as well as from previous years.

b. Compliance Review Report. The IRO shall prepare a report based upon the Compliance Review performed (the "Compliance Review Report"). The Compliance Review Report shall include:

i. the IRO's findings, supporting rationale, and a summary of such findings and rationale regarding UroCor's compliance with the terms of sections I through VIII of the CIA, as applicable; and

ii. the IRO's findings and supporting rationale regarding whether UroCor has complied with its obligation not to charge to, or otherwise seek payment from, Federal or State payors for unallowable costs (as defined in the Settlement Agreement) and its obligation to identify to applicable Federal or State payors any unallowable costs included in payments previously sought from such payor

4. *Validation Review.* In the event the OIG has reason to believe that: (a) UroCor's Billing or Compliance Engagement fails to conform to the requirements of this CIA; or (b) the findings or Claims Review results are inaccurate, the OIG may, at its

sole discretion, conduct its own review to determine whether the Billing and Compliance Engagements comply with the requirements of the CIA and/or the findings or Claims Review results are inaccurate. Should the OIG make such request, UroCor agrees to pay for the reasonable cost of any such review performed by the OIG or any of its designated agents so long as it is initiated before one year after UroCor's final submission (as described in section II) is received by the OIG.

Prior to initiating a Validation Review, the OIG shall notify UroCor of its intent to do so and provide an explanation for believing why such a review is necessary. In order to resolve any concerns raised by the OIG, UroCor may request a meeting with the OIG to discuss the results of any Engagement submissions or any Claims Review findings; present any additional or relevant information to clarify the results of the Engagements or to correct the inaccuracy of the Claims Review; and/or propose alternatives to the proposed Validation Review. UroCor agrees to provide any additional information as may be reasonably requested by the OIG under this section in an expedited manner. The OIG will attempt in good faith to resolve any Billing or Compliance Engagement and/or Claims Review issues with UroCor prior to conducting a Validation Review. However, the final determination as to whether or not to proceed with a Validation Review shall be made at the sole discretion of the OIG.

5. *Independence Certification.* Within 150 days from the effective date of this CIA, the IRO shall provide to UroCor a certification or sworn affidavit that it has evaluated its professional independence with regard to the Billing and Compliance Engagements and that it has concluded that it is, in fact, independent. Such certification shall be included in UroCor's Implementation Report submission.

E. Disclosure Program.

For the duration of this CIA, UroCor shall maintain a Disclosure Program, that must include a mechanism (e.g., a toll-free compliance telephone line) to enable individuals to disclose, to the Compliance Officer or some other person who is not in the disclosing individual's chain of command, any identified issues or questions associated with UroCor's policies, conduct, practices, or procedures with respect to a Federal health care program, believed by the individual to be a potential violation of criminal, civil or administrative law. UroCor shall appropriately publicize the existence of the disclosure mechanism (e.g., via periodic e-mails to employees or by posting the information in prominent common areas).

The Disclosure Program shall emphasize a non-retribution, non-retaliation policy, and shall include a reporting mechanism for anonymous, confidential communications. Upon receipt of a disclosure, the Compliance Officer (or designee) shall gather all relevant information from the disclosing individual. The Compliance Officer (or designee) shall make a preliminary, good faith inquiry into the allegations set forth in every disclosure to ensure that he or she has obtained all of the information necessary to determine whether a further review should be conducted. For any disclosure that is sufficiently specific so that it reasonably: (1) permits a determination of the appropriateness of the alleged improper practice; and (2) provides an opportunity for taking corrective action, UroCor shall conduct an internal review of the allegations set forth in such a disclosure and ensure that proper follow-up is conducted.

The Compliance Officer (or his or her designee) shall maintain a disclosure log, which shall include a record and summary of each disclosure received (whether anonymous or not), the status of the respective internal reviews, and any corrective action taken in response to the internal reviews. The disclosure log shall be available to OIG, upon request.

F. Ineligible Persons.

1. *Definition*. For purposes of this CIA, an "Ineligible Person" shall be any individual or entity who: (a) is currently excluded, debarred or otherwise ineligible to participate in the Federal health care programs or in Federal procurement or non-procurement programs; or (b) has been convicted of a criminal offense related to the provision of health care items or services, but has not yet been excluded, debarred or otherwise declared ineligible.

2. *Screening Requirements*. UroCor shall not hire as employees or engage as contractors, who meet the definition of Covered Persons, any Ineligible Person. To prevent hiring or contracting with any Ineligible Person, UroCor shall screen all prospective employees and prospective contractors, who meet the definition of Covered Persons, prior to engaging their services by: (a) requiring applicants to disclose whether they are Ineligible Persons; and (b) reviewing the General Services Administration's List of Parties Excluded from Federal Programs (available through the Internet at http://epls.arnet.gov) and the HHS/OIG List of Excluded Individuals/Entities (available through the Internet at http://www.hhs.gov/oig) (these lists will hereinafter be referred to as the "Exclusion Lists").

3. *Review and Removal Requirement.* Within 120 days of the effective date of this CIA, UroCor shall review its list of current employees and contractors against the Exclusion Lists. Thereafter, UroCor shall review its list of current employees and contractors against the Exclusion Lists annually. In addition, UroCor shall require employees and contractors to disclose immediately any debarment, exclusion or other event that makes the employee an Ineligible Person.

If UroCor has notice that an employee or contractor has become an Ineligible Person, UroCor shall remove such person from responsibility for, or involvement with, UroCor's business operations related to the Federal health care programs and shall remove such person from any 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 at least until such time as the person is reinstated into participation in the Federal health care programs.

4. *Pending Charges and Proposed Exclusions.* If UroCor has notice that an employee or contractor is charged with a criminal offense related to any Federal health care program, or is proposed for exclusion during his or her employment or contract, UroCor shall take all appropriate actions to ensure that the responsibilities of that employee or contractor 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 of discovery, UroCor shall notify OIG, in writing, of any ongoing investigation or legal proceeding conducted or brought by a federal governmental entity or its agents involving an allegation that UroCor 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. UroCor shall also provide written notice to OIG within 30 days of the resolution of the matter, and shall provide OIG with a description of the findings and/or results of the proceedings, if any. The term "discovery" for purposes of this Paragraph III.G. shall mean any UroCor employee occupying a supervisory, managerial or executive position or exercising supervisory, managerial or executive duties that knows or has reason to know of an investigation or legal proceeding as further described above.

H. Reporting.

1. *Overpayments*

a. Definition of Overpayments. For purposes of this CIA, an "overpayment" shall mean the amount of money UroCor has received in excess of the amount due and payable under any Federal health care program requirements. UroCor may not subtract any underpayments for purposes of determining the amount of relevant "overpayments" for CIA reports.

b. Reporting of Overpayments. If, at any time, UroCor identifies or learns of any overpayments, UroCor shall notify the payor (e.g., Medicare fiscal intermediary or carrier) within 30 days of identification of the overpayment and take remedial steps within 60 days of discovery (or such additional time as may be agreed to by the payor) to correct the problem, including preventing the underlying problem and the overpayments from recurring. Also, within 30 days of identification of the overpayment, UroCor shall repay the overpayment to the appropriate payor to the extent such overpayment has been quantified. If not yet quantified, within 30 days of identification, UroCor shall notify the payor of its efforts to quantify the overpayment amount along with a schedule of when such work is expected to be completed. Notification and repayment to the contractor should be done in accordance with the contractor policies, and for Medicare contractors, must include the information contained on the Overpayment Refund Form, provided as Appendix B to this CIA.

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. *Material Deficiencies.*

a. Definition of Material Deficiency. For purposes of this CIA, a "Material Deficiency" means anything that involves:

(i) a substantial overpayment;

(ii) a matter that a reasonable person would consider a potential violation of criminal, civil, or administrative laws applicable to any Federal health care program for which penalties or exclusion may be authorized.

A Material Deficiency may be the result of an isolated event or a series of occurrences.

b. Reporting of Material Deficiencies. If UroCor determines through any means that there is a Material Deficiency, UroCor shall notify OIG, in writing, within 30 days of making the determination that the Material Deficiency exists. The report to the OIG shall include the following information:

(i) If the Material Deficiency results in an overpayment, the report to the 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) on which the overpayment was repaid/refunded;

(ii) a complete description of the Material Deficiency, including the relevant facts, persons involved, and legal and Federal health care program authorities implicated;

(iii) a description of UroCor's actions taken to correct the Material Deficiency; and

(iv) any further steps UroCor plans to take to address the Material Deficiency and prevent it from recurring.

I. Cooperation

UroCor (and any predecessor) agrees to provide continued cooperation to the FBI and United States Attorney's Office for the Western District of Oklahoma for the course of the criminal investigation, including the production of documents and data from the Cortex system. UroCor (and any predecessor) agrees to maintain the Cortex System and its data in tact. UroCor (and any predecessor) agrees to provide technical assistance when needed to retrieve data and information from the Cortex system. All such cooperation described above shall continue until the termination of the criminal investigation, including prosecution of all defendants.

"Criminal Investigation" means the investigation of conduct and/or practices at UroCor from 1992 to 2000 that may violate the anti-kickback statute, 42 U.S.C. § 1320a-7b, or the health care fraud statute, 18 U.S.C. § 1347; and conduct that may constitute obstruction of justice, 18 U.S.C. §§ 1510 and 1518, from 1997 through the present date.

IV. NEW BUSINESS UNITS OR LOCATIONS

In the event that, after the effective date of this CIA, UroCor changes locations or purchases or establishes new business units related to the furnishing of items or services that may be reimbursed by Federal health care programs, UroCor shall notify OIG of this fact as soon as possible, but no later than within 30 days of the date of change of location, purchase or establishment. This notification shall include the location of the new operation(s), phone number, fax number, Medicare provider number(s) (if any), and the corresponding contractor's name and address that has issued each Medicare provider number. All Covered Persons at such locations shall be subject to the applicable requirements in this CIA (e.g., completing certifications and undergoing training).

V. IMPLEMENTATION AND ANNUAL REPORTS

A. Implementation Report. Within 150 days after the effective date of this CIA, UroCor shall submit a written report to OIG summarizing the status of its implementation of the requirements of this CIA. This Implementation Report shall include:

1. the name, address, phone number, position description, and summary of other non-compliance job responsibilities of the Compliance Officer required by section III.A;

2. the names and positions of the members of the Compliance Committee required by section III.A;

3. a copy of UroCor's Code of Conduct required by section III.B.1;

4. a copy of all compliance-related Policies and Procedures required by section III.B.2 and a summary of all other Policies and Procedures required by section III.B.2;

5. a copy of all training materials used for the training required by section III.C, a description of such training, including a description of the targeted audiences, length of sessions, which sessions were mandatory and for whom, percentage of attendance, and a schedule of when the training sessions were held;

6. a certification by the Compliance Officer that:

   a. the Policies and Procedures required by section III.B have been developed, are being implemented, and have been distributed to all appropriate Covered Persons;

   b. all Covered Persons have completed the Code of Conduct certification required by section III.B.1; and

   c. all Covered Persons have completed the applicable training and executed the certification(s) required by section III.C.;

The documentation supporting this certification shall be available to OIG, upon request.

7. a description of the Disclosure Program required by section III.E;

8. the identity of the IRO(s), a summary/description of all engagements between UroCor and the IRO, including, but not limited to, any outside financial audits, compliance program engagements, or reimbursement consulting, and the proposed start and completion dates of the first annual review;

9. a certification from the IRO regarding its professional independence from UroCor;

10. a summary of personnel actions (other than hiring) taken pursuant to section III.F.;

11. a list of all of UroCor'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 identification number(s) and the contractor's name and address that issued each provider identification number;

12. to the extent not already furnished to OIG, or if modified, a description of UroCor's corporate structure, including identification of any parent and sister companies, subsidiaries and their respective lines of business; and

13. the certification required by section V.C.

B. Annual Reports. UroCor shall submit to OIG Annual Reports with respect to the status of, and findings regarding, UroCor's compliance activities for each of the five one-year periods beginning on the effective date of the CIA. (The one-year period covered by each Annual Report shall be referred to as "the Reporting Period").

Each Annual Report shall include:

1. any change in the identity, position description, or other non-compliance job responsibilities of the Compliance Officer and any change in the membership of the Compliance Committee described in section III.A;

2. a certification by the Compliance Officer that:

a. all Covered Persons have completed any Code of Conduct certifications required by section III.B.1;

b. all Covered Persons have completed the applicable training and executed the certification(s) required by section III.C;

c. UroCor has complied with its obligations under the Settlement Agreement: (i) not to resubmit to any Federal health care program payors any previously denied claims related to the Covered Conduct addressed in the Settlement Agreement, and not to appeal any such denials of claims; (ii) not to charge to or otherwise seek payment from Federal or State payors for unallowable costs (as defined in the Settlement Agreement); and (iii) to identify and adjust any past charges or claims for unallowable costs;

The documentation supporting this certification shall be available to OIG, upon request.

3. a summary of any significant changes or amendments to the Policies and Procedures required by section III.B and the reasons for such changes (e.g., change in contractor policy) and copies of any compliance-related Policies and Procedures;

4. a copy of all training materials used for the training required by section III.C (to the extent it has not already been provided as part of the Implementation Report), a description of such training conducted during the Reporting Period, including a description of the targeted audiences, length of sessions, which sessions were mandatory and for whom, percentage of attendance, and a schedule of when the training sessions were held;

5. a complete copy of all reports prepared pursuant to the IRO's billing and compliance engagements, including a copy of the methodology used, along with a copy of the IRO's engagement letter;

6. UroCor's response and corrective action plan(s) related to any issues raised by the IRO(s);

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

8. a summary of Material Deficiencies (as defined in III.H) identified during the Reporting Period and the status of any corrective and preventative action relating to all such Material Deficiencies;

9. a report of the aggregate overpayments that have been returned to the Federal health care programs. Overpayment amounts should be broken down into the following categories: inpatient Medicare, outpatient Medicare, Medicaid (report each applicable state separately) and other Federal health care programs;

10. a summary of the disclosures in the disclosure log required by section III.E that relate to Federal health care programs;

11. a description of any personnel actions (other than hiring) taken by UroCor as a result of the obligations in section III.F, and the name, title, and responsibilities of any person that falls within the ambit of section III.F.4, and the actions taken in response to the obligations set forth in that section;

12. 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;

13. a description of all changes to the most recently provided list (as updated) of UroCor's locations (including locations and mailing addresses) as required by section V.A.10, the corresponding name under which each location is doing business, the corresponding phone numbers and fax numbers, each location's Federal health care program provider identification number(s), and the contractor name and address that issued each provider identification number; and

14. the certification required by section V.C.

The first Annual Report shall be received by the OIG no later than 120 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. Certifications. The Implementation Report and Annual Reports shall include a certification by the Compliance Officer that: (1) except as otherwise described in the applicable report, UroCor is in compliance with all of the requirements of this CIA, to the best of his or her knowledge; and (2) the Compliance Officer has reviewed the Report and has made reasonable inquiry regarding its content and believes that the information is accurate and truthful.

D. Designation of Information: UroCor shall clearly identify any portions of its submissions that it 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. UroCor shall refrain from identifying any information as exempt from disclosure if it has reason to believe 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 of this CIA, all notifications and reports required under this CIA shall be submitted to the following entities:

OIG:

Civil Recoveries 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, SW
Washington, DC 20201
Phone 202.619.2078
Fax 202.205.0604

UroCor:

Melissa A. Walker
Chief Compliance Officer
UroCor, Inc.
840 Research Parkway
Oklahoma City, OK 73104
Phone 405.290.4112
Fax 405.290.4059

Unless otherwise specified, all notifications and reports required by this CIA 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.

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 upon reasonable notice examine or request copies of UroCor's books, records, and other documents and supporting materials

and/or conduct on-site reviews of any of UroCor's locations for the purpose of verifying and evaluating: (a) UroCor's compliance with the terms of this CIA; and (b) UroCor's compliance with the requirements of the Federal health care programs in which it participates. The documentation described above shall be made available by UroCor 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 UroCor'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. UroCor agrees to assist OIG or its duly authorized representative(s) in contacting and arranging interviews with such individuals upon OIG's request. UroCor's employees may elect to be interviewed with or without a representative of UroCor present.

VIII. DOCUMENT AND RECORD RETENTION

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

IX. DISCLOSURES AND PRIVILEGES

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

Nothing in this CIA, or any communication or report made pursuant to this CIA, shall constitute a waiver of, or be construed to require UroCor to waive its attorney-client, work product or other applicable privileges. Notwithstanding that fact, the existence of any such privilege does not affect UroCor's obligation to comply with the provisions of this CIA.

X. BREACH AND DEFAULT PROVISIONS

UroCor is expected to fully and timely comply with all of its CIA obligations.

A. Stipulated Penalties for Failure to Comply with Certain Obligations. As a contractual remedy, UroCor and OIG hereby agree that failure to comply with certain obligations set forth in this CIA 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 $2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day UroCor fails to have in place any of the obligations described in section III:

a. a Compliance Officer;

b. a Compliance Committee;

c. a written Code of Conduct;

d. written Policies and Procedures;

e. a requirement that Covered Persons be trained; and

f. a Disclosure Program.

2. A Stipulated Penalty of $2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day UroCor fails to retain an IRO, as required in section III.D.

3. A Stipulated Penalty of $2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day UroCor fails to meet any of the deadlines for the submission of the Implementation Report or the Annual Reports to OIG.

4. A Stipulated Penalty of $2,000 (which shall begin to accrue on the date the failure to comply began) for each day UroCor employs or contracts with an Ineligible Person and that person: (i) has responsibility for, or involvement with, UroCor'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 UroCor can demonstrate that it did not discover the person's exclusion or other ineligibility after making a reasonable inquiry (as described in section III.F) as to the status of the person).

5. A Stipulated Penalty of $1,500 for each day UroCor fails to grant access to the information or documentation as required in section VII of this CIA. (This Stipulated Penalty shall begin to accrue on the date UroCor fails to grant access.)

6. A Stipulated Penalty of $1,000 for each day UroCor fails to comply fully and adequately with any obligation of this CIA. In its notice to UroCor, OIG shall state the specific grounds for its determination that UroCor has failed to comply fully and adequately with the CIA obligation(s) at issue and steps UroCor must take to comply with the CIA. (This Stipulated Penalty shall begin to accrue 10 days after the date that OIG provides notice to UroCor 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 1-5 of this section. With respect to the Stipulated Penalty provision described in this section X.A.6 only, the OIG shall not seek a Stipulated Penalty if UroCor demonstrates to the OIG's satisfaction that the alleged failure to comply could not be cured within the 10-day period, but that: (i) UroCor has begun to take action to cure the failure to comply, (ii) UroCor is pursuing such action with due diligence, and (iii) UroCor has provided to OIG a reasonable timetable for curing the failure to comply.

B. Timely Written Requests for Extensions. UroCor 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 CIA. 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 UroCor fails to meet the revised deadline set by OIG. Notwithstanding any other provision in this section, if OIG denies such a timely written request, Stipulated Penalties for failure to perform the act or file the notification or report shall not begin to accrue until three business days after UroCor receives OIG's written denial of such request or the original due date, whichever is later. A "timely written request" is defined as a request in writing received by OIG at least five business

days prior to the date by which any act is due to be performed or any notification or report is due to be filed.

C. Payment of Stipulated Penalties.

1. *Demand Letter.* Upon a finding that UroCor has failed to comply with any of the obligations described in section X.A and after determining that Stipulated Penalties are appropriate, OIG shall notify UroCor of: (a) UroCor'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, UroCor shall either: (a) cure the breach to OIG's satisfaction and pay the applicable Stipulated Penalties; or (b) request 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 UroCor elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until UroCor cures, to OIG's satisfaction, the alleged breach in dispute. Failure to respond to the Demand Letter in one of these two manners within the allowed time period shall be considered a material breach of this CIA 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 UroCor has materially breached this CIA, 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 CIA

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

a. a failure by UroCor to report a material deficiency, 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 CIA, including, but not limited to, the obligations addressed in section X.A;

c. a failure to respond to a Demand Letter concerning the payment of Stipulated Penalties in accordance with section X.C; or

d. a failure to retain and use an Independent Review Organization in accordance with section III.D.

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

3. *Opportunity to Cure.* UroCor 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. UroCor is in compliance with the obligations of the CIA 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) UroCor has begun to take action to cure the material breach; (ii) UroCor is pursuing such action with due diligence; and (iii) UroCor has provided to OIG a reasonable timetable for curing the material breach.

4. *Exclusion Letter.* If at the conclusion of the 30-day period, UroCor fails to satisfy the requirements of section X.D.3, OIG may exclude UroCor from participation in the Federal health care programs. OIG will notify UroCor in writing of its determination to exclude UroCor (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 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, UroCor wishes to apply for reinstatement, UroCor must 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 OIG's delivery to UroCor of its Demand Letter or of its Exclusion Letter, and as an agreed-upon contractual remedy for the resolution of disputes arising under this CIA, UroCor 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 CIA. 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 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 CIA shall be: (a) whether UroCor was in full and timely compliance with the obligations of this CIA for which the OIG demands payment; and (b) the period of noncompliance. UroCor shall have the burden of proving its full and timely compliance and the steps taken to cure the noncompliance, if any. If the ALJ agrees with OIG with regard to a finding of a breach of this CIA and orders UroCor to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable 20 days after the ALJ issues such a decision unless UroCor 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 CIA shall be:

a. whether UroCor was in material breach of this CIA;

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) UroCor had begun to take action to cure the material breach within that period;

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

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

For purposes of the exclusion herein, exclusion shall take effect only after an ALJ decision favorable to OIG, or, if the ALJ rules for the UroCor, only after a DAB decision in favor of OIG. UroCor's election of its contractual right to appeal to the DAB shall not abrogate the OIG's authority to exclude UroCor 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 UroCor 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. UroCor agrees to waive its/his/her right to any notice of such an exclusion if a decision upholding the exclusion is rendered by the ALJ or DAB.

XI. EFFECTIVE AND BINDING AGREEMENT

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

A. This CIA shall be binding on the successors, assigns, and transferees of UroCor; however, the OIG at its sole discretion, may waive this requirement upon request

from UroCor and/or any such successor, assignee or transferee, provided that they provide to the OIG all necessary information to enable the OIG to determine the applicability of the CIA to the successor entity.

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

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

D. OIG may agree to a suspension of UroCor's obligations under the CIA in the event of UroCor's cessation of participation in Federal health care programs. If UroCor withdraws from participation in Federal health care programs and is relieved from its CIA obligations by the OIG, UroCor agrees to notify OIG 30 days in advance of UroCor's intent to reapply as a participating provider or supplier with the Federal health care programs. Upon receipt of such notification, OIG will evaluate whether the CIA should be reactivated or modified.

E. The undersigned UroCor signatories represent and warrant that they are authorized to execute this CIA. The undersigned OIG signatory represents that he is signing this CIA in his official capacity and that he is authorized to execute this CIA.

ON BEHALF OF UROCOR, INC.

Michael W. George
Chief Executive Officer
UroCor, Inc.

June 12, 2001
DATE

Joe D. Whitley, Esq.
Alston & Bird LLP
Counsel to UroCor, Inc.

June 9, 2001
DATE

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

LEWIS MORRIS
Assistant Inspector General for Legal Affairs
Office of Inspector General
U. S. Department of Health and Human Services

6/14/07
DATE

APPENDIX A

A. Claims Review.

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

a. Claims Review Sample: A statistically valid, randomly selected, sample of items selected for appraisal in the Claims Review.

b. Item: Any discrete unit that can be sampled (e.g., code, line item, beneficiary, patient encounter, etc.).

c. Overpayment: Consistent with the definition of Overpayment as articulated in section III.H.1.a of the CIA, the amount of money UroCor has received in excess of the amount due and payable under any Federal health care program requirements. For the purposes of the Claims Review and all reporting to the OIG under this CIA, UroCor shall not subtract or "net out" underpayments when determining the amount of relevant Overpayments.

d. Paid Claim: A code or line item submitted by UroCor and for which UroCor has received reimbursement from the Medicare or Medicaid program.

e. Population: All Items for which UroCor has submitted a code or line item and for which UroCor has received reimbursement from the Medicare or Medicaid program (i.e., a Paid Claim) during the 12-month period covered by the Claims Review. To be included in the Population, an Item must have resulted in at least one Paid Claim.

f. Probe Sample: A sample of Items selected through simple random sampling from the Population for the purpose of estimating the mean and standard deviation of Overpayments in the Population. The estimated mean and standard deviation of Overpayments in the Population are to be used to calculate the minimum number of Items that shall be included in the Claims Review Sample in order to achieve the required confidence and precision levels.

g. RAT-STATS: OIG's Office of Audit Services Statistical Sampling Software. RAT-STATS is publicly available to download through the

Internet at "www.hhs.gov/oig/oas/ratstat.html".

2. ***Description of Claims Review***. The Claims Review shall consist of an appraisal of a statistically valid sample of Items (the Claims Review Sample) that can be projected to the total Population.

a. Confidence and Precision Requirements. The Claims Review Sample should contain a sufficient number of Items (according to the RAT-STATS calculation) so that if the Overpayments identified in the Claims Review Sample were projected to the Population, the projection would provide a 90% confidence level and a maximum relative precision (i.e., semi-width of the confidence interval) of plus or minus 25% of the point estimate. In other words, if the Claims Review Overpayment results were projected to the Population at a 90% confidence level, the confidence interval (expressed in dollars) should be sufficiently narrow that the upper bound of the confidence interval would not exceed 125% of the midpoint of the confidence interval (the point estimate), and the lower bound of the confidence interval would not be less than 75% of the midpoint of the confidence interval.

b. Use of a Probe Sample to Determine Claims Review Sample Size. To determine how many Items must be included in the Claims Review Sample to meet the 90% confidence level and 25% precision requirements, the mean and the standard deviation of Overpayments in the Population must be estimated. Estimates for each unique Population shall be developed through the use of a single Probe Sample. The Probe Sample shall be used to determine the minimum Claims Review Sample size through one of the two following options:

i. *Probe Sample with a Minimum Size of Thirty Items*. The Probe Sample shall include at least 30 Items, and shall be selected through the use of RAT-STATS' "Random Numbers" function. Once all Paid Claims associated with the Items included in the Probe Sample have been reviewed, the estimated mean and standard deviation of Overpayments in the Population shall be determined. This determination is based on the Overpayment amount received by UroCor for each Item in the sample. The "Difference Values Only" function located under the "Variable Appraisals" component of RAT-STATS shall be used to calculate the estimated mean and standard deviation of Overpayments in the Population. For purposes

of estimating the mean and standard deviation of Overpayments in the Population, and entering this information into the "Variable Appraisals", "Difference Values Only" function of RAT-STATS, any underpayment identified for a Paid Claim in the Probe Sample shall be treated as a zero overpayment. If no Overpayments are found in this Probe Sample, then a second Probe Sample, of at least 30 Items, must be selected and reviewed. The estimated mean and standard deviation of Overpayments in the Population (based on the amount of Overpayments received by UroCor for each sample Item) shall be determined from this Probe Sample, using RAT-STATS' "Difference Values Only" function located under the "Variable Appraisals" component. If no Overpayments are found in this second Probe Sample, then the Claims Review can be terminated with the results of the second Probe Sample, and the results of the two Probe Samples shall be reported in lieu of the Claims Review when preparing and submitting the Claims Review Report (see section B, below); or

ii. *Probe Sample with a Minimum Size of Fifty Items*. The Probe Sample shall include at least 50 Items, and shall be selected through the use of RAT-STATS' "Random Numbers" function. Once all Paid Claims associated with the Items included in the Probe Sample have been reviewed, the estimated mean and standard deviation of Overpayments in the Population shall be determined. This determination is based on the Overpayment amount received by UroCor for each Item in the sample. The "Difference Values Only" function located under the "Variable Appraisals" component of RAT-STATS shall be used to calculate the estimated mean and standard deviation of Overpayments in the Population. For purposes of estimating the mean and standard deviation of Overpayments in the Population, and entering this information into the "Variable Appraisals", "Difference Values Only" function of RAT-STATS, any underpayment identified for a Paid Claim in the Probe Sample shall be treated as a zero overpayment. If no Overpayments are found in this 50 Item Probe Sample, then the Claims Review can be terminated with the review of the Probe Sample and the results of the Probe Sample shall be reported in lieu of the results of the Claims Review when preparing and submitting the Claims Review Report (see section B, below).

c. Calculation of Claims Review Sample Size and Selection of the Claims Review Sample. The estimates of the mean and the standard deviation of Overpayments in the Population obtained through the review of the Probe Sample shall be used to estimate the minimum size of the Claims Review Sample. In order to estimate the number of Items that must be included in the Claims Review Sample to meet the 90% confidence level and 25% precision requirements, RAT-STATS' "Sample Size Estimators" (located under the "Utility Programs" file) shall be used. Whereas the Claims Review Sample size is estimated from the results of the probe sample, there is a possibility that examining the number of Items identified by RAT-STATS may not achieve the 90% confidence and 25% precision levels. If the reviewer can demonstrate that the review was properly conducted, but the 90% confidence level and 25% precision interval could not be achieved, the reviewer will not be required to examine additional items.

The Claims Review Sample shall be selected by using RAT-STATS' "Random Numbers" function, and shall be selected from the entire Population, with the Population including those Items reviewed as part of the Probe Sample, so that all Items in the Population have an equal chance of inclusion in the Claims Review Sample.

d. Item Appraisal. For each Item appraised (either as part of the Claims Review Sample or of the Probe Sample), only Paid Claims shall be evaluated. Every Paid Claim in the Claims Review Sample shall be evaluated by the IRO to determine whether the claim submitted was correctly coded, submitted, and reimbursed. Each appraisal must be sufficient to provide all information required under the Claims Review Report.

e. Paid Claims without Supporting Documentation. For the purpose of appraising Items included in the Claims Review and/or the Probe Sample, any Paid Claim for which UroCor cannot produce documentation sufficient to support the Paid Claim shall be considered an error and the total reimbursement received by UroCor for such Paid Claim shall be deemed an Overpayment. Replacement sampling for Paid Claims with missing documentation is not permitted.

f. Use of First Samples Drawn. For the purposes of all samples (Probe Sample(s) and Claims Review Sample(s)) discussed in this Appendix, the Paid Claims associated with the Items selected in the first sample (or first

sample for each strata, if applicable) shall be used. In other words, it is not permissible to generate a number of random samples and then select one for use as the Probe Sample or Claims Review Sample.

B. Claims Review Report. The following information shall be included in each Claims Review Report:

1. ***Claims Review Methodology***

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

b. Sampling Unit: A description of the Item as that term is utilized for the Claims Review. As noted in section A.1.b above, for purposes of this Billing Engagement, the term "Item" may refer to any discrete unit that can be sampled (e.g., claim, line item, beneficiary, patient encounter, etc.).

c. Claims Review Population: A description of the Population subject to the Claims Review.

d. Sampling Frame: A description of the sampling frame, which is the totality of Items from which the Probe and Claims Review Sample have been selected and an explanation of the methodology used to identify the sampling frame. In most circumstances, the sampling frame will be identical to the Population.

e. Sources of Data: A description of the documentation relied upon by the IRO when performing the Claims Review (e.g., medical records, physician orders, certificates of medical necessity, requisition forms, local medical review policies, HCFA program memoranda, Medicare carrier or intermediary manual or bulletins, other policies, regulations, or directives).

f. Review Protocol: A narrative description of how the Claims Review was conducted and what was evaluated.

2. ***Statistical Sampling Documentation***

a. The number of Items appraised in the Probe Sample(s) and in the Claims Review Sample.

b. A copy of the RAT-STATS printout of the random numbers generated by the "Random Numbers" function.

c. A copy of the RAT-STATS printout of the "Sample Size Estimators" results used to calculate the minimum number of Items for inclusion in the Claims Review Sample.

d. A copy of the RAT-STATS printout of the "Variable Appraisals", "Difference Vaues Only" function results for the Probe Sample, including a copy of the data file.

e. The Sampling Frame used in the Probe Sample(s) and the Claims Review Sample will be available to the OIG upon request.

3. ***Claims Review Results***

a. Total number and percentage of instances in which the IRO determined that the Paid Claims submitted by UroCor ("Claim Submitted") differed from what should have been the correct claim ("Correct Claim"), regardless of the effect on the payment.

b. Total number and percentage of instances in which the Claim Submitted differed from the Correct Claim and in which such difference resulted in an Overpayment to UroCor.

c. The total dollar amount of all Paid Claims in the Claims Review Sample and the total dollar amount of Overpayments associated with the Paid Claims identified by the Claims Review. (This is the total dollar amount of the Overpayments identified in section B.3.b above.) The IRO may, in its report to UroCor, identify underpayments, but any underpayments identified during the Claims Review shall not be offset or "netted out" of the total dollar amount of Paid Claims or of the Overpayments when reporting these amounts in the Claims Review Report to the OIG.

d. The level of precision achieved by the Claims Review at a 90% confidence level.

e. A spreadsheet of the Claims Review results that includes the following information for each Paid Claim appraised: Federal health care program billed, beneficiary health insurance claim number, date of service,

procedure code submitted, procedure code reimbursed, allowed amount reimbursed by payor, correct procedure code (as determined by the IRO), correct allowed amount (as determined by the IRO), dollar difference between allowed amount reimbursed by payor and the correct allowed amount. (See Attachment 1 to this Appendix.)

4. ***Credentials.*** The names and credentials of the individuals who: (1) designed the statistical sampling procedures and the review methodology utilized for the Claims Review; and (2) performed the Claims Review.

Attachment 1

Claim Review Results

Federal Health Care Program Billed	Bene HIC #	Date of Service	Procedure Code Submitted	Procedure Code Reimbursed	Allowed Amount Reimbursed	Correct Procedure Code (IRO determined)	Correct Allowed Amt (IRO determined)	Dollar Difference between Amt Reimbursed and Correct Allowed Amt

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/SUPPLIERNAME_____
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 reaso
n 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		

AMENDMENT TO THE CORPORATE INTEGRITY AGREEMENT BETWEEN THE OFFICE OF INSPECTOR GENERAL OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES AND UROCOR, INC.

The Office of Inspector General ("OIG") of the Department of Health and Human Services and UroCor, Inc. ("UroCor") entered into a Corporate Integrity Agreement ("CIA") on June 14, 2001.

A. Pursuant to section XI.C. of UroCor's CIA, modifications to the CIA may be made with the prior written consent of both the OIG and UroCor. Therefore, the OIG and UroCor hereby agree that UroCor's CIA will be amended as follows:

Section III.D., Review Procedures of the CIA is hereby superceded by the attached new section III.D., Review Procedures.

Appendix A of UroCor's CIA is hereby superceded by the attached new Appendix A.

B. The OIG and UroCor agree that all other sections of UroCor's CIA will remain unchanged and in effect, unless specifically amended upon the prior written consent of the OIG and UroCor.

C. The undersigned UroCor signatory represents and warrants that he is authorized to execute this Amendment. The undersigned OIG signatory represents that he is signing the Amendment in his official capacity and that he is authorized to execute this Amendment.

D. The effective date of this Amendment will be the date on which the final signatory of this Amendment signs this Amendment.

ON BEHALF OF UROCOR

Kevin Johnson
President, Chief Executive Officer
and Chairman of the Board
DIANON Systems (formerly UroCor)

6/12/02
DATE

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

Lewis Morris
Assistant Inspector General for Legal Affairs
Office of Inspector General
U.S. Department of Health and Human Services

6/21/02
DATE

D. Review Procedures.

1. *General Description.*

a. Retention of Independent Review Organization. Within 120 days of the effective date of this CIA, UroCor shall retain an entity (or entities), such as an accounting, auditing or consulting firm (hereinafter "Independent Review Organization" or "IRO"), to perform reviews to assist UroCor in assessing and evaluating its billing and coding practices and systems, and its compliance obligations pursuant to this CIA and the Settlement Agreement. Each IRO retained by UroCor shall have expertise in the billing, coding, reporting, and other requirements of the particular section of the health care industry pertaining to this CIA and in the general requirements of the Federal health care program(s) from which UroCor seeks reimbursement. Each IRO shall assess, along with UroCor, whether it can perform the IRO review in a professionally independent fashion taking into account any other business relationships or other engagements that may exist. The IRO(s) review shall address and analyze UroCor's billing and coding to the Federal health care programs ("Claims Review"), shall analyze whether UroCor sought payment for certain unallowable costs ("Unallowable Cost Review"), and shall analyze UroCor's compliance with the obligations assumed under this CIA and the Settlement Agreement ("Compliance Review").

b. Frequency of Claims Review. The Claims Review shall be performed annually and shall cover each of the one-year periods of the CIA beginning with the first day of the month immediately following the effective date of this CIA. The IRO(s) shall perform all components of each annual Claims Review.

c. Frequency of Unallowable Cost Review. The Unallowable Cost Review shall be performed by the IRO for the first one-year reporting period beginning with the effective date of this CIA.

d. Frequency of Compliance Review. The Compliance Review shall be performed by the IRO for the first one-year period beginning with the effective date of this CIA.

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

2. *Claims Review*. The Claims Review shall include a Discovery Sample and, if necessary, a Full Sample. The applicable definitions, procedures, and reporting requirements are outlined in Appendix A to this CIA, which is incorporated by reference.

a. Discovery Sample. The IRO shall randomly select and review a sample of 50 Medicare Paid Claims submitted by or on behalf of UroCor. The Paid Claims shall be reviewed based on the supporting documentation available at UroCor or under UroCor's control and applicable billing and coding regulations and guidance to determine whether the claim submitted was correctly coded, submitted, and reimbursed.

i. If the Error Rate (as defined in Appendix A) for the Discovery Sample is less than 5%, no additional sampling is required, nor is the Systems Review required. (Note: The threshold listed above does not imply that this is an acceptable error rate. Accordingly, UroCor should, as appropriate, further analyze any errors identified in the Discovery Sample. UroCor recognizes that the OIG or other HHS component, in its discretion and as authorized by statute, regulation, or other appropriate authority may also analyze or review Paid Claims included, or errors identified, in the Discovery Sample.)

ii. If the Discovery Sample indicates that the Error Rate is 5% or greater, the IRO shall perform a Full Sample and a Systems Review, as described below.

b. Full Sample. If necessary, as determined by procedures set forth in Section III.D.2.a, the IRO shall perform an additional sample of Paid Claims using commonly accepted sampling methods and in accordance with Appendix A. The Full Sample should be designed to (1) estimate the actual Overpayment in the population with a 90% confidence level and with a maximum relative precision of 25% of the point estimate and (2) conform with the Centers for Medicare and Medicaid Services' statistical sampling for overpayment estimation guidelines. The Paid Claims shall be reviewed based on supporting documentation available at UroCor or under UroCor's control and applicable billing and coding regulations and guidance to determine whether the claim submitted was correctly coded, submitted, and reimbursed. For purposes of calculating the size of the Full Sample, the Discovery Sample may serve as the probe sample, if statistically appropriate. Additionally, UroCor may use the Items sampled as part of the Discovery Sample, and the corresponding findings for those 50 Items, as part of its Full Sample, if statistically appropriate. The OIG, in

its full discretion, may refer the findings of the Full Sample (and any related workpapers) received from UroCor to the appropriate Federal health care program payor, including the Medicare contractor (*e.g.*, carrier, fiscal intermediary, or DMERC), for appropriate follow-up by that payor.

c. Systems Review. If UroCor's Discovery Sample identifies an Error Rate of 5% or greater, UroCor's IRO shall also conduct a Systems Review. Specifically, for each claim in the Discovery Sample and Full Sample that resulted in an Overpayment, the IRO should perform a "walk through" of the system(s) and process(es) that generated the claim to identify any problems or weaknesses that may have resulted in the identified Overpayments. The IRO shall provide to UroCor the IRO's observations and recommendations on suggested improvements to the system(s) and the process(es) that generated the claim.

d. Repayment of Identified Overpayments. In accordance with section III.H.1 of the CIA, UroCor agrees to repay within 30 days any Overpayment(s) identified in the Discovery Sample or the Full Sample (if applicable), regardless of the Error Rate, to the appropriate payor and in accordance with payor refund policies. UroCor agrees to make available to the OIG any and all documentation that reflects the refund of the Overpayment(s) to the payor.

3. *Claims Review Report.* The IRO shall prepare a report based upon the Claims Review performed (the "Claims Review Report"). Information to be included in the Claims Review Report is detailed in Appendix A.

4. *Unallowable Cost Review.* The IRO shall conduct a review of UroCor's compliance with the unallowable cost provisions of the Settlement Agreement. The IRO shall determine whether UroCor has complied with its obligations not to charge to, or otherwise seek payment from, Federal or State payors for unallowable costs (as defined in the Settlement Agreement) and its obligation to identify to applicable Federal or State payors any unallowable costs included in payments previously sought from the United States, or any State Medicaid program. This unallowable cost analysis shall include, but not be limited to, payments sought in any cost reports, cost statements, information reports, or payment requests already submitted by UroCor or any of its subsidiaries. To the extent that such cost reports, cost statements, information reports or payment requests, even if already settled, have been adjusted to account for the effect of the inclusion of the unallowable costs, the IRO will determine if such adjustments were proper. In making this determination, the IRO may need to review cost reports and/or financial statements from the year in which the Settlement Agreement was executed, as well as from previous years.

5. *Unallowable Cost Review Report.* The IRO shall prepare a report based upon the Unallowable Cost Review performed. The Unallowable Cost Review Report shall include the IRO's findings and supporting rationale regarding the Unallowable Costs Review and whether UroCor has complied with its obligation not to charge to, or otherwise seek payment from, Federal or State payors for unallowable costs (as defined in the Settlement Agreement) and its obligation to identify to applicable Federal or State payors any unallowable costs included in payments previously sought from such payor.

6. *Compliance Review.* The IRO shall conduct a review of UroCor's compliance activities. The Compliance Review shall consist of a review of UroCor's compliance with the obligations set forth in each section of this CIA.

7. *Compliance Review Report.* The IRO shall prepare a report based upon the Compliance Review performed. The Compliance Review Report shall include the IRO's findings and supporting rationale regarding UroCor's compliance with the terms of each section of the CIA, as applicable.

8. *Validation Review.* In the event the OIG has reason to believe that: (a) UroCor's Claims Review, Unallowable Cost Review or Compliance Review fails to conform to the requirements of this CIA; or (b) the IRO's findings or Claims Review results are inaccurate, the OIG may, at its sole discretion, conduct its own review to determine whether the Claims Review, Unallowable Cost Review or Compliance Review complied with the requirements of the CIA and/or the findings or Claims Review results are inaccurate ("Validation Review"). UroCor agrees to pay for the reasonable cost of any such review performed by the OIG or any of its designated agents so long as it is initiated before one year after UroCor's final Annual Report and any additional information requested by the OIG is received by the OIG.

Prior to initiating a Validation Review, the OIG shall notify UroCor of its intent to do so and provide a written explanation of why the OIG believes such a review is necessary. To resolve any concerns raised by the OIG, UroCor may request a meeting with the OIG to discuss the results of any Claims Review, Unallowable Cost Review, or Compliance Review submissions or findings; present any additional or relevant information to clarify the results of the Claims Review, Unallowable Cost Review, or Compliance Review or to correct the inaccuracy of the Claims Review; and/or propose alternatives to the Validation Review. UroCor agrees to provide any additional information as may be requested by the OIG under this section in an expedited manner. The OIG will attempt in good faith to resolve any Claims Review, Unallowable Cost Review or Compliance Review issues with UroCor prior to conducting a Validation Review. However, the final

determination as to whether or not to proceed with a Validation Review shall be made at the sole discretion of the OIG.

9. *Independence Certification.* The IRO shall include in its report(s) to UroCor a certification or sworn affidavit that it has evaluated its professional independence with regard to the Claims Review, Unallowable Cost Review, and Compliance Review and that it has concluded that it is, in fact, independent.

APPENDIX A

A. **Claims Review**.

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

a. Overpayment: The amount of money UroCor has received in excess of the amount due and payable under any Federal health care program requirements.

b. Item: Any discrete unit that can be sampled (e.g., code, line item, beneficiary, patient encounter, etc.).

c. Paid Claim: A code or line item submitted by UroCor and for which UroCor has received reimbursement from the Medicare program.

d. Population: All Items for which UroCor has submitted a code or line item and for which UroCor has received reimbursement from the Medicare program (i.e., a Paid Claim) during the 12-month period covered by the Claims Review. To be included in the Population, an Item must have resulted in at least one Paid Claim.

e. Error Rate: The Error Rate shall be the percentage of net Overpayments identified in the sample. The net Overpayments shall be calculated by subtracting all underpayments identified in the sample from all gross Overpayments identified in the sample. (Note: Any potential cost settlements or other supplemental payments should not be included in the net Overpayment calculation. Rather, only underpayments identified as part of the Discovery Sample or Full Sample (as applicable) shall be included as part of the net Overpayment calculation.)

The Error Rate is calculated by dividing the net Overpayment identified in the sample by the total dollar amount associated with the Items in the sample.

2. **Other Requirements.**

a. Item Appraisal. For each Item appraised (either as part of the Discovery Sample or Full Sample), only Paid Claims shall be evaluated. Every Paid Claim in each Sample shall be evaluated by the IRO determine whether the Paid Claim was correctly coded, submitted, and reimbursed. Each

appraisal must be sufficient to provide all information required under the Claims Review Report.

b. Paid Claims without Supporting Documentation. For the purpose of appraising Items included in the Discovery Sample and/or Full Sample, any Paid Claim for which UroCor cannot produce documentation sufficient to support the Paid Claim shall be considered an error and the total reimbursement received by UroCor for such Paid Claim shall be deemed an Overpayment. Replacement sampling for Paid Claims with missing documentation is not permitted.

c. Use of First Samples Drawn. For the purposes of all samples (Discovery Sample(s) and Full Sample(s)) discussed in this Appendix, the Paid Claims associated with the Items selected in each first sample (or first sample for each strata, if applicable) shall be used. In other words, it is not permissible to generate more than one list of random samples and then select one for use with the Discovery Sample or Full Sample.

B. Claims Review Report. The following information shall be included in the Claims Review Report for each Discovery Sample and Full Sample (if applicable).

1. **Claims Review Methodology.**

a. Sampling Unit. A description of the Item as that term is utilized for the Claims Review.

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

c. Claims Review Objective. A clear statement of the objective intended to be achieved by the Claims Review.

d. Sampling Frame. A description of the sampling frame, which is the totality of Items from which the Discovery Sample and, if any, Full Sample has been selected and an explanation of the methodology used to identify the sampling frame. In most circumstances, the sampling frame will be identical to the Population.

e. Source of Data. A description of the specific documentation relied upon by the IRO when performing the Claims Review (e.g., medical records, physician orders, certificates of medical necessity, requisition forms, local

medical review policies, CMS program memoranda, Medicare carrier or intermediary manual or bulletins, other policies, regulations, or directives).

f. Review Protocol. A narrative description of how the Claims Review was conducted and what was evaluated.

2. **Statistical Sampling Documentation.**

a. The number of Items appraised in the Discovery Sample and, if applicable, in the Full Sample.

b. A copy of the printout of the random numbers generated by the "Random Numbers" function of the statistical sampling software used by the IRO.

c. A copy of the statistical software printout(s) estimating how many Items are to be included in the Full Sample, if applicable.

d. A description or identification of the statistical sampling software package used to conduct the sampling.

e. The Sampling Frame used in the Discovery Sample and/or Full Sample will be available to the OIG upon request.

3. **Claims Review Findings.**

a. Narrative Results.

i. A description of UroCor's billing and coding system(s), including the identification, by position description, of the personnel involved in coding and billing.

ii. A narrative explanation of the IRO's findings and supporting rationale (including reasons for errors, patterns noted, etc.) regarding the Claims Review, including the results of the Discovery Sample, and the results of the Full Sample (if any) with the gross Overpayment amount, the net Overpayment amount, and the corresponding Error Rate(s) related to the net Overpayment.

b. Quantitative Results.

i. Total number and percentage of instances in which the IRO determined that the Paid Claims submitted by UroCor ("Claim

Submitted") differed from what should have been the correct claim ("Correct Claim"), regardless of the effect on the payment.

ii. Total number and percentage of instances in which the Claim Submitted differed from the Correct Claim and in which such difference resulted in an Overpayment to UroCor.

iii. Total dollar amount of paid Items included in the sample and the net Overpayment associated with the sample.

iv. Error Rate in the sample.

v. A spreadsheet of the Claims Review results that includes the following information for each Paid Claim appraised: Federal health care program billed, beneficiary health insurance claim number, date of service, procedure code submitted, procedure code reimbursed, allowed amount reimbursed by payor, correct procedure code (as determined by the IRO), correct allowed amount (as determined by the IRO), dollar difference between allowed amount reimbursed by payor and the correct allowed amount. (See Attachment 1 to this Appendix.)

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

5. **Credentials.** The names and credentials of the individuals who: (1) designed the statistical sampling procedures and the review methodology utilized for the Claims Review; and (2) performed the Claims Review.

Attachment 1

Claim Review Results

Federal Health Care Program Billed	Bene HIC #	Date of Service	Procedure Code Submitted	Procedure Code Reimbursed	Allowed Amount Reimbursed	Correct Procedure Code (IRO determined)	Correct Allowed Amt (IRO determined)	Dollar Difference between Amt Reimbursed and Correct Allowed Amt