

**CORPORATE INTEGRITY AGREEMENT  
BETWEEN THE  
OFFICE OF INSPECTOR GENERAL  
OF THE  
DEPARTMENT OF HEALTH AND HUMAN SERVICES  
AND  
ZALE LIPSHY UNIVERSITY HOSPITAL**

**I. PREAMBLE**

Zale Lipshy University Hospital (“Zale Lipshy”) 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 ensure compliance by its employees, contractors, physicians with staff privileges, and agents, in accordance with the specific provisions of this CIA, with the requirements of Medicare, Medicaid and all other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)) (hereinafter collectively referred to as the “Federal health care programs”).

Zale Lipshy represents it has adopted a voluntary Compliance Program prior to entering this CIA. Zale Lipshy and the OIG agree that Zale Lipshy may utilize and adapt any components of Zale Lipshy's Compliance Program existing at the time of execution of this CIA as necessary to be in compliance with the corporate integrity obligations assumed by Zale Lipshy pursuant to this CIA. To the extent that Zale Lipshy's existing

Compliance Program can not be adapted or maintained to meet the corporate integrity obligations of this CIA, Zale Lipshy shall adopt new components to its Compliance program, or create a new compliance program, so that Zale Lipshy will meet the corporate integrity obligations assumed by Zale Lipshy pursuant to this CIA. Zale Lipshy's compliance with the terms and conditions in this CIA shall constitute an element of Zale Lipshy's present responsibility with regard to participation in the Federal health care programs. Contemporaneously with this CIA, Zale Lipshy is entering into a settlement agreement with the United States (the "Settlement Agreement"), into which this CIA is incorporated by reference and to which this CIA is attached as an Exhibit.

**II. TERM OF THE CIA**

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

**III. CORPORATE INTEGRITY OBLIGATIONS**

Zale Lipshy shall utilize, preserve and enhance its existing Compliance Program or create a new compliance program to include the following elements.

A. Compliance Officer and Committee.

1. *Compliance Officer.* Within one hundred and twenty (120) days after the effective date of this CIA, Zale Lipshy shall appoint an individual to serve as Compliance Officer, who 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 the requirements of the Federal health care programs. The Compliance Officer shall be a member of senior management of Zale Lipshy, shall make regular (at least quarterly) reports regarding compliance matters directly to the CEO and/or to the Board of Directors of Zale Lipshy, and shall be authorized to report to the Board of Directors at any time. The Compliance Officer shall be responsible for monitoring the day-to-day activities engaged in by Zale Lipshy to further its compliance objectives as well as for any reporting obligations created under this CIA. In the event a different Compliance Officer is appointed during the term of this CIA, Zale Lipshy shall notify the OIG, in writing, within fifteen (15) days of such a change.

2. *Compliance Committee.* Within one hundred and twenty (120) days of the effective date of this CIA, Zale Lipshy shall have in place a Compliance Committee. The Compliance Committee shall, at a minimum, include the Compliance Officer and any other appropriate officers as necessary to meet the requirements of this CIA within Zale Lipshy's corporate structure (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.

B. Written Standards.

1. *Code of Conduct.* Within one hundred and twenty (120) days of the effective date of this CIA, Zale Lipshy shall have in place a Code of Conduct. The Code of Conduct shall be distributed to all employees, contractors involved in the provision of services or items reimbursable by the Federal health care programs or in the preparation or submission of claims or other requests for reimbursement from the Federal health care programs, and agents, (hereinafter referred to as the "covered persons") within one hundred and twenty (120) days of the effective date of this CIA. Zale Lipshy shall make the promotion of, and adherence to, the Code of Conduct an element in evaluating the performance of managers, supervisors, and all other employees. The Code of Conduct shall, at a minimum, set forth:

- a. Zale Lipshy's commitment to full compliance with all statutes, regulations, and guidelines applicable to Federal health care programs, including its commitment to prepare and submit accurate billings consistent with Federal health care program regulations and procedures or instructions

otherwise communicated by appropriate regulatory agencies, e.g., the Health Care Financing Administration (“HCFA”), and/or their agents;

- b. Zale Lipshy’s requirement that all of its covered persons shall be expected to comply with all statutes, regulations, and guidelines applicable to Federal health care programs and with Zale Lipshy’s own Policies and Procedures (including the requirements of this CIA);
- c. the requirement that all of Zale Lipshy’s covered persons shall be expected to report suspected violations of any statute, regulation, or guideline applicable to Federal health care programs or of Zale Lipshy’s own Policies and Procedures;
- d. the possible consequences to both Zale Lipshy and covered persons of failure to comply with all statutes, regulations, and guidelines applicable to Federal health care programs and with Zale Lipshy’s own Policies and Procedures or of failure to report such non-compliance; and

- e. the right of all covered persons to use the Confidential Disclosure Program, as well as Zale Lipshy's commitment to confidentiality and non-retaliation with respect to disclosures.

Within one hundred and twenty (120) days of the effective date of the CIA, each covered person shall certify, in writing, that he or she has received, has read, understands, and will abide by Zale Lipshy'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 one hundred and twenty (120) days of the effective date of the CIA, whichever is later.

Zale Lipshy will annually review the Code of Conduct and will make any necessary revisions. These revisions shall be distributed within thirty (30) days of initiating such a change. Covered persons shall certify on an annual basis that they have received, have read, understand and will abide by the Code of Conduct.

*2. Policies and Procedures.* Within one hundred and twenty (120) days of the effective date of this CIA, Zale Lipshy shall have adapted or developed, and initiated implementation of written Policies and Procedures regarding the operation of Zale Lipshy's compliance program and its compliance with all federal and state health care statutes, regulations, and guidelines, including the requirements of the Federal health care programs. At a minimum, the Policies and Procedures shall specifically address the

proper billing of self-administered drugs for Medicare outpatient beneficiaries, and the proper billing of medical supplies both on HCFA Forms UB-92 and on all cost reports. In addition, the Policies and Procedures shall include disciplinary guidelines and methods for employees to make disclosures or otherwise report on compliance issues to Zale Lipshy management through the Confidential Disclosure Program required by section III.E. Zale Lipshy shall assess and update as necessary the Policies and Procedures at least annually and more frequently, as appropriate. A summary of the Policies and Procedures will be provided to the OIG in the Implementation Report. The Policies and Procedures will be available to the OIG upon request.

Within one hundred and twenty (120) days of the effective date of the CIA, the relevant portions of the Policies and Procedures shall be made available to all appropriate covered persons. Compliance staff or supervisors should be available to explain any and all Policies and Procedures.

C. Training and Education.

1. *General Training.* Within one hundred and twenty (120) days of the effective date of this CIA, Zale Lipshy shall provide at least two (2) hours of training to each covered person. This general training shall explain Zale Lipshy's:

- a. Corporate Integrity Agreement requirements;

- b. Compliance Program (including the Policies and Procedures as they pertain to general compliance issues and accuracy of charting, billing and coding); and
- c. Code of Conduct.

These training materials shall be made available to the OIG, upon request.

New covered persons shall receive the general training described above within thirty (30) days of becoming a covered person or within one hundred and twenty (120) days after the effective date of this CIA, whichever is later. Each covered person shall receive at least one (1) hour of such general training on an annual basis.

2. *Specific Training.* Within one hundred and twenty (120) days of the effective date of this CIA, each covered person who is involved directly or indirectly in the preparation or submission of claims for reimbursement for such care (including, but not limited to, coding and billing) for any Federal health care programs shall receive at least six (6) hours of training in addition to the general training required above. This training shall include a discussion of:

- a. the submission of accurate bills for services rendered to Federal health care program patients;
- b. policies, procedures and other requirements applicable to the documentation of medical records;



- c. the personal obligation of each individual involved in the billing process to ensure that such billings are accurate;
- d. applicable reimbursement statutes, regulations, and program requirements and directives, including, where appropriate, the proper billing of self-administered drugs for Medicare outpatient beneficiaries, and the proper billing of medical supplies both on HCFA Forms UB-92 and on all cost reports;
- e. the legal sanctions for improper billings; and
- f. examples of proper and improper billing practices.

These training materials shall be made available to the OIG, upon request. Persons providing the training must be knowledgeable about the subject area.

Affected new covered persons shall receive this training within thirty (30) days of the beginning of their employment or within one hundred and twenty (120) days of the effective date of this CIA, whichever is later. If a new covered person has any responsibility for the preparation or submission of claims and/or the assignment of procedure codes prior to completing this specific training, a Zale Lipshy employee, contractor, or agent who has completed the substantive training shall review all of the untrained person's work regarding the preparation or submission of claims, and the assignment of billing codes including, but not limited to, the proper billing of self-

administered drugs for Medicare outpatient beneficiaries and the proper billing of medical supplies on HCFA Forms UB-92 and on all cost reports.

Every covered person required to receive this specific training shall receive such specific training on an annual basis.

3. *Exception for Physicians with Privileges.* Notwithstanding any other provision of this CIA, Zale Lipshy shall make the General Training and the Specific Training, where appropriate, available to all physicians with privileges at Zale Lipshy, and shall use its best efforts to encourage their attendance and participation. The Compliance Officer shall maintain records of the percentage of all physicians with privileges who attend such training.

4. *Exception for Pre-Existing Contractors.* The term "Pre-Existing Contractors" shall refer to covered individuals who are independent contractors with whom Zale Lipshy has an existing contract on the effective date of this CIA that has not been renewed or modified after the effective date of this CIA. Once Zale Lipshy renegotiates, modifies, or renews a contract with a Pre-Existing Contractor, such Contractor ceases to be a Pre-Existing Contractor as that term is used for the purposes of this CIA, and Zale Lipshy will have full responsibility for the certification and training compliance obligations as pertain to such Contractor as contemplated by Sections III.B.2 and III.C. Notwithstanding any other provision of this CIA, the following are Zale

Lipshy's only obligations hereunder with respect to training and certification for Pre-Existing Contractors: (i) Zale Lipshy shall attempt to renegotiate contracts with Pre-Existing Contractors to require such contractors to meet all of the certification and training requirements of this CIA; and (ii) Zale Lipshy shall make the General Training and the Specific Training, where appropriate, available to all Pre-Existing Contractors, and shall use its best efforts to encourage their attendance and participation. The Compliance Officer shall keep a record of all Pre-Existing Contractors who attend such training.

5. *Certification.* Each individual who is required to attend training shall certify, in writing, that he or she has attended the required training. The certification shall specify the type of training received and the date received. The Compliance Officer shall retain the certifications, along with specific course materials. These shall be made available to the OIG upon request.

D. Review Procedures. Zale Lipshy shall retain an entity, such as an accounting, auditing or consulting firm (hereinafter "Independent Review Organization"), to perform review procedures to assist Zale Lipshy in assessing the adequacy of its billing and compliance practices pursuant to this CIA. The reviews will be performed annually and cover each of the one year periods beginning on the effective date of this CIA or the anniversary of that date. The Independent Review Organization must have expertise in

the billing, coding, reporting and other requirements of the Federal health care programs from which Zale Lipshy seeks reimbursement. The Independent Review Organization must be retained to conduct the audit of the first year within one hundred and twenty (120) days of the effective date of this CIA.

The Independent Review Organization will conduct two separate engagements. One will be an analysis of Zale Lipshy's billing to the Federal health care programs to assist Zale Lipshy and the OIG in determining Zale Lipshy's compliance with all applicable statutes, regulations, and directives or guidance ("billing engagement"). The second engagement will determine whether Zale Lipshy is in compliance with this CIA ("compliance engagement").

1. *Billing Engagement.* The billing engagement shall consist of a review of a statistically valid sample of claims that can be projected to the population of claims submitted to the Federal health care programs during the relevant year covered by the engagement. The sample size shall be determined through the use of a probe sample. The probe sample must contain at least thirty (30) sample units and cannot be used as part of the full sample. The full sample must contain a sufficient number of units so that when the sample results are projected to the population of claims, the projection provides a minimum 90% confidence level and a maximum precision of plus or minus 25% of the point estimate (i.e., the upper and lower bounds of the 90% confidence interval shall not

exceed 125% and shall not fall below 75% of the midpoint of the confidence interval, respectively). Both the probe sample and the full sample must be selected through random number sampling. To generate the random sample, Zale Lipshy shall use OIG's Office of Audit Services Statistical Sampling Software, also known as "RAT-STATS," which is available through the Internet at "[www.hhs.gov/oig/oas/ratstat.html](http://www.hhs.gov/oig/oas/ratstat.html)."

Each annual billing engagement review shall include the following components in its methodology:

- a. Billing Engagement Objective: a clear statement of the objective intended to be achieved by the billing engagement and the procedure or combination of procedures that will be applied to achieve the objective.
- b. Billing Engagement Population: the identity of the population, which is the group about which information is needed and an explanation of the methodology used to develop the population and provide the basis for this determination.
- c. Sources of Data: a full description of the source of the information upon which the billing engagement conclusions will be based, including the legal or other standards applied,

documents relied upon, payment data, and/or any contractual obligations.

- d. Sampling Unit: a definition of the sampling unit, which is any of the designated elements that comprise the population of interest.
- e. Sampling Frame: the identity of the sampling frame, which is the totality of the sampling units from which the sample will be selected.

The billing engagement shall provide:

- a. findings regarding Zale Lipshy's billing and coding operation (including, but not limited to, the operation of the billing system, strengths and weaknesses of this system, internal controls, and effectiveness of the system);
- b. findings based at a minimum upon statistical sampling as set forth in Section III.D.1 regarding whether Zale Lipshy is submitting accurate claims and corresponding cost report entries for services billed to the Federal health care programs;

- c. findings regarding the existence and appropriateness of Zale Lipshy's procedures to correct inaccurate billings or codings to the Federal health care programs;
- d. findings regarding the accuracy of Zale Lipshy's billing of self-administered drugs for Medicare outpatient beneficiaries and of medical supplies both on HCFA Forms UB-92 and on all cost reports;
- e. findings regarding whether Zale Lipshy has complied with its obligation under the Settlement Agreement: (i) not to resubmit to any Federal health care program payors any previously denied claims related to the conduct addressed in the Settlement Agreement, and its obligation not to appeal any such denials of claims, and (ii) 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 and adjust any past charges of such unallowable costs; and

- f. findings regarding the steps Zale Lipshy is taking to bring its operations into compliance or to correct problems identified by the review.

A complete copy of the Independent Review Organization's billing engagement shall be included in each of Zale Lipshy's Annual Reports to the OIG.

2. *Compliance Engagement.* The compliance engagement shall provide findings regarding whether Zale Lipshy's program, policies, procedures, and operations comply with the terms of this CIA. This engagement shall include section by section findings regarding the requirements of this CIA.

A complete copy of the Independent Review Organization's compliance engagement shall be included in each of Zale Lipshy's Annual Reports to the OIG.

3. *Verification/Validation.* In the event the OIG has reason to believe that Zale Lipshy's Billing Engagement Review fails to conform to its obligations under this CIA or indicates improper billings not otherwise adequately addressed in the billing engagement, and thus determines that it is necessary to conduct an independent review to determine whether or the extent to which Zale Lipshy is complying with its obligations under this CIA, Zale Lipshy agrees to pay for the reasonable cost of any such review or engagement by the OIG or any of its designated agents.



E. Confidential Disclosure Program. Within one hundred and twenty (120) days after the effective date of this CIA, Zale Lipshy shall have in place a Confidential Disclosure Program, which must include measures (e.g., a toll-free compliance telephone hotline) to enable employees, contractors, agents or other 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 Zale Lipshy's policies, practices or procedures with respect to a Federal health care program, believed by the individual to be inappropriate. Zale Lipshy shall publicize the existence of the hotline (e.g., e-mail to employees or post hotline number in prominent common areas).

The Confidential Disclosure Program shall emphasize a non-retribution, non-retaliation policy, and shall include a reporting mechanism for anonymous, confidential communication. Upon receipt of a disclosure, the Compliance Officer (or designee) shall gather the information in such a way as to elicit 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, Zale Lipshy 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 shall maintain a confidential disclosure log, which shall include a record and summary of each allegation received, the status of the respective investigation(s), and any corrective action taken in response to the investigation(s).

F. Ineligible Persons.

1. *Definition.* For purposes of this CIA, an “Ineligible Person” shall be any individual or entity who: (i) is currently excluded, suspended, debarred or otherwise ineligible to participate in the Federal health care programs; or (ii) has been convicted of a criminal offense related to the provision of health care items or services and has not been reinstated in the Federal health care programs after a period of exclusion, suspension, debarment, or ineligibility.

2. *Screening Requirements.* Zale Lipshy shall not hire, engage as a contractor, or grant staff privileges to any Ineligible Person. To prevent hiring or contracting with any Ineligible Person, Zale Lipshy shall screen all prospective employees and prospective contractors prior to engaging their services and screen physicians prior to granting staff privileges by (i) requiring each applicant to disclose whether he, she, or it is an Ineligible Person, and (ii) reviewing the General Services Administration’s List of Parties Excluded from Federal Programs (available through the

Internet at <http://www.arnet.gov/epls>) and the HHS/OIG List of Excluded Individuals/Entities (available through the Internet at <http://www.dhhs.gov/oig>) (these lists will hereinafter be referred to as the "Exclusion Lists").

3. *Review and Removal Requirement.* Within one hundred and twenty (120) days of the effective date of this CIA, Zale Lipshy will review its list of current employees, contractors, and physicians with staff privileges against the Exclusion Lists. Thereafter, Zale Lipshy will review the list semi-annually. If Zale Lipshy has notice that an employee, contractor, or physician with staff privileges has become an Ineligible Person, Zale Lipshy will remove such person from responsibility for, or involvement with, Zale Lipshy'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 Zale Lipshy 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, Zale Lipshy shall take all appropriate actions to ensure that the responsibilities

of that employee or contractor do not adversely affect the quality of care rendered to any patient or resident or the accuracy of any claims submitted to any Federal health care program.

G. Notification of Proceedings. Within thirty (30) days of discovery, Zale Lipshy shall notify the OIG, in writing, of any ongoing investigation or legal proceeding conducted or brought by a governmental entity or its agents involving an allegation that Zale Lipshy has committed a crime or has engaged in fraudulent activities or any other knowing misconduct. 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. Zale Lipshy shall also provide written notice to the OIG within thirty (30) days of the resolution of the matter, and shall provide the OIG with a description of the findings and/or results of the proceedings, if any.

H. Reporting.

1. *Reporting of Overpayments.* If, at any time, Zale Lipshy identifies or learns of any billing, coding or other policies, procedures, and/or practices that result in an overpayment, Zale Lipshy shall notify the payor (e.g., Medicare fiscal intermediary or carrier) within thirty (30) days of discovering the overpayment and take remedial steps within sixty (60) days of discovery (or such additional time as may be agreed to by the payor or intermediary) to correct the problem, including preventing the underlying

problem and the overpayments from recurring. If the overpayment is discovered as the result of any of the activities required by this CIA, the notice to the payor or intermediary shall include:

- a. a statement that the refund is being made pursuant to this CIA;
- b. a description of the complete circumstances surrounding the overpayment;
- c. the methodology by which the overpayment was determined;
- d. the amount of the overpayment;
- e. any claim-specific information used to determine the overpayment (e.g., beneficiary health insurance number, claim number, service date, and payment date);
- f. the provider identification number under which the repayment is being made;
- g. the cost reporting period, if applicable; and
- h. any applicable Overpayment Refund Form provided and required by the payor.

2. *Reporting of Material Deficiencies.* If Zale Lipshy determines that there is a material deficiency, Zale Lipshy shall notify the OIG within thirty (30) days of discovering the material deficiency. If the material deficiency results in an overpayment,

the report to the OIG shall be made at the same time as the report to the payor and shall include all of the information required by section III.H.1 plus: (i) the payor's name, address, and contact person where the overpayment was sent; and (ii) the date of the check and identification number (or electronic transaction number) on which the overpayment was repaid. Regardless of whether the material deficiency resulted in an overpayment, the report to the OIG shall include:

- a. a complete description of the material deficiency, including the relevant facts, persons involved, and legal and program authorities;
- b. Zale Lipshy's actions to correct the material deficiency; and
- c. any further steps Zale Lipshy plans to take to address such material deficiency and prevent it from recurring.

3. *Definition of "Overpayment."* For purposes of this CIA, an "overpayment" shall mean the amount of money the provider has received in excess of the amount due and payable under the Federal health care programs' statutes, regulations or program directives, including carrier and intermediary instructions.

4. *Definition of "Material Deficiency."* For purposes of this CIA, a "material deficiency" means anything that involves: (i) a substantial overpayment relating to any Federal health care program; (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; or (iii) a failure to provide items or services of a quality that meets professionally recognized standards of health care where such violation has occurred in one or more instances that presents an imminent danger to the health, safety, or well-being of a Federal health care program beneficiary or places the beneficiary unnecessarily in high-risk situations. A material deficiency may be the result of an isolated event or a series of occurrences.

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

In the event that Zale Lipshy purchases or establishes new business units after the effective date of this CIA, Zale Lipshy shall notify the OIG of this fact within thirty (30) days of the date of purchase or establishment. This notification shall include the location of the new operation(s), phone number, fax number, Federal health care program provider number(s) (if any), and the corresponding payor(s) (contractor specific) that has issued each provider number. All covered persons at such locations shall be subject to the requirements in this CIA that apply to new covered persons (e.g., completing certifications and undergoing training).

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

A. Implementation Report. Within one hundred and fifty (150) days after the effective date of this CIA, Zale Lipshy shall submit a written report to the OIG

summarizing the status of its implementation of the requirements of this CIA. This

Implementation Report shall include:

1. the name, address, phone number and position description 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 Zale Lipshy's Code of Conduct required by section III.B.1;
4. the summary of the Policies and Procedures required by section III.B.2;
5. a description of the training programs required by section III.C, including a description of the targeted audiences 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 made available to all pertinent 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 training and executed the certification required by section III.C.
7. a description of the Confidential Disclosure Program required by section III.E;
8. the identity of the Independent Review Organization(s) and the proposed start and completion date of the first review;
9. a summary of personnel actions taken pursuant to section III.F.; and
10. a list of all of Zale Lipshy'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 Federal health care program provider identification number(s) and the payor (specific contractor) that issued each provider identification number.

B. Annual Reports. Zale Lipshy shall submit to the OIG Annual Reports with respect to the status and findings of Zale Lipshy's compliance activities.

Each Annual Report shall include:

1. any change in the identity or position description of the Compliance Officer and/or members of the Compliance Committee described in section III.A;

2. a certification by the Compliance Officer that:
  - a. all covered persons have completed the annual Code of Conduct certification required by section III.B.1;
  - b. all covered persons have completed the training and executed the certification required by section III.C; and
  - c. Zale Lipshy 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 conduct addressed in the Settlement Agreement, and its obligation not to appeal any such denials of claims, and (ii) 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 and adjust any past charges of such unallowable costs; and
3. notification of any 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);

4. a complete copy of the report prepared pursuant to the Independent Review Organization's billing and compliance engagements, including a copy of the methodology used;
5. Zale Lipshy's response/corrective action plan to any issues raised by the Independent Review Organization;
6. a summary of material deficiencies identified and reported throughout the course of the previous twelve (12) months pursuant to section III.H;
7. a report of the aggregate overpayments that have been returned to the Federal health care programs that were discovered as a direct or indirect result of implementing this CIA. Overpayment amounts should be broken down into the following categories: Medicare, Medicaid (report each applicable state separately) and other Federal health care programs;
8. a copy of the confidential disclosure log required by section III.E;
9. a description of any personnel action (other than hiring) taken by Zale Lipshy 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.

10. a summary describing any ongoing investigation or legal proceeding conducted or brought by a governmental entity involving an allegation that Zale Lipshy has committed a crime or has engaged in fraudulent activities, which have been reported pursuant to section III.G. The statement shall include a description of the allegation, the identity of the investigating or prosecuting agency, and the status of such investigation, legal proceeding or requests for information;
11. a corrective action plan to address all material deficiencies (as defined in section III.H) identified over the previous twelve (12) months; and
12. a description of all changes to the most recently provided list (as updated) of Zale Lipshy'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 Federal health care program provider identification number(s), and the payor (specific contractor) that issued each provider identification number.

The first Annual Report shall be received by the OIG no later than one year and sixty (60) days after the effective date of this CIA. Subsequent Annual Reports shall be received by the 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 under penalty of perjury, that: (1) Zale Lipshy is in compliance with all of the requirements of this CIA, to the best of his or her knowledge; and (2) he or she has reviewed the Report and has made reasonable inquiry regarding its content and believes to the best of his or her knowledge that, upon such inquiry, the information is accurate and truthful.

**VI. NOTIFICATIONS AND SUBMISSION OF REPORTS**

Unless otherwise stated in writing subsequent to the effective date of this CIA, all notifications and reports required under this CIA shall be submitted via certified mail, return receipt requested, to the entities listed below:

**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  
Telephone (202) 619-2078  
Facsimile (202) 205-0604

**Zale Lipshy:**

Zale Lipshy University Hospital  
Attn: Elizabeth Lasky, Corporate Compliance Officer  
5151 Harry Hines Boulevard  
Dallas, TX 77235-7786  
Telephone (214) 648-6568  
Facsimile (214) 590-3769

**VII. OIG INSPECTION, AUDIT AND REVIEW RIGHTS**

In addition to any other rights the OIG may have by statute, regulation, or contract, the OIG or its duly authorized representative(s), may examine Zale Lipshy's books, records, and other documents and supporting materials and/or conduct an on-site review

of any of Zale Lipshy's locations for the purpose of verifying and evaluating: (a) Zale Lipshy's compliance with the terms of this CIA; and (b) Zale Lipshy's compliance with the requirements of the Federal health care programs in which it participates. The documentation described above shall be made available by Zale Lipshy to the OIG or its duly authorized representative(s) at all reasonable times for inspection, audit or reproduction. Furthermore, for purposes of this provision, the OIG or its duly authorized representative(s) may interview any of Zale Lipshy'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 the OIG. Zale Lipshy agrees to assist the OIG in contacting and arranging interviews with such individuals upon the OIG's request. Zale Lipshy's employees may elect to be interviewed with or without a representative of Zale Lipshy present or with any other representative of his or her choice.

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

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

## **IX. DISCLOSURES**

Subject to HHS's Freedom of Information Act ("FOIA") procedures, set forth in 45 C.F.R. Part 5, the OIG shall make a reasonable effort to notify Zale Lipshy prior to any release by the OIG of information submitted by Zale Lipshy pursuant to its obligations under this CIA and identified upon submission by Zale Lipshy as trade secrets, commercial or financial information and privileged and confidential under the FOIA rules. Zale Lipshy shall refrain from identifying any information as trade secrets, commercial or financial information and privileged and confidential that does not meet the criteria for exemption from disclosure under FOIA.

## **X. BREACH AND DEFAULT PROVISIONS**

Zale Lipshy is expected to fully and timely comply with all of the obligations herein throughout the term of this CIA or other time frames herein agreed to. Nothing in this CIA shall be construed so as to alter the burden of proof otherwise necessary to find Zale Lipshy liable in any action arising under the False Claims Act, 31 U.S.C. §§ 3729-3733.

A. Stipulated Penalties for Failure to Comply with Certain Obligations. As a contractual remedy, Zale Lipshy and the 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, beginning one hundred twenty (120) days after the effective date of this CIA and concluding at the end of the term of this CIA, Zale Lipshy fails to have in place any of the following:

- a. a Compliance Officer;
- b. a Compliance Committee;
- c. a written Code of Conduct;
- d. written Policies and Procedures;
- e. a training program; and
- f. a Confidential 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 Zale Lipshy fails meet any of the deadlines to submit the Implementation Report or the Annual Reports to the OIG, unless extended in writing by the OIG.

3. A Stipulated Penalty of \$2,000 (which shall begin to accrue on the date the failure to comply began) for each day Zale Lipshy:

a. hires or enters into a contract with or grants staff privileges to an Ineligible Person after that person has been listed by a federal agency as excluded, debarred, suspended or otherwise ineligible for participation in the Medicare, Medicaid or any other Federal health care program (as defined in 42 U.S.C. § 1320a-7b(f)) (this Stipulated Penalty shall not be demanded for any time period during which Zale Lipshy 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);

b. employs or contracts with or grants staff privileges to an Ineligible Person and that person: (i) has responsibility for, or involvement with, Zale Lipshy'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 (this Stipulated Penalty shall not be demanded for any time period during which Zale Lipshy 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).

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

5. A Stipulated Penalty of \$1,000 (which shall begin to accrue ten (10) days after the date that OIG provides notice to Zale Lipshy of the failure to comply) for each day Zale Lipshy fails to comply fully and adequately with any obligation of this CIA. In its notice to Zale Lipshy, the OIG shall state the specific grounds for its determination that Zale Lipshy has failed to comply fully and adequately with the CIA obligation(s) at issue.

B. Payment of Stipulated Penalties.

1. *Demand Letter.* Upon a finding that Zale Lipshy has failed to comply with any of the obligations described in section X.A and determining that Stipulated Penalties are appropriate, the OIG shall notify Zale Lipshy by personal service or certified mail of (a) Zale Lipshy'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"). Zale Lipshy's decision to cure any alleged breach shall not be construed as or constitute evidence of an admission of non-compliance under this CIA in any subsequent legal proceeding.

Within fifteen (15) days of the date of the Demand Letter, Zale Lipshy shall either (a) cure the breach to the OIG's satisfaction and pay the applicable stipulated penalties; or (b) request a hearing before an HHS administrative law judge ("ALJ") to dispute the OIG's determination of noncompliance, pursuant to the agreed upon provisions set forth

below in section X.D. In the event Zale Lipshy elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until Zale Lipshy cures, to the OIG's satisfaction, the alleged breach in dispute, or until the ALJ determines that no breach of this CIA has occurred, in which case no Stipulated Penalties shall be assessed. 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.C.

2. *Timely Written Requests for Extensions.* Zale Lipshy may 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 the OIG grants the timely written request with respect to an act, notification, or report, Stipulated Penalties for failure to perform the act or file the notification or report shall not begin to accrue until one (1) day after Zale Lipshy fails to meet the revised deadline set by the OIG, unless further extended by the OIG. Notwithstanding any other provision in this section, if the OIG denies such a timely written request, Stipulated Penalties for failure to perform the act or file the notification or report shall not begin to accrue until two (2) business days after Zale Lipshy receives the OIG's written denial of such request. A "timely written request" is defined as a request in writing received by the OIG at least five (5) 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. Receipt of such "timely written request" shall be deemed to have occurred on the date it is actually received by the OIG at the address listed in Section VI.

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

4. *Independence from Material Breach Determination.* Except as otherwise noted, these provisions for payment of Stipulated Penalties shall not affect or otherwise set a standard for the OIG's determination that Zale Lipshy has materially breached this CIA, which decision shall be made at the OIG's discretion and governed by the provisions in section X.C, below.

C. Exclusion for Material Breach of this CIA

1. *Notice of Material Breach and Intent to Exclude.* The parties agree that a material breach of this CIA by Zale Lipshy constitutes an independent basis for Zale Lipshy's exclusion from participation in the Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)). Upon a determination by the OIG that Zale Lipshy has materially breached this CIA and that exclusion should be imposed, the OIG shall notify Zale Lipshy by certified mail of (a) Zale Lipshy's material breach; and (b) the OIG's

intent to exercise its contractual right to impose exclusion (this notification is hereinafter referred to as the "Notice of Material Breach and Intent to Exclude").

2. *Opportunity to cure.* Zale Lipshy shall have thirty (30) days from the date of Zale Lipshy's receipt of the Notice of Material Breach and Intent to Exclude to demonstrate to the OIG's satisfaction that:

- a. Zale Lipshy is in full compliance with this CIA;
- 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) Zale Lipshy has begun to take action to cure the material breach, (ii) Zale Lipshy is pursuing such action with due diligence, and (iii) Zale Lipshy has provided to the OIG a reasonable timetable for curing the material breach.

3. *Exclusion Letter.* If at the conclusion of the thirty (30) day period, Zale Lipshy fails to satisfy the requirements of section X.C.2, the OIG may exclude Zale Lipshy from participation in the Federal health care programs. The OIG will notify Zale Lipshy in writing of its determination to exclude Zale Lipshy (this letter shall be referred to hereinafter as the "Exclusion Letter"). Subject to the Dispute Resolution provisions in section X.D, below, the exclusion shall go into effect thirty (30) days after the date of the

Exclusion Letter. The exclusion shall have national effect and will also apply to all other federal procurement and non-procurement programs. If Zale Lipshy is excluded under the provisions of this CIA, Zale Lipshy may seek reinstatement pursuant to the provisions at 42 C.F.R. §§ 1001.3001-.3004.

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

- a. a failure by Zale Lipshy to report a material deficiency, take corrective action and pay the appropriate refunds, as provided in section III.H;
- b. repeated or flagrant violations of the obligations under this CIA, including, but not limited to, the obligations addressed in section X.A of this CIA;
- c. a failure to respond to a Demand Letter concerning the payment of Stipulated Penalties in accordance with section X.B above; or
- d. a failure to retain and use an Independent Review Organization for review purposes in accordance with section III.D.

#### D. Dispute Resolution

1. *Review Rights.* Upon the OIG's delivery to Zale Lipshy of its Demand Letter or of its Exclusion Letter, and as an agreed-upon contractual remedy for the resolution of disputes arising under the obligation of this CIA, Zale Lipshy 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, the OIG's determination to demand payment of Stipulated Penalties or to seek exclusion shall be subject to review by an ALJ and, in the event of an appeal, the 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 fifteen (15) days of the date of the Demand Letter and the request for a hearing involving exclusion shall be made within thirty (30) days of the date 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 Zale Lipshy was in full and timely compliance with the obligations of this CIA for which the OIG demands payment; and (b) the period of noncompliance. Zale Lipshy shall have the



burden of proving its full and timely compliance and the steps taken to cure the noncompliance, if any. If the ALJ finds for the OIG with regard to a finding of a breach of this CIA and orders Zale Lipshy to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable twenty (20) days after the ALJ issues such a decision notwithstanding that Zale Lipshy may request review of the ALJ decision by the DAB.

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 Zale Lipshy 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) Zale Lipshy had begun to take action to cure the material breach within that period, (ii) Zale Lipshy has pursued and is pursuing such action with due diligence, and (iii) Zale Lipshy provided to OIG within that period a reasonable timetable for curing the material breach. For purposes of the exclusion herein, exclusion shall take effect only after an ALJ decision that is favorable to the OIG. Zale Lipshy's election of its contractual right to appeal to the DAB shall not abrogate the OIG's authority to exclude Zale Lipshy upon the issuance of the ALJ's decision. If the ALJ sustains the determination of the OIG and determines that exclusion is authorized,

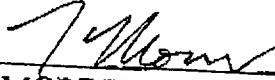
such exclusion shall take effect twenty (20) days after the ALJ issues such a decision, notwithstanding that Zale Lipshy may request review of the ALJ decision by the DAB.

**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, Zale Lipshy and the OIG agree as follows:

- A. This CIA shall be binding on the successors, assigns, and transferees of Zale Lipshy;
- 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; and
- D. The undersigned Zale Lipshy 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 THE OFFICE OF INSPECTOR GENERAL  
OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES

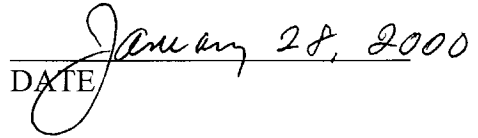



LEWIS MORRIS  
Assistant Inspector General for Legal Affairs  
Office of Inspector General  
U. S. Department of Health and Human Services

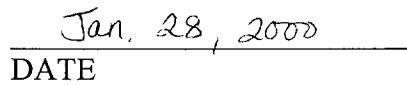
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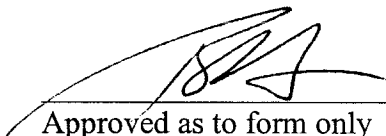
ON BEHALF OF ZALE LIPSHY UNIVERSITY HOSPITAL

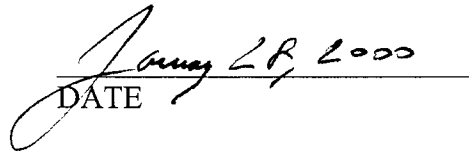
  
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ROBERT B. SMITH  
Chief Executive Officer  
Zale Lipshy University Hospital

  
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DATE

  
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ELIZABETH G. LASKY  
Compliance Officer  
Zale Lipshy University Hospital

  
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DATE

  
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Approved as to form only  
ARTER & HADDEN, L.L.P.  
By Bruce F. Howell, Esq.  
Counsel for Zale Lipshy University Hospital

  
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DATE