

**CORPORATE INTEGRITY AGREEMENT
BETWEEN THE
OFFICE OF INSPECTOR GENERAL
OF THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND
HCA--THE HEALTHCARE COMPANY**

I. PREAMBLE

HCA--The Healthcare Company ("HCA") 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 itself, its subsidiaries, and their employees, contractors, agents, and physicians 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.") This CIA shall be applicable only to those operations of HCA that are subject to United States law and regulations. HCA's compliance with the terms and conditions in this CIA shall constitute an element of HCA's present responsibility with regard to participation in the Federal health care programs. Whenever the term "HCA" is used in this CIA, it includes all of HCA's subsidiaries, as defined in this agreement. Contemporaneously with this CIA, HCA is entering into a Settlement

Agreement with the United States, and this CIA is incorporated by reference into the Settlement Agreement. HCA currently operates an Ethics and Compliance Program, which HCA agrees to operate in a manner consistent with the terms of this CIA.

II. TERM OF THE CIA AND DEFINITIONS

A. **Term.** The period of the compliance obligations assumed by HCA under this CIA shall be eight years from the effective date of this CIA (unless otherwise specified). The effective date of this CIA shall be the date that the court(s) accept the plea(s) and impose a sentence in the criminal proceedings related to the plea agreement entered into between HCA and the United States on or about the date of the signing of this CIA. Sections VII, VIII, IX, X and XI of this CIA shall remain in effect until OIG has completed its review of the final annual report and any additional materials submitted by HCA pursuant to OIG's request. The compliance obligations of the Corporate Integrity Agreement in place for Lanier Park Hospital in Gainesville, Georgia, shall not apply to the time period beginning on the effective date of this CIA (sections II.D, II.E, III, V, and VI of the Lanier Park CIA shall remain in effect until OIG has completed its review of the most recent annual report and any additional materials submitted by HCA pursuant to OIG's request), and upon the effective date of this CIA Lanier Park Hospital shall be subject to the provisions of this CIA to the same extent as other HCA facilities.

B. Definitions. For the purposes of this CIA, the following terms have the following meanings.

1. **Covered Person:** (a) any officer, director, or employee of HCA or any of its subsidiaries; or (b) any agent or other individual who furnishes health care items or services to any Federal health care program beneficiary at a facility owned or operated by HCA or any of its subsidiaries for which HCA or any of its subsidiaries claims reimbursement from any Federal health care program. Notwithstanding the above, this term does not include part-time or *per diem* employees, agents or other individuals who are not reasonably expected to work more than 160 hours per year, except that any such individuals shall become “Covered Persons” at the point when they work more than 160 hours during the calendar year.

2. **Subsidiary:** any corporation or other entity that provides items or services for which payment may be made by any Federal health care program, or prepares or submits requests for such payment, and in which HCA (i) has at least a 50% ownership interest, or (ii) has at least a 5% ownership interest and either manages or controls.

3. **Covered Contractor:** any agent or other individual (who is not a covered person) who prepares claims, cost reports, or other requests for reimbursement from any Federal health care program on behalf of HCA or any of its subsidiaries on a regular basis (i.e., for more than 80 hours within the calendar year).

III. CORPORATE INTEGRITY OBLIGATIONS

HCA shall ensure that its Ethics and Compliance Program includes the following elements during the term of this CIA.

A. Compliance Officers and Committees.

1. *Ethics, Compliance and Corporate Responsibility Committee of the Board of Directors.* HCA currently has an Ethics, Compliance and Corporate Responsibility Committee of the Board of Directors (“Board Committee”) comprised of five outside directors of HCA. The Board Committee is responsible for the review of matters related to the Ethics and Compliance Program, this CIA, and compliance with requirements of Federal health care programs. The Board Committee shall meet at least quarterly. When new members of the Board Committee are appointed or the responsibilities or authorities of the Board Committee are substantially changed, HCA shall notify the OIG, in writing, within 15 days of such a change.

2. *Senior Vice President for Compliance.* HCA currently has a Senior Vice President for Ethics, Compliance, and Corporate Responsibility (“SVP-Compliance”). The SVP-Compliance is and 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 SVP-Compliance is and shall be a member of senior management of HCA, shall make

regular (at least quarterly) reports regarding compliance matters directly to the CEO and/or to the Board of Directors (including the Board Committee) of HCA, and shall be authorized to report to the Board of Directors (including the Board Committee) at any time. The SVP-Compliance shall be responsible for monitoring the day-to-day activities engaged in by HCA to further its compliance objectives as well as for any reporting obligations created under this CIA. In the event a new SVP-Compliance is appointed or the responsibilities or authorities of the SVP-Compliance are substantially changed, HCA shall notify the OIG, in writing, within 15 days of such a change.

3. *Ethics, Compliance and Corporate Responsibility Department.* HCA currently has an Ethics, Compliance and Corporate Responsibility Department (“EC Department”). The EC Department is managed by the SVP-Compliance and is responsible for the operation of the Ethics and Compliance Program and for compliance with the requirements of this CIA and of the Federal health care programs. In the event the responsibilities or authorities of the EC Department are substantially changed, HCA shall notify the OIG, in writing, within 15 days of such a change.

4. *Local Ethics and Compliance Officers.* HCA currently has a Local Ethics and Compliance Officer (“ECO”) at each of its facilities (for the purpose of this CIA, a “facility” is any hospital, ambulatory surgery center, clinic or group of clinics, or other location where health care items or services are provided by HCA or one of its

subsidiaries). Each ECO shall have sufficient management responsibility so as permit the effective performance of his or her duties. Each ECO is responsible for implementation and oversight of the Ethics and Compliance Program at the facility and for the facility's compliance with the requirements of this CIA and of the Federal health care programs. HCA shall make proper execution of ECO duties a major component of the performance evaluations of ECOs. HCA shall continually assess the effectiveness of ECOs and the methods and findings of any such assessments shall be made available to the OIG upon request. HCA shall not implement any substantial change in the responsibilities or authorities of the ECOs relating to HCA's Ethics and Compliance Program without prior written approval from the OIG.

5. *Corporate Ethics and Compliance Committees.* HCA currently has a Corporate Ethics and Compliance Steering Committee ("Compliance Steering Committee"). The Compliance Steering Committee is chaired by the SVP-Compliance and includes the Corporate CEO, COO, the two group presidents, and certain senior vice presidents. The Compliance Steering Committee oversees the effectiveness of the Ethics and Compliance Program and makes decisions on investments in the Program. The Compliance Steering Committee shall be responsible for overseeing the implementation of the requirements of this CIA. HCA also currently has a Corporate Ethics and Compliance Policy Committee ("Compliance Policy Committee"). The Compliance

Policy Committee is chaired by the SVP-Compliance and includes the group CFOs, three hospital presidents, a number of senior vice presidents, e.g., Internal Audit, General Counsel, Quality, Information Systems, Human Resources, Government Programs, and executives representing major compliance areas, such as coding, billing, physician relationships, and cost reports. The Compliance Policy Committee reviews and approves all compliance-related policies. The two committees shall conduct at least 12 meetings per year in aggregate. The committees shall keep a record of their proceedings that shall be available to the OIG upon request.

6. *Hospital Compliance Committees.* Each Hospital shall have a Hospital Ethics and Compliance Committee (“Hospital Committee”). The Hospital Committee shall be chaired by the ECO of the facility and include the heads of each of the facility’s major compliance-related departments. The Hospital Committee shall be responsible for assisting the ECO in implementing the Ethics and Compliance Program, and ensuring compliance by the facility with this CIA and the requirements of Federal health care programs. The Hospital Committee shall also be responsible for reporting on compliance issues to the ECO.

7. *Responsible Executives.* HCA has designated certain individuals (“Responsible Executives”) to be responsible for development and implementation of a portion of the Ethics and Compliance Program related to a specific compliance risk area.

For example, the Vice President, Health Information Management Services, is the Responsible Executive for coding compliance. The Responsible Executives work with the SVP-Compliance, EC Department, Compliance Policy Committee, and others to develop, oversee, monitor, and implement compliance policies within their designated areas of responsibility. HCA shall not discontinue or materially alter its current Responsible Executive structure without written approval from the OIG.

B. Written Standards.

1. *Code of Conduct.* HCA currently has a Code of Conduct. HCA has implemented a program to distribute the Code of Conduct to covered persons. HCA 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. HCA has implemented a program to obtain an acknowledgment from each covered person that he or she has received HCA's Code of Conduct and understands that it represents the mandatory policies of the organization. Within 90 days of the effective date of this CIA, HCA shall obtain a certification from each of its facilities and corporate departments that, based on information and belief, this distribution and acknowledgment process is complete. New covered persons shall receive the Code of Conduct and shall complete the required acknowledgment within 30 days after becoming a covered person. HCA shall annually review the Code of Conduct and shall make any necessary revisions. These

revisions shall be distributed as expeditiously as possible after initiating such a change and no later than 30 days after the effective date of the revised Code of Conduct. HCA shall implement a program to obtain an acknowledgment from each covered person that he or she has received the revised Code of Conduct, understands that it represents the mandatory policies of the organization, and agrees to abide by it. Within 90 days of the effective date of the revised Code of Conduct, HCA shall obtain a certification from each of its facilities and corporate departments that, based on information and belief, this distribution and acknowledgment process is complete. HCA shall obtain the acknowledgments and certifications described in the preceding two sentences every time that a revised Code of Conduct is distributed (but in any event no less frequently than every three years).

2. *Covered Contractor Requirements.* HCA shall require a Covered Contractor to: (a) agree to abide by HCA's Code of Conduct or adopt its own Code of Conduct substantially similar to HCA's Code of Conduct; (b) distribute either (i) HCA's Code of Conduct or (ii) its Code of Conduct and information about HCA's Confidential Disclosure Program (including the Ethics Line number) to employees working on HCA matters; and, (c) certify to HCA that employees working on HCA matters have received a copy of (i) HCA's Code of Conduct or (ii) its Code of Conduct and information about HCA's Confidential Disclosure Program (including the Ethics Line number). Where the

Covered Contractor is a solo practitioner, the Covered Contractor must be provided with HCA's Code of Conduct and certify that he or she will abide by it.

3. *Policies and Procedures.* HCA is developing written compliance Policies and Procedures. Prior to the effective date of this CIA, HCA has implemented many such Policies and Procedures and provided them to the OIG. HCA shall assess and update as necessary the Policies and Procedures at least annually and more frequently, as appropriate. HCA shall provide a summary of changes to its Policies and Procedures in its Annual Reports under this CIA and the current Policies and Procedures shall continue to be available to OIG upon request. HCA represents that it has distributed its Policies and Procedures to its facilities. Compliance staff at both the facilities and the corporate headquarters, including the Responsible Executives, shall be available to explain any and all Policies and Procedures.

C. Training and Education. HCA shall meet the following training requirements. The training requirements are cumulative (not exclusive) so that one person may be required to attend training in several substantive areas in addition to the general training. All training requirements set forth below in paragraphs 1 to 5 shall be implemented as specified below. With respect to the initial training required to be provided within a certain time period after the effective date of this CIA, HCA need not provide such training to persons who have received training in the six-month period prior to the

effective date of this CIA, if the training provided meets all the subject matter and duration requirements that would apply to the initial training under the CIA.

1. *General Training.* HCA shall provide at least two hours of training initially (within 90 days of the effective date of this CIA) to each covered person, and one hour of refresher training annually thereafter. The training shall cover HCA's Ethics and Compliance Program, its Code of Conduct, and the requirements of this CIA. The training conducted by HCA when it issued its Code of Conduct, *One Clear Voice*, and its ethics and compliance refresher training, *Commitments We Share*, and/or its revised Code of Conduct, *A Tradition of Caring*, (all of which explained HCA's Ethics and Compliance Program and its Code of Conduct) regardless of the date the training occurred will satisfy this requirement for training within 90 days notwithstanding the fact that such training did not cover the CIA. Covered persons who have received prior training described in the previous sentence must receive at least one hour of refresher training (including discussion of the CIA) during the first year covered by the CIA and annually thereafter. Within 90 days after the effective date of this CIA, HCA shall notify all covered persons of the execution of the CIA and provide a summary of the key provisions of this CIA through electronic mail, its internet and/or intranet sites, newsletters, and other appropriate means. All general training conducted after the effective date of this CIA shall include training on the CIA.

2. *Coding Training.* HCA shall continue to have in place an introductory training course for each hospital inpatient coder, as well as an intermediate coding course. HCA shall provide at least eight hours of coding training to inpatient hospital coders and supervisors within 180 days of the effective date of this CIA. HCA shall maintain its DRG coding course for hospital inpatient coders accessible through its intranet. HCA shall maintain and enforce its current policy requiring 30 hours of continuing education annually for hospital inpatient coders.

3. *Billing Training.* HCA shall provide training to all individuals (including Laboratory and Business Office Directors and other billing personnel) responsible for Federal health care program billing in their facilities. HCA shall provide at least eight hours of such training within 180 days of the effective date of this CIA and during each subsequent year. The training shall include the following subject matters:

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

- e. the legal sanctions for improper billings; and
- f. examples of proper and improper billing practices.

4. *Cost Report Training.* HCA shall ensure that covered persons who prepare cost reports receive at least eight hours of training on preparation of cost reports for Federal health care programs within 180 days of the effective date of this CIA. HCA shall maintain and enforce its current practice requiring 40 hours of continuing education annually to include Federal and/or state statutes, regulations, and guidelines, compliance, and Corporate policies for covered persons who prepare cost reports.

5. *Physician Relations Training.* Within 90 days of the effective date of this CIA and annually thereafter, HCA shall provide at least one hour of training to its Hospital CEOs, CFOs, and all other personnel substantially involved in negotiating or monitoring physician relationships on the statutes and regulations related to hospital/physician relationships (including but not limited to 42 U.S.C. §§ 1320a-7b(b) and 1395nn). HCA shall annually distribute its physician relationship policy checklist to such personnel.

6. *Overall Compliance Training.* HCA shall continue its process of establishing individual training profiles for its employees. HCA shall pursue the implementation of these training profiles in order to ensure that all covered persons are familiar with areas of compliance risk relevant to their positions.

7. *New Persons.* Affected new covered persons shall receive the General Training described in section III.C.1 above by the end of the first 30 days after the person begins work. The orientation training (which is defined as all other training required, under section III.C, to be accomplished within 180 days or less after the effective date of this CIA) required by this CIA shall also be promptly provided to appropriate new covered persons (but in no event later than 90 days after the person begins work on the matter for which they must be trained) so that the persons are fully qualified by virtue of such training to perform whatever responsibilities may be assigned to them. In any situation where training requirements have not been completed, a fully trained HCA employee shall carefully monitor the work of the untrained person.

8. *Covered Contractor Requirements.* HCA must document completion of the applicable coding, billing, cost report, or physician relationships training to employees of Covered Contractors working on HCA matters if: (i) the Covered Contractor is a solo-practitioner; (ii) the Covered Contractor was not retained because of its professional expertise in the area for which training is necessary; or (iii) the Covered Contractor has not complied with the requirements of section III.B.2. HCA is responsible for ensuring the expertise and compliance of Covered Contractors.

9. *Certifications and Retention.* HCA shall maintain sufficient records to demonstrate that the required training has occurred. These records shall include certifications from covered persons that they have attended the required training. The

certifications may be acquired through: attendance/sign-in sheets for in-person group training sessions; computer attestations for computer-based training; or similar mechanisms for other forms of training. Facility ECOs and/or Responsible Executives shall retain training records and certifications in a manner that permits reporting to the SVP-Compliance to enable the SVP-Compliance to report on the training, and provide the specific course materials and certifications, to the OIG upon request.

D. Review Procedures.

1. *Retention of Independent Review Organization.* HCA shall retain an entity (or entities), such as an accounting, auditing or consulting firm (hereinafter “Independent Review Organization” or “IRO”), to perform review procedures to assist HCA in assessing the adequacy of its Policies and Procedures, Ethics and Compliance Program, its compliance with this CIA, and its compliance with the requirements of Federal health care programs. The reviews shall be performed annually during the term of the CIA in accordance with the attached workplans. These reviews shall cover the calendar years 2001 through 2008, unless otherwise specified in a workplan. The Independent Review Organization used for each review must have expertise in the matters to be reviewed and particularly with the requirements of the Federal health care programs relevant to that area of review. The Independent Review Organization must be retained to conduct the reviews for the first year within 90 days of the effective date of this CIA. An IRO may engage qualified sub-IROs (including, as appropriate, law firms),

as necessary and HCA shall have the right to designate a different IRO for any particular area of compliance concern if it believes that such different IRO would be better qualified to undertake a particular focused review. HCA shall have the right to designate a new IRO at any time it chooses. If HCA designates a new IRO, it shall provide written notice to the OIG within 15 days of designating the new IRO. This written notice will include the following: (a) the name, address, and primary contact person at the new IRO; (b) a brief description of the qualifications of the new IRO; and (c) a brief description of the reasons that a new IRO was designated.

2. *Types of Reviews.* The IRO(s) and HCA appropriate internal resources or directed external resources shall annually perform the reviews described in the audit work plans (“workplans”) attached to, and incorporated by reference into, this CIA. The workplans address the following areas: (1) Diagnosis Related Groups (DRGs); (2) Laboratory Billing; (3) Outpatient Prospective Payment; and (4) Physician Relationships. The workplans require reviews of systems and processes in place at HCA and its facilities, and of claims submitted by HCA and paid by Federal health care programs (the physician relationship workplan includes review of physician relationships rather than claims). The reviews of claims more specifically described in the workplans fall into two general categories: (1) probe samples of a set number of claims (with no pre-determined statistical confidence or precision parameters); and (2) full samples of claims from which an overpayment amount can be projected to the total population of claims in question

within pre-determined statistical confidence and precision parameters. HCA and the IRO will evaluate the IRO work plans annually based upon prior year results. If appropriate, HCA will submit revised IRO work plan(s) to the OIG for its review and action.

3. Statistical Sampling and Appraisal Methodologies for Reviews. All matters related to this CIA and the workplans that involve statistical sampling or appraisal, or the review of claims, including probe samples and full samples, shall be conducted in accordance with the provisions of Appendix A to this CIA.

4. Ethics and Compliance Program Review. The IRO shall conduct a compliance review providing findings regarding whether HCA's Ethics & Compliance Program, Policies and Procedures, and operations comply with the terms of this CIA. This review shall include section by section findings regarding the requirements of this CIA. In addition, the IRO shall provide findings regarding whether HCA has complied with its obligation under the Settlement Agreement: (a) 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 (b) 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 unallowable costs.

5. Review Reports. HCA and the IRO(s) shall annually produce reports corresponding to all of the required reviews and including all of the information required

by this section of the CIA, workplans, and the Claims Review Reports described in Appendix A. A complete copy of all of the reports for the reporting year shall be included in each of HCA's Annual Reports to OIG.

6. *Verification/Validation.* In the event that the OIG has reason to believe that any of HCA's reviews fail to conform to its obligations under the CIA or indicates improper billings not otherwise adequately addressed in the audit report, and thus determines that it is necessary to conduct an independent review to determine whether or the extent to which HCA is complying with its obligations under this CIA, HCA agrees to pay for the reasonable cost of any such review by the OIG or any of its designated agents. Prior to proceeding with such an independent review, the OIG shall notify HCA of its intent to do so and its reasons for believing such a review is necessary, and shall attempt to resolve any issues without proceeding with an independent review. This attempt to resolve issues may include permitting HCA to recommend further work it or the IRO may undertake to address the OIG's concerns. However, it shall remain in the sole discretion of the OIG to proceed with an independent review as described above.

E. Confidential Disclosure Program. HCA has established a Confidential Disclosure Program. HCA provides a toll free "Ethics Line" to enable employees, contractors, agents or other individuals to disclose, to the EC Department or some other person who is not in the disclosing individual's chain of command, any identified issues or questions associated with HCA's Policies and Procedures, practices, or operations with

respect to any Federal health care program, believed by the individual to be inappropriate. HCA shall continue to publicize the existence of the Ethics Line to all covered persons. HCA has established a Policy governing its handling of disclosures made through the Ethics Line. HCA shall continue to operate the Ethics Line through such Policy. HCA shall continue to forbid retribution or retaliation for disclosures and allow for anonymous, confidential disclosures. The EC Department shall maintain a confidential disclosure log, which shall include a record and summary of each allegation received, the status of the respective investigations, and any corrective action taken in response to the investigation.

F. Ineligible Persons.

1. *Definition.* For purposes of this CIA, an “Ineligible Person” shall be any individual or entity who: (i) is currently excluded, debarred, or otherwise ineligible to participate in the Federal health care programs; or (ii) 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.* HCA shall not hire or engage as contractors, or grant staff privileges to, any Ineligible Person. To prevent hiring or contracting with, or granting staff privileges to, any Ineligible Person, HCA shall screen all prospective employees and prospective contractors prior to engaging their services and screen physicians prior to granting staff privileges by (i) requiring applicants to disclose whether they are Ineligible Persons, and (ii) 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.* HCA has reviewed its list of current employees and contractors paid through automated means against the Exclusion Lists. Within 180 days of the effective date of this CIA, HCA shall review its list of current physicians with staff privileges against the Exclusion Lists. HCA shall review the lists of employees, contractors, and physicians with staff privileges against the Exclusion Lists at least semi-annually during the duration of this CIA. In addition, HCA shall require employees, contractors and physicians with staff privileges to disclose immediately any debarment, exclusion or other event that makes the person an Ineligible Person. If HCA has notice that an employee, agent, or physician has become an Ineligible Person, HCA shall remove such person from responsibility for, or involvement with, HCA'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 HCA 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, HCA 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 Proceedings. Within 30 days of discovery by HCA, HCA shall notify OIG, in writing, of any ongoing investigation or legal proceeding conducted or brought by a governmental entity or its agents involving an allegation that HCA 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. HCA 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.

H. Reporting.

1. *Overpayments*

a. *Definition of Overpayments.* For purposes of this CIA, an “overpayment” shall mean the amount of money HCA has received in excess of the amount due and payable under any Federal health

care program requirements. HCA may not subtract any underpayments for purposes of determining the amount of relevant “overpayments.”

b. Reporting of Overpayments. If, at any time, HCA identifies or learns of any overpayments, HCA shall notify the payor (e.g., Medicare fiscal intermediary or carrier) and repay any identified overpayments within 30 days of identification and take remedial steps within 60 days of identification (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, HCA shall repay the overpayment to the appropriate payor to the extent such overpayment has been quantified (submission of corrected bills in conformance with payor policy within 30 days fulfills this requirement). If not yet quantified, within 30 days of identification, HCA 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.

For Medicare overpayments identified through HCA’s Ethics and

Compliance Program and/or the processes required under this CIA, (including internal and IRO audits, Ethics Line cases, or other corporate-level monitoring or review), the notice to the contractor must include the information contained on the Overpayment Refund Form, attached to this as Appendix B to this CIA (unless the contractor has authorized the form not to be submitted for this particular type of claim correction).

2. *Reportable Events.*

a. *Definition of Reportable Event.* For purposes of this CIA, a “Reportable Event” means anything that involves:

- (i) a substantial overpayment; or
- (ii) a matter that a reasonable person would consider a potential violation of any criminal, civil, or administrative statute or regulation applicable to any Federal health care program for which criminal penalties, civil monetary penalties, or exclusion may be authorized.

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

b. *Reporting of Reportable Events.* If HCA determines that there is a Reportable Event, HCA shall notify OIG, in writing, within 30

days of making the determination that the Reportable Event exists.

The report to the OIG shall include the following information:

(i) If the Reportable Event 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 Reportable Event, including the relevant facts, persons involved, and legal and Federal health care program authorities implicated;

(iii) a description of HCA's actions taken to correct the Reportable Event; and

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

I. Corrective Actions Related to Investigation of Physician Relationships.

In the context of the investigation, self-audit, and settlement discussions related to the issue of physician relationships, certain such relationships have been identified as anomalies. HCA shall take appropriate measures to review these anomalous relationships. Those relationships that are determined by HCA to be non-compliant shall be terminated or amended to conform to HCA's Ethics and Compliance Program and the requirements of the Federal health care programs. HCA shall report on these measures as required in section V and all supporting documents shall be available to the OIG upon request.

IV. NEW AND DIVESTED LOCATIONS

In the event that HCA: (1) purchases or establishes a new hospital, freestanding ambulatory surgery center, home health agency, or another line of business that provides services that are billed to Federal health care programs; or (2) sells or divests an existing hospital, freestanding ambulatory surgery center, or home health agency, HCA shall notify OIG of this fact within 30 days of the date of purchase, establishment, sale, or divestiture. This notification shall include the location of the operation(s), telephone number, fax number, Federal health care program provider number(s) (if any), and the corresponding payor(s) (contractor specific). All covered persons at new locations shall be subject to the requirements in this CIA that apply to new covered persons (e.g., completing certifications and undergoing training). If HCA sells all of the assets or its

ownership interest related to a location, then that location shall no longer be considered part of HCA for the purposes of this CIA. If the location is still owned or operated in whole or in part by HCA or any of its subsidiaries or their successors, then the location shall continue to be considered part of HCA for the purposes of this CIA. If a hospital or ambulatory surgery center shall no longer be subject to the CIA due to a sale or transfer from HCA, HCA shall require as a condition of the sale that buyer or transferee represents and agrees that it has or shall implement and maintain with respect to its operations of the facility an effective program to prevent and detect violations of the legal requirements applicable to the delivery of goods and services in connection with any health care benefits and that such a program will comply with the provisions of the U.S. Sentencing Guidelines relating to corporate compliance programs and will be mindful of any applicable guidance issued by the OIG or other components of HHS; and that the buyer or transferee agrees that it will maintain such program for no less than five years from the date of sale or transfer.

V. IMPLEMENTATION AND ANNUAL REPORTS

A. Implementation Report. Within 120 days after the effective date of this CIA, HCA 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, title, address, facility name (if applicable), and telephone number of all of the individuals who are in positions, or on committees,

described in section III.A (except that with respect to section III.A.6 only, the SVP-Compliance shall certify that the Hospital Committees are in place as required and the information otherwise required by this section shall be available to the OIG upon request);

2. the copy of all Policies and Procedures required by section III.B.2 that have not been previously provided to the OIG;

3. a description of the training required by section III.C, including a description of the targeted audiences and a schedule of when the training sessions were held;

4. a certification by the SVP-Compliance that:

a. the Policies and Procedures required by section III.B have been developed and implemented, and have been distributed 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.

5. the identity of the Independent Review Organization(s) and the proposed start and completion date of the first set of reviews by the Independent

Review Organization(s) and appropriate HCA internal resources or directed external resources;

6. a summary of personnel actions taken pursuant to section III.F (other than hiring or granting of staff privileges);

7. a summary of the actions taken to ensure that the anomalous physician relationships identified in the investigation, self-audit, and settlement discussions have been reviewed, and terminated or amended, as appropriate, in conformance with section III.I.;

8. a list of all of HCA's locations (including physical 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; and

9. To the extent not already furnished to OIG, or if modified, a description of HCA's corporate structure, including identification of any parent, sister, and other related companies, subsidiaries and their respective lines of business.

B. Annual Reports. HCA shall submit to OIG Annual Reports with respect to the status and findings of HCA's compliance activities. The first Annual Report shall cover the time period from the effective date of this CIA through December 31, 2001 and shall

be received by the OIG no later than April 30, 2002. Subsequent Annual Reports shall cover each of the calendar years 2002 through 2008 and shall be received by the OIG no later than April 30 of the year following the year covered in the report. Each Annual Report shall include:

1. any change in the identity, title, address, facility name (if applicable), telephone number, and position description of all of the individuals who are in positions, or on committees, described in section III.A (except that with respect to section III.A.6 only, the SVP-Compliance shall certify that the Hospital Committees are in place as required and the information otherwise required by this section shall be available to the OIG upon request);
2. a certification by the SVP-Compliance 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. HCA has complied with the following specified 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 unallowable costs.

3. notification of any changes or amendments to the Policies and Procedures referenced in section III.B and the reasons for such changes (e.g., change in contractor policy);

4. a complete copy of the reports prepared pursuant to the reviews required in section III.D, including a copy of the methodologies used, along with a copy of the IRO's engagement letter;

5. HCA's response/corrective action plan to any issues raised in the reviews conducted under section III.D;

6. a summary of Reportable Events required to be identified and reported by section III.H and an update on corrective actions taken in response to such Reportable Events;

7. a report of the aggregate overpayments identified through HCA's Ethics and Compliance Program and/or the processes required under this CIA, (including internal and IRO audits, Ethics Line cases, or other corporate-level monitoring or review) that have been returned to the Federal health care programs. Overpayment amounts shall be broken down into the following categories: inpatient Medicare; outpatient 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 and a description of any changes to the Confidential Disclosure Program or Ethics Line referenced in that section;

9. a description of any personnel actions (other than hiring or granting staff privileges) taken by HCA as a result of the obligations in section III.F; and, with respect to any person that falls within the ambit of section III.F.4, the name, title, and responsibilities of the person, and the actions taken by HCA 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 HCA has committed a crime or has engaged in fraudulent activities, which is required to be reported by 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. to the extent that such relationships still exist and have not been appropriately altered and reported in an earlier report to the OIG, a summary of the actions taken to ensure that the anomalous physician

relationships identified in the investigation, self-audit, and settlement discussions have been reviewed, and terminated or amended, as appropriate, in conformance with section III.I; and

12. a description of all changes to the most recently provided list (as updated) of HCA's locations (including physical locations and mailing addresses) as required by section V.A.7, 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.

C. Certifications. The Implementation Report and Annual Reports shall include a certification by the SVP-Compliance that: (1) except as otherwise explicitly described in the applicable report, HCA is in compliance with all of the requirements of this CIA, to the best of his or her knowledge; and (2) the SVP-Compliance has reviewed the report and has made reasonable inquiry regarding its content and believes that 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 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
Phone 202.619.2078
Fax 202.205.0604

HCA:

Alan Yuspeh
Senior Vice President
Ethics, Compliance, and Corporate Responsibility
HCA -- The Healthcare Company
One Park Plaza
Nashville, TN 37203
Phone 615.344.1005
Fax 615.344.1045

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 examine HCA's books, records, and other documents and supporting materials and/or conduct an on-site review for the

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

VIII. DOCUMENT AND RECORD RETENTION

In addition to any other requirements for record retention, HCA shall maintain for inspection all documents and records: (1) related to reimbursement from the Federal health care programs for at least five years after the submission of the request for reimbursement (or longer if otherwise required); and (2) necessary to establishing HCA's compliance with this CIA for at least three years following the submission of the Annual Report covering the relevant year. Imaged copies of documents shall satisfy this requirement.

IX. DISCLOSURES

Consistent with 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 HCA prior to any release by OIG of information submitted by HCA pursuant to its obligations under this CIA and identified upon submission by HCA as trade secrets, commercial or financial information and privileged and confidential under the FOIA rules. With respect to such releases, HCA shall have the rights set forth at 45 C.F.R. § 5.65(d). HCA 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

HCA 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, HCA 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 \$2,500.00 (which shall begin to accrue on the day after the date the obligation became due) for each day, beginning 90 days after the

effective date of this CIA and concluding at the end of the term of this CIA, HCA fails to have in place any of the following:

- a. all of the personnel and committees required in section III.A;
- b. a written Code of Conduct as required in section III.B.1;
- c. written Policies and Procedures as required in section III.B.2;
- d. a training program as required in section III.C; and
- e. a Confidential Disclosure Program as required in section III.E;

2. A Stipulated Penalty of \$2,500.00 (which shall begin to accrue on the day after the date the obligation became due) for each day HCA fails meet any of the deadlines to submit the Implementation Report or the Annual Reports to the OIG.

3. A Stipulated Penalty of \$2,500.00 (which shall begin to accrue on the date the failure to comply began) for each day HCA employs, contracts with, or grants staff privileges to an Ineligible Person and that person: (i) has responsibility for, or involvement with, HCA'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 HCA

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 \$2,500.00 (which shall begin to accrue on the date the HCA fails to grant access) for each day HCA fails to grant access to the information or documentation as required in section VII of this CIA.

5. A Stipulated Penalty of \$2,500.00 (which shall begin to accrue on the date the failure began) for a failure by HCA to report a Reportable Event, take corrective action, and pay the appropriate refunds, as provided in section III.H;

6. A Stipulated Penalty of \$2,000.00 (which shall begin to accrue 10 days after the date that OIG provides notice to HCA of the failure to comply) for each day HCA fails to comply fully and adequately with any obligation of this CIA and such failure is not already subject to a penalty in section X.A.1 through 5 above. In its notice to HCA, the OIG shall state the specific grounds for its determination that the HCA 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 HCA has failed to comply with any of the obligations described in section X.A and determining that Stipulated Penalties are appropriate, OIG shall notify HCA of: (a) HCA'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"). Within 10 days after

receiving the Demand Letter, HCA 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 HCA elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until HCA cures, to the 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.C.

2. *Timely Written Requests for Extensions.* HCA 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 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 HCA fails to meet the revised deadline set by the 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 two business days after HCA receives OIG's written denial of such request. 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.

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 otherwise noted, these provisions for payment of Stipulated Penalties shall not affect or otherwise set a standard for the OIG's determination that HCA 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 HCA constitutes an independent basis for OIG to exclude HCA and/or any of its subsidiaries from participation in the Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)). Upon a determination by OIG that HCA has materially breached this CIA and that exclusion should be imposed, the OIG shall notify HCA by certified mail of: (a) HCA'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 Letter").

2. *Opportunity to Cure.* HCA shall have 30 days after receiving the Notice of Material Breach Letter to demonstrate to the OIG's satisfaction that:

- a. HCA 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) HCA has begun to take action to cure the material breach; (ii) HCA is pursuing such action with due diligence; and (iii) HCA has provided to OIG a reasonable timetable for curing the material breach.

3. *Exclusion Letter.* If at the conclusion of the 30-day period, HCA fails to satisfy the requirements of section X.C.2, OIG may exclude HCA and/or any of its subsidiaries from participation in the Federal health care programs. OIG shall notify HCA in writing of its determination to exclude HCA and/or any of its subsidiaries (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 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. If HCA and/or any of its subsidiaries is excluded under the provisions of this CIA, HCA 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 HCA to report a Reportable Event, take corrective action and pay the appropriate refunds, as provided in section III.H, provided that any of the following individuals at HCA had notice of the Reportable Event: an officer; a director; a Responsible Executive; an ECO; a member of the EC Department; or an attorney in the Legal Department;
- 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 HCA 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, HCA 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 10 days of HCA receiving the Demand Letter and the request for a hearing involving exclusion shall be made within 20 days of HCA receiving 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 HCA was in full and timely compliance with the obligations of this CIA for which the OIG demands payment; and (b) the period of noncompliance. HCA 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 HCA to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable 20 days after the ALJ issues such a decision notwithstanding that HCA 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

HCA 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) HCA had begun to take action to cure the material breach within that period, (ii) HCA has pursued and is pursuing such action with due diligence, and (iii) HCA 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. HCA's election of its contractual right to appeal to the DAB shall not abrogate the OIG's authority to exclude HCA and/or any of its subsidiaries 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 20 days after the ALJ issues such a decision, notwithstanding that HCA 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, HCA and OIG agree as follows:

A. This CIA shall be binding on the successors, assigns, and transferees of HCA, consistent with the terms of Section IV;

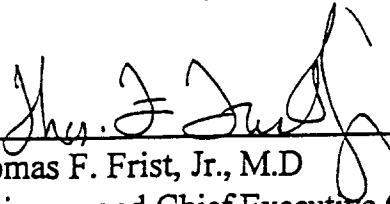
B. This CIA shall become final and binding on the date that the court(s) accept the plea(s) and impose a sentence in the criminal proceedings related to the plea agreement

entered into between HCA and the United States on or about the date of the signing of this 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 HCA 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.

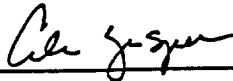
ON BEHALF OF HCA



Thomas F. Frist, Jr., M.D
Chairman and Chief Executive Officer
HCA -- The Healthcare Company

12/12/00

DATE



Alan Yuspeh
Senior Vice President
Ethics, Compliance, and Corporate Responsibility
HCA -- The Healthcare Company

12/12/00

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

DATE

ON BEHALF OF HCA


Thomas F. Frist, Jr., M.D
Chairman and Chief Executive Officer
HCA -- The Healthcare Company

DATE

Alan Yuspeh
Senior Vice President
Ethics, Compliance, and Corporate Responsibility
HCA -- The Healthcare Company

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

12/14/00
DATE

APPENDIX B

OVERPAYMENT REFUND

TO BE COMPLETED BY MEDICARE CONTRACTOR

Date: _____
Contractor Deposit Control # _____ Date of Deposit: _____
Contractor Contact Name: _____ Phone _____

Contractor
Address: _____
Contractor Fax: _____

TO BE COMPLETED BY PROVIDER/PHYSICIAN/SUPPLIER

Please complete and forward to Medicare Contractor. This form, or a similar document containing the following information, should accompany every voluntary refund so that receipt of check is properly recorded and applied.

PROVIDER/PHYSICIAN/SUPPLIER NAME _____
ADDRESS _____
PROVIDER/PHYSICIAN/SUPPLIER # _____ CHECK
NUMBER# _____
CONTACT PERSON: _____ PHONE
_____ AMOUNT OF CHECK \$ _____ CHECK
DATE _____

REFUND INFORMATION

For each Claim, provide the following:
Patient Name _____ HIC

Medicare Claim Number _____ Claim Amount Refunded
\$ _____
Reason Code for Claim Adjustment: _____ (Select reason code from list below. Use one reason per claim)

(Please list all claim numbers involved. Attach separate sheet, if necessary)

Note: If Specific Patient/HIC/Claim #/Claim Amount data not available for all claims due to Statistical Sampling, please indicate methodology and formula used to determine amount and reason for overpayment: _____

For Institutional Facilities Only:

Cost Report Year(s) _____

(If multiple cost report years are involved, provide a breakdown by amount and corresponding cost report year.)

For OIG Reporting Requirements:

Do you have a Corporate Integrity Agreement with OIG? _____ Yes _____ No

Reason Codes:

<u>Billing/Clerical Error</u>	<u>MSP/Other Payer Involvement</u>	<u>Miscellaneous</u>
01 - Corrected Date of Service	08 - MSP Group Health Plan Insurance	13 - Insufficient Documentation
02 - Duplicate an HMO	09 - MSP No Fault Insurance	14 - Patient Enrolled in
03 - Corrected CPT Code Rendered	10 - MSP Liability Insurance	15 - Services Not
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		

APPENDIX A
to
HCA Corporate Integrity Agreement

A. Claims Review.

1. *Definitions.*

- a. **Claims Review**: Any review procedure described in the CIA or the workplans that involves the review of bills, claims, or other submissions to any Federal health care program.
- b. **Claims Review Sample**: A statistically valid, randomly selected, sample of items selected for appraisal in a Claims Review.
- c. **Item**: Any discrete unit that can be sampled (e.g., code, line item, beneficiary, patient encounter, etc.).
- d. **Overpayment**: Consistent with the definition of Overpayment in section III.H.1.a of the CIA, the amount of money HCA has received in excess of the amount due and payable under any Federal health care program requirements. For the purposes of the workplans, any Claims Reviews, and all reporting to the OIG under this CIA, HCA shall not subtract or “net out” underpayments when determining the amount of relevant Overpayments.
- e. **Gross Financial Error Rate**: the total amount of overpayments divided by the total payment amounts received under Federal health care programs for the sample Items reviewed.
- f. **Paid Claim**: A code or line item submitted by HCA and for which HCA has received reimbursement from the Medicare program.
- g. **Population**: All Items for which HCA has submitted a code or line item and for which HCA has received reimbursement from the Medicare program (i.e., a Paid Claim) during the one year period covered by the Claims Review, unless a different period is specified in the appropriate workplan. To be included in the Population, an Item must have resulted in at least one Paid Claim.
- h. **Probe Sample**: A Claims Review Sample of a pre-determined number of Items selected through random sampling from the Population. The Probe Sample may be used for the purpose of determining whether to perform a Claims Review with

a Full Sample, or for the purpose of estimating the mean and standard deviation of the Population (to calculate the minimum number of Items to be included in the Full Sample), or both. If the results from the probe sample already achieve the statistical confidence and precision parameters set forth in this Appendix A, then the Probe Sample results can be used as the Full Sample results and another sample will not be required.

i. Full Sample: A Claims Review Sample from which an overpayment amount can be projected to the total population of claims in question within the statistical confidence and precision parameters set forth in this Appendix A.

j. 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 Methodology*. Each Claims Review shall be conducted in the manner set forth in the applicable workplans consistent with the CIA and this Appendix A.

a. Selection of Samples. Whenever a sample of anything, e.g., claims, beneficiaries, hospitals, is selected pursuant to the CIA or the workplans, the sample shall be selected through the use of the RAT-STATS "Random Numbers" function.

b. Confidence and Precision Requirements for Full Samples. To the extent that a workplan requires a Full Sample, it shall meet the following requirements (or alternatively, the full universe of Items may be reviewed). The Full Sample must contain a sufficient number of Items so that if the Overpayments identified in the Full 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 Full Sample Overpayment results were projected to the Population at a 90% confidence level, the confidence interval (expressed in dollars) must 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.

c. Probe Sample to Determine Whether to Review a Full Sample. Whenever a Probe Sample is required by a workplan to determine whether to conduct a review of a Full Sample, the determination shall be based upon the Gross Financial Error

Rate based on the estimated Overpayment identified in the Probe Sample. To the extent that a financial error threshold (such as 5%) is used for sample expansion, the threshold has no bearing on other matters (such as extrapolation of overpayments). Nothing in the CIA, this Appendix A, or the workplans relieves HCA of its responsibility to correct and repay Overpayments identified in a Probe Sample.

d. Probe Sample to Determine Sample Size for Full Sample. Whenever a Probe Sample is used to determine the sample size for a Full Sample, it shall meet the following criteria. The Probe Sample shall include a random sample of at least 50 Items. Once all Paid Claims associated with the Items included in the Probe Sample have been reviewed, the estimated mean and standard deviation of the Population shall be determined. This determination is based on the Overpayment amount received by HCA for each Item in the sample. The “Variable Appraisals” function of RAT-STATS shall be used to calculate the estimated mean and standard deviation of the Population. For purposes of estimating the mean and standard deviation of the Population, and entering this information into the “Variable Appraisals” 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 the Probe Sample, then the Claims Review can be terminated with the results of the Probe Sample, and the results of the Probe Sample shall be reported in lieu of the Claims Review of the Full Sample.

e. Calculation of Full Sample Size and Selection of the Full Sample. The estimates of the mean and the standard deviation of the Population obtained through the review of the Probe Sample shall be used to calculate the minimum size of the Full Sample. In order to determine the minimum number of Items that must be included in the Full 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. The Full Sample shall be a random sample 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 Full Sample.

f. Item Appraisal. For each Item appraised (either as part of a Probe Sample or a Full Sample), only Paid Claims shall be evaluated. Every Paid Claim in the Claims Review Sample shall be evaluated 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.

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

h. Use of First Samples Drawn. For the purposes of all samples selected pursuant to the CIA and the workplans, 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 a Probe Sample or Full Sample.

B. Claims Review Report. In addition to the information specifically required by the workplans, the following information shall be included in a Claims Review Report for each Claims Review performed:

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.

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 Full Samples 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 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 Samples and in the Full Samples.
- b. A copy of the RAT-STATS printouts of the random numbers generated by the “Random Numbers” function.
- c. A copy of the RAT-STATS printouts of the “Sample Size Estimators” results used to calculate the minimum number of Items for inclusion in the Full Samples.
- d. A copy of the RAT-STATS printout of the “Variable Appraisals” function results for the Probe Samples.
- e. The Sampling Frame used in the Probe Samples and the Full Samples will be available to the OIG upon request.

3. *Claims Review Results*

- a. The total number and percentage of instances in which it was determined that the Paid Claim submitted by HCA (“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 HCA.
- 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.)
- d. 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, correct allowed amount, 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 Reviews; and (2) performed the Claims Reviews.

HCA DRG WORKPLAN

I. INTRODUCTION

This workplan describes the review procedures that HCA–The Healthcare Company (the Company) and the Independent Review Organization (IRO) will be required to follow with respect to the Company’s inpatient DRG coding processes. The focus of this testing will be to investigate outliers identified through a benchmarking process of certain Medicare inpatient DRG ratios.

In addition, the IRO will obtain an understanding of the Company’s processes and controls that are designed to prevent and detect Federally funded payor inpatient DRG coding errors. The IRO and the Company will use this understanding of processes and controls to select the acute care hospitals to test in detail and subject, as appropriate, to record level DRG validation testing. The focus of the procedures will be on the Company’s acute care hospitals’ processes and controls designed to ensure compliance with DRG coding requirements.

II. CORPORATE FEDERALLY FUNDED PAYOR INPATIENT DRG COMPLIANCE RISK MANAGEMENT PROCESS

The IRO will begin its understanding of the Company’s DRG coding compliance by understanding the process performed at the Corporate level. The focus will be on the Company’s controls affecting the entire acute care hospital system. After gaining this understanding, the IRO and the Company will design agreed upon procedures which will allow the Company and the OIG to evaluate the effectiveness of the Corporate Compliance Risk Management Process. The key steps the IRO will follow to gain an understanding of the corporate compliance control environment include the following:

A. Understand the Federally Funded Payor Inpatient DRG Coding Compliance Process

The IRO will obtain an understanding of the regulatory environment, of key assumptions underlying DRG coding processes and the impact of changes on potential compliance risks to the Company. Procedures will include:

1. Interview the Corporate Ethics and Compliance Officer, SVP Government Programs, Health Information Management Services (HIMS) VP and other key personnel to:

- a. Understand how the Company evaluates risk and changes in the compliance environment.
 - b. Understand how these changes become integrated into the overall compliance strategy.
 - c. Understand how these changes are implemented in the acute care hospitals.
2. Read related documentation such as written assessments of changes in regulations.

B. Understand Federally Funded Payor DRG Coding Policies, Procedures, Tools and Resources

The IRO will understand how the Company establishes the DRG coding policies and procedures by performing the following procedures:

1. Read organizational charts to understand compliance infrastructure.
2. Read policy and procedure manuals and other tools and resources and compare to regulatory requirements.
3. Understand how the Federally funded inpatient DRG coding policies and procedures are established by interviewing the Corporate Ethics and Compliance Officer, SVP Government Programs, HIMS VP and other key personnel.
4. Read the Company's documentation regarding the process for creating, updating and distributing the policies and procedures.

C. Understand the Design and Implementation of Education and Training Control Processes

The IRO will understand how the Company ensures that DRG Coding personnel have the appropriate training and expertise to implement risk control processes by performing the following procedures:

1. Interview key personnel regarding the design and implementation of education and training processes.

2. Read training materials at the corporate and facility levels and compare to Company policies for content.
3. Select a random sample of HIMS coding personnel and determine if training requirements are being met.

D. Understand the Compliance Monitoring Function

The IRO will understand how the Company measures, monitors and assesses the performance of the compliance process by performing the following procedures:

1. Inquire as to the types of monitoring tools and plans that are in place to prevent and detect non-compliance.
2. Understand and observe benchmarking techniques utilized by the Company in identifying outliers for subsequent testing.
3. Read a random sample of interim monitoring reports.
4. Review a random sample of implementation plans for process improvements and error correction.
5. Read the findings of a random sample of the Company DRG coding reviews.

E. Understanding the Information Technology Framework

The IRO will identify the electronic data processing systems that are used to process data relevant to the DRG coding practices. The IRO shall gain an understanding of the control environment over these systems related to:

1. Access to critical data.
2. Security over data and critical applications.
3. Application and program change controls.

F. Understand the Process for Corrective Action

The IRO will understand how the Company's procedures for ensuring that non-compliance within the DRG coding process is addressed by performing the following procedures:

1. Interview key personnel regarding the process for reporting errors and creating action plans.
2. Determine that action plans were prepared and select a random sample of 5 action plans and incorporate into the design of detailed testing procedures.
3. Read the Company's recommendations for process improvements to prevent potential future non-compliance and integrate into the design of detailed tests.

III. BENCHMARKING AND COMPLIANCE REVIEWS OF MEDICARE INPATIENT DRG OUTLIERS

The Company and IRO will perform coding engagement procedures upon completion of the Corporate level process testing as follows:

A. Benchmarking of Medicare Inpatient DRG Outliers

1. The Company will benchmark its acute care hospitals' Medicare inpatient DRGs against industry peer groups for 17 Medicare Inpatient DRG ratios for the immediately preceding calendar year each January. The DRG ratios to be benchmarked will be agreed upon by the OIG and the Company at the end of each calendar year. Unless the OIG notifies the Company otherwise, the Company will benchmark the 17 Medicare DRG ratios listed in Attachment A. (If the Company proposes to amend the list of DRG ratios to be benchmarked, it shall provide notice to the OIG of the proposed DRG ratios at least 90 days before the end of the calendar year.) The benchmarking will be performed as follows:

- a. Each January, the most recently available MedPar data, comprised of all non-HCA hospitals, will be used to determine non-HCA DRG ratio benchmarks and case counts.

- b. The definition of non-HCA acute care hospitals which will be used to determine the non-HCA Medicare DRG ratios is those acute care hospitals that the Company did not own during the timeframe that is represented in the MedPar data being used. For example, if an acute care hospital had been owned by the Company in 1999 but was sold during 2000, this acute care hospital would be included as an HCA acute care hospital and excluded as a non-HCA acute care hospital for the benchmarks that are based on MedPar 1999 data.
- c. Each January, internal Company data from the twelve months of the just-completed calendar year will be used to determine the acute care hospitals' ratios and the case counts used in the benchmarking process.
- d. The industry Medicare DRG ratio benchmarks will be calculated as the national 75th percentile.
- e. Each acute care hospital's Medicare DRG ratio results will be compared to the industry Medicare DRG ratio benchmarks and those Medicare DRG ratio results in excess of the industry Medicare DRG ratio benchmark will be identified.
- f. For each of the 17 DRGs in the numerator of a DRG ratio, the national 90th percentile of case counts for non-HCA acute care hospitals will be determined using MedPar data.
- g. For each of the Medicare DRG ratios over the benchmark identified in section III.A.1.e., at a particular acute care hospital, it will be determined if the case count for that DRG at that acute care hospital is at or above the national 90th percentile of case counts for that DRG among non-HCA hospitals.
- h. Subject to the following provisions, an acute care hospital shall be identified for further review if it has at least 2 of the 17 DRG ratios over the industry benchmark and the case count for these DRGs is at or above the national 90th percentile of case counts for that DRG among non-HCA hospitals.

i. The hospitals that meet the criteria in section III.A.1.h shall be ranked based on the number of “primary” (non-cc) DRG ratios that are over the industry benchmark at that hospital, regardless of the case counts for these DRGs, e.g., a hospital that has 4 primary DRG ratios over the industry benchmark would be ranked higher than a hospital that has 3 primary DRG ratios over the industry benchmark.

j. The 20 highest ranked hospitals shall be selected for DRG review. If fewer than 20 hospitals are ranked, then all of the ranked hospitals will be selected for review. If fewer than 16 hospitals are ranked, then the highest ranked hospitals will be reviewed along with the unranked hospitals with the highest case counts of DRGs above the industry benchmarks in order to ensure that at least 16 hospitals are reviewed. In no event shall fewer than 16 hospitals be reviewed.

k. The hospitals to be reviewed under this analysis shall be reviewed over the four quarters of the calendar year.

2. The IRO will verify that current Company data is the source for establishing the Company’s Medicare DRG ratios that will be benchmarked.

3. The IRO will verify that the most recent MedPar data as described in section III.A.1.a-b, comprised of all non-HCA acute care hospitals is the source for establishing industry Medicare DRG ratio benchmarks and case counts and will annually recompute the industry peer group Medicare DRG ratio benchmarks and case counts utilized by the Company.

4. Each February (or the month after any benchmarking takes place), the IRO will obtain current Company data and recalculate benchmarking on a random sample of at least 10% of the Company’s hospitals. For example, if the number of acute care hospitals owned was 220, a minimum of 22 acute care hospitals Medicare DRG ratio results would be reviewed (220 acute care hospitals X 10% = 22 acute care hospitals to be tested).

B. DRG Claims Review of Outliers

1. For those hospitals selected for review in section III.A.1.j above, the Company will perform a DRG Claims Review of a Full Sample (as described in Appendix A to the CIA) of the higher weighted DRG for each DRG ratio above the benchmark. For the purpose of a Claims Review under this audit work plan, the Items to be reviewed shall be the paid inpatient Medicare bills for the DRGs in question. The Claims Review of each Item shall include an independent code validation of the medical record to assess the accuracy of the diagnosis and procedure codes, financial class, discharge disposition, sex, age, and DRG assignment. The Population of Claims to be reviewed in each Claims Review shall be the Items from the rolling 12-month period immediately preceding the Claims Review.

2. If a Probe Sample is conducted pursuant to Appendix A and that Probe Sample meets the statistical parameters set forth in Appendix A for Full Samples, e.g., the 90% confidence level and 25% precision requirements, then the Company may treat the Probe Sample as the Full Sample for that DRG. Wherever a DRG Claims Review of a Full Sample is required, the Company may choose to review 100% of the claims in the universe rather than selecting a sample.

3. The IRO will verify the benchmarking approach, e.g., acute care hospitals identified, case counts, subsequent review methodology (probe or universe) and the Company's Medicare DRG Claims Review results.

4. The IRO will select a random sample of at least 10% of the medical records included in the Medicare DRG Claims Reviews performed by the Company and re-perform the Company's workplan steps. Findings will be summarized in the IRO's Report. For example, if the Company reviewed 20,000 files, the IRO would reperform reviews of 10% or 2,000 files.

IV. ACUTE CARE HOSPITAL LEVEL FEDERALLY FUNDED PAYOR INPATIENT DRG COMPLIANCE PROCESS REVIEW

A. Overall Acute Care Hospital Assessment

1. The Company will annually complete and maintain a DRG risk and controls profile for each acute care hospital. The profile will contain indicators including:

- Number of Medicare outlier DRGs
- Accuracy results of Federal health care program inpatient DRG coding reviews
- Percentage increase in Medicare Case Mix Index
- Percentage of Medicare complications and co-morbidities (“CC’s”)
- Implementation of Company Coding Policies and Procedures
- Turnover of certain hospital management and coding personnel
- Existence of internal quality assessment monitoring program
- Coding staff fulfillment of continuing education requirements

(See Attachment B for the DRG Risk and Controls Profile.)

2. Based on the results of step IV.A.1, the Company will gain an understanding of the acute care hospital’s compliance and control environment and identify the “higher” risk acute care hospitals for further detailed process and controls testing based on the risk score determined using the profiles. The profile will consist of a series of indicators that will be assigned points. Each of the criteria in the risk and controls profile will be worth a certain number of points as indicated in Attachment B.

3. At a minimum, the Company will annually test (as outlined in sections IV.B and C, below) a minimum of 10% of its acute care hospitals or 22 hospitals, whichever is greater, (but in no event shall the Company be required to test more than 15% of its acute care hospitals annually under this provision) that will include at least 2/3 “higher risk” acute care hospitals and 1/3 randomly selected “lower risk” acute care hospitals.

a. The acute care hospitals with the lowest scores from the risk profiling described in step 2, other than those acute care hospitals tested in step III.B above will be considered “higher risk.”

b. The “lower risk” acute care hospitals will be a random selection of the remaining acute care hospitals not selected in step IV.A.3.a above and not tested in step III.B.

4. The IRO will:

a. Read the Company’s DRG risk and controls profiles.

- b. Compare the information contained in this profile for a random sample of at least 10% of the Company's acute care hospitals to source documents and recompute their overall risk score. For example, if the Company owned 220 acute care hospitals, this would include a minimum of 22 acute care hospitals.
 - c. Compare the Company's identification of the "higher" risk acute care hospitals to the acute care hospital sample population based on the computed risk score.
5. For the acute care hospitals selected for detailed review in steps IV.A.1 through 3 above, steps IV.B and C, outlined below, will be performed.
 6. The hospitals to be reviewed under this analysis shall be reviewed over the four quarters of the calendar year.

B. Understand the DRG Coding Process and Controls

1. The Company will obtain an understanding of the compliance controls and the Federal health care programs inpatient DRG Coding processes operating at each acute care hospital identified in section IV.A by performing the following procedures:
 - a. Interview acute care hospital personnel.
 - b. Read documentation at the acute care hospital level that supports the DRG coding process.
 - c. Observe the use of various tools and materials provided to the acute care hospitals from Corporate.
 - d. Determine if coding training requirements are being met for acute care hospital inpatient DRG coding personnel.
 - e. Document the process and significant control points in the workpapers.
2. The Company will compare the process at each acute care hospital identified in section IV.A.3 process to the model process from Corporate (reviewed in Section

II above) and identify any control gaps or points within the processes for the acute care hospitals selected that may result in non-compliance. Where primary controls are not properly implemented as outlined in the model process from Corporate, the Company will review documentation to determine if any secondary controls exist to reduce the risk of inaccurate Federal health care program inpatient DRG assignment.

3. The Company will perform procedures for the acute care hospitals identified in section IV.A.3 above that focus on the control gaps and key control points identified in step IV.B.2. Procedures will include inquiry, observation of process steps, and testing of supporting information relating to the following:

- a. Controls regarding the physician documentation in the inpatient medical record.
- b. Inpatient medical record completion.
- c. Encoder use for DRG assignment.
- d. Code editing and submission on Federal health care program inpatient DRGs.

4. The IRO will:

- a. Read all documentation prepared by the Company in steps IV.B.1-3 above.
- b. Jointly perform the steps above for a random selection of at least 10% of the acute care hospitals to be tested. For example, if the Company tested 22 acute care hospitals, the IRO would jointly perform testing at 3 of the acute care hospitals.
- c. Perform the Company's workplan steps on a random sample selected by the IRO of at least 10% of the acute care hospitals to be tested. For example, if the Company tested 22 acute care hospitals, the IRO would perform testing at 3 of the acute care hospitals.

C. Testing of Federal Health Care Program Payor Inpatient DRG Coding Process Controls

The Company will test the controls for the Company's acute care hospitals as identified in step IV.A to determine if the controls are operating effectively to reduce the compliance risk associated with the Federal health care program DRG coding process. The Company will review a sample of Federal health care program inpatient DRG medical records to test the overall controls at the acute care hospitals selected in step IV.A for testing as follows:

1. The Company will perform a Claims Review of a Probe Sample of at least 30 inpatient Federal health care program DRG bill (Item) from the rolling 12-month period immediately preceding the review at each selected acute care hospital. The Claims Review of each Item shall include an independent code validation of the medical record to assess the accuracy of the diagnosis and procedure codes, financial class, discharge disposition, sex, age, and DRG assignment. Based on the results of this testing, the Company will determine whether a Claims Review of a Full Sample is required as follows:

a. If the Probe Sample results indicate a gross financial error rate of less than 5%, no further testing will be performed.

b. If the Probe Sample results indicate a gross financial error rate of 5% or more, the Company will conduct a Claims Review of a Full Sample of Federal health care program DRG claims from the CIA year at each acute care hospital in accordance with Appendix A.

2. The IRO will:

a. Read the Company's documentation regarding the review results and determine whether the appropriate reviews, including Probe Sample and Full Sample Claims Reviews, were performed based on the criteria outlined above, the CIA, and Appendix A.

b. Select a random sample of at least 10% of the acute care hospitals reviewed by the Company in section IV.C and reperform the testing described above.

- c. Perform testing on the acute care hospitals the IRO reviewed in section IV.B.
- d. Read the documentation of the DRG Claims Reviews noting completion of all workplan steps.
- e. Recompute a random sample of the extrapolations of error rates resulting from the Claims Reviews of Full Samples performed by Company.

V. TREATMENT OF REVIEWS IN FIRST YEAR

Notwithstanding the other provisions of this workplan, the Company may choose to conduct the reviews in the first year after the effective date of the CIA in the following manner.

- A. The quarterly reviews shall cover Items related to the time period from January 1, 2001, to the date of the review (rather than always relating to the full preceding 12-month time period as is required in other years).
- B. At least 25% of each type of review conducted (e.g., those conducted pursuant to section III and those conducted pursuant to section IV) shall cover the preceding 12-month period.
- C. At least 25% of each type of review conducted (e.g., those conducted pursuant to section III and those conducted pursuant to section IV) shall cover the preceding 9-month period.
- D. The remaining reviews (those not described in sections V.B and C above) shall include the preceding 6-month period.

VI. NOTIFICATION OF SELECTED ACUTE CARE HOSPITALS

The Company and the IRO will ensure that information about which acute care hospitals are subject to review under this work plan will not be disclosed to personnel at the acute care hospitals until notice is necessary to make arrangements to conduct on-site review processes required in the work plan, but in no event earlier than four weeks prior to commencement of such review.

VII. REPORTING

Upon completion of all testing of process controls, Medicare benchmarking and testing of Federal health care program DRG coding engagement procedures, the Company will quantify the results and findings and will report to the OIG. The Company's report will include the following:

A. The information required for the Claims Review Report in Appendix A.

- Claims Review Objective
- Sampling Unit: DRG
- Claims Review Population
- Sampling Frame
- Sources of Data
- Review Protocol
- Statistical Sampling Documentation
- Claims Review Results
- Credentials

B. The results of testing the Company's Federal health care program inpatient DRG coding operations (including, but not limited to, the operation of the coding system, strengths and weaknesses of the system, internal controls, effectiveness of the system).

C. The Company's procedures to correct inaccurate DRG assignment or reporting to Federal health care programs.

D. The steps the Company is taking to bring its operations into compliance or to correct problems identified by any of the reviews described above.

The IRO will read the Company's results and findings reported to the OIG and issue a report that enumerates the procedures performed and the findings for each procedure.

The IRO will report the results of all reperformed work required in the DRG Work Plan. Based on the review results, the IRO will make appropriate recommendations for improvement of Company practices.

HCA
DRG Workplan
17 Medicare DRG Ratios to be Benchmarked in Year One

76	82	$76/(76+82)$	Primary Medicare DRG
79	89	$79/(79+89)$	Primary Medicare DRG
87	88, 127	$87/(87+88+127)$	Primary Medicare DRG
89	90	$89/(89+90)$	CC Medicare DRG
121	122	$121/(121+122)$	CC Medicare DRG
124	125	$124/(124+125)$	CC Medicare DRG
132	140, 143	$132/(132+140+143)$	Primary Medicare DRG
138	139	$138/(138+139)$	CC Medicare DRG
148	149	$148/(148+149)$	CC Medicare DRG
174	175	$174/(174+175)$	CC Medicare DRG
182	183	$182/(182+183)$	CC Medicare DRG
197	198	$197/(197+198)$	CC Medicare DRG
210	211	$210/(210+211)$	CC Medicare DRG
296	297	$296/(296+297)$	CC Medicare DRG
316	127	$316/(316+127)$	Primary Medicare DRG
416	320, 277	$416/(416+320+277)$	Primary Medicare DRG
475	(Total # cases for all Medicare DRGs)	$475/\text{Total Medicare Discharges}$	Primary Medicare DRG

**HCA ACUTE CARE HOSPITAL DRG RISK
AND CONTROLS PROFILE**

1. **Benchmarking** The results of the Benchmarking of Medicare DRG ratios performed in section III of the workplan, using no case count thresholds, will be used as a component to determine “higher risk” facilities. Scores will be awarded based on the number of times a hospital’s DRG ratios are over the benchmark (i.e., “outliers”) as follows:

10 or more outliers	0 points
9 outliers	3 points
8 outliers	6 points
7 outliers	9 points
6 outliers	12 points
5 outliers	15 points
4 outliers	17 points
3 outliers	19 points
2 outliers	21 points
1 outliers	23 points
0 outliers	25 points

2. **Accuracy Reviews** The results of the most recently performed Medicare, Medicaid, and/or CHAMPUS/TriCare Inpatient DRG accuracy reviews relating to coding will be used to award points based on the % of accuracy achieved are as follows:

98% or better	30 points
95%-97%	20 points
90%-94%	10 points
86%-89%	0 points
80%-85%	-5 points
Less than 80%	-10 points

3. Percentage Increase in Medicare CMI A hospital will receive 15 points if the percent increase in the Medicare Case Mix Index, compared to the prior year, is less than the mean plus 1 standard deviation. The hospital will receive 0 points if the percent increase in the Medicare Case Mix Index, compared to the prior year, is greater than the mean plus 1 standard deviation. (NOTE: the mean and standard deviation will be calculated using the hospital's most recent 8 quarters Medicare Case Mix Index results.)

4. Medicare CC% A hospital will receive 20 points if their Medicare CC% is below the National 75th percentile. The hospital will receive 0 points if their Medicare CC% is above the National 75th percentile.

5. Policy Implementation The Hospital will lose 2 points for each of the following policies that it has not implemented.

HIM COD 001 – Coding Documentation Policy for Inpatient Services

HIM COD 003 – Coding References and Tools

HIM COD 004 – Coding Help Line

HIM COD 005 – Coding Orientation and Training

HIM COD 006 – Coding Continuing Education Requirements

6. Turnover Deductions will be made for turnover in the following positions over the prior year.

CEO	-2 points
CFO	-2 points
ECO	-2 points
Coding Manager/Lead Coder	-5 points
HIMS Director	-5 points
Inpatient Coders	-5 points (up to a maximum of 15 points)

7. Quality Assessment 10 points will be added if the hospital currently has an internal quality assessment monitoring program for coding accuracy and productivity in place. (This would also include quality assessment monitoring outsourced to external vendors sub-contracted by the hospital, but not Corporate HIMS.)

8. Continuing Education Deduct points based on the percentage of the hospital's inpatient coding staff that has met their 30 hours of continuing education and other training requirements during the prior year.

<u>Percentage of Staff that has met requirements</u>	<u>Points added or (deducted)</u>
100%	0
96-99%	-2
91-95%	-4
86-90%	-6
81-85%	-8
75-80%	-10
75% or less	-15

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HCA - The Healthcare Company.
OUTPATIENT LABORATORY WORKPLAN

I. INTRODUCTION

This workplan describes the review process that HCA – The Healthcare Company (the “Company”) and the Independent Review Organization (“IRO”) will follow with respect to testing the Company’s Outpatient Laboratory (“Lab”) billing process related to Medicare, Medicaid and other federally funded payors.

The IRO will gain an understanding of the Company’s processes and controls that are designed to prevent and detect billing errors. The Company and IRO will use their understanding of processes and controls to select which hospitals to review in detail. The focus of the procedures will be on the Company and hospitals’ processes and controls designed to ensure compliance with Outpatient Laboratory billing requirements.

II. OUTPATIENT LABORATORY BILLING CORPORATE COMPLIANCE PROCESS

The IRO will begin its understanding of the Company's Outpatient Laboratory billing compliance by understanding the process performed at the Corporate level. The focus will be on the Company's controls affecting the hospitals. After gaining this understanding, the IRO and the Company will design agreed upon procedures which will allow the Company and the OIG to evaluate the effectiveness of the Corporate Compliance Infrastructure. Focusing on the Company’s infrastructure, processes, controls, and monitoring systems, the IRO will:

A. Understand Outpatient Laboratory Billing Compliance Process

The IRO will understand the Company Outpatient Laboratory Billing Compliance Plan (“Plan”) which is based on the OIG’s Clinical Laboratory Compliance Program Guidance (OIG-CPG). The following interviews/reviews will be performed to understand the implementation of the Plan designed to mitigate risk and achieve compliance:

1. Read organizational charts and understand outpatient laboratory billing compliance infrastructure.
2. Interview the Corporate Ethics and Compliance Officer, VP Governmental Operations Support (GOS) and other key personnel to:
 - Understand the strategy and process used to create the Plan.

- Understand the process used to review and revise the Plan, including laboratory billing policies and procedures.
3. Compare the Plan to the OIG-CPG, identify variations and determine if these variations have a significant impact on compliance.
4. Understand the process used to implement changes and revisions to the Plan and how they are communicated to the hospitals.
5. Read training plans developed at corporate level and understand how they are implemented at the hospital level. Identify critical areas not covered by such training.
6. Understand the use and role of the corporate preferred electronic billing vendor and corporate defined edits through discussions with GOS VP, Director, Monitoring and other key personnel.

B. Review Outpatient Laboratory Billing Compliance Plan Controls

The IRO will understand how the Company ensures that controls are in place that support the Plan in order to reduce compliance risk, identify laboratory overpayments, and repay the appropriate payors. Procedures to gain this understanding include:

1. Compare the Company suite of electronic billing vendor edits to GOS outpatient laboratory policies which incorporate regulatory requirements. Check for validity of all HCPCS/CPT codes and identify variances.
2. Read and/or observe the Company's quality control process for established electronic billing vendor edits and determine if any defined edits referenced in Section B.1. above are missing or not operating correctly.
3. Understand the process of accessing and revising the application and maintenance of the Company's standardized Laboratory chargemaster and the process qualified personnel use to access and update the chargemaster.
4. Review the results of the assessment performed by an external review organization of the Company's standardized Laboratory chargemaster.
5. Read selected training programs and related materials to assess implementation and consistency with regulations.

6. Select a sample of 10 hospitals from the corporate compliance training database and test for hospital attendance/participation.
7. Understand the Company's efforts to keep abreast of new federal laboratory billing rules and changes and understand how the Company informs its hospitals to conform their billing processes and controls to such a change(s).
8. Determine whether changes in new federal laboratory billing rules and requirements have been incorporated into GOS outpatient laboratory billing policies.

C. Understand Outpatient Laboratory Billing Compliance Monitoring Function

The IRO will understand how the Company measures, monitors and assesses the performance of the compliance process through the following procedures:

1. Interview the Corporate Ethics and Compliance Officer, GOS and other key personnel.
2. Identify the types of monitoring plans, tools and reports that are in place to prevent and detect non-compliance.
3. Review a representative sample of 10 results of monitoring activities from 10 hospitals, including corrective action plans. Compare the action taken to appropriate billing rules and regulations and identify any non-conformance.
4. Compare plans, tools, and reports to rules, regulations and policies, identify variances and make recommendations for additional tools to facilitate monitoring activities.

D. Summarize the Outpatient Laboratory Billing Compliance Process

The IRO will summarize its procedures and findings from sections II.A through C outlined above to allow the OIG and the Company to evaluate the following:

1. Whether the established outpatient laboratory infrastructure is successfully designed to comply with relevant regulations.
2. Whether the Company's existing processes, controls and monitoring activities address major areas of outpatient laboratory compliance risk.

3. Whether controls may not exist in certain areas to reduce risk to an appropriate level.

4. The IRO will review with and make recommendations to Company management for improvements to the infrastructure, including processes, controls, and monitoring activities.

III. OUTPATIENT LABORATORY BILLING HOSPITAL LEVEL COMPLIANCE PROCESS REVIEW

A. Test of Laboratory Billing Process Controls

1. As part of the Company's monitoring program, the Company will implement appropriate procedures and tools to ensure proper CPT/HCPCS coding and billing of tests by performing the following procedures:

- a. Apply HCFA's National Correct Coding Initiative (NCCI) edits included in HCFA's Outpatient Code Editor (OCE) to the Company's Medicare outpatient laboratory billing and test actual claims data for bundling, billing of mutually exclusive codes and comprehensive/component codes simultaneously.
- b. Adopt a standard laboratory chargemaster and assess the hospitals' adoption in full of the Company standard.
- c. Implement edits to prevent duplicate charges on the same claim .
- d. Analyze frequency of potential add-on tests, by utilizing benchmarks from HCFA's non-HCA industry data to compare each hospital's use of the six most common tests that are billed with chemistry, organ or blood gas panels to the appropriate industry benchmark for Medicare only. Use results to identify hospitals for further review.
- e. Analyze and institute corrective action plans for significant compliance issues identified.
- f. Assess if Company has taken appropriate steps to ensure overpayments are returned to the payor.
- g. Create a compliance risk profile for each hospital that summarizes the hospital's:

- Accuracy rates of outpatient laboratory billing audits;
- Use of the six most common tests that are billed with chemistry, organ or disease, hematology or blood gas panels;
- Adoption of the standardized laboratory chargemaster;
- Training and education efforts for applicable personnel;
- Frequency of Billing Compliance Committee meetings; and
- Appropriate development of action plans;

(See Attachment A for a copy of the Risk Profile.)

2. The IRO will:

- a. Select a 10% random sample of risk profiles outlined in step III.A.1.g. and compare the information contained in these profiles to source documents.
- b. Reperform the benchmarking process as outlined in step III.A. 1.d. above for a random sample of at least 10% of the hospitals.
- c. Select a random sample of 30 outpatient laboratory overpayments and confirm that overpayments discovered by the Company were promptly repaid to the appropriate payor.

B. Understand and Review the Outpatient Laboratory Billing Compliance Process and Controls

1. Using the results of section III.A, the IRO and the Company will gain an understanding of the hospital compliance and control environment and identify the “higher” risk hospitals for further process and control review. The Company will select the higher risk hospitals for detailed process and control testing based on the risk profile outlined in section III.A.1.g. The risk profile will consist of a series of statistical measures as well as process and controls assessment consisting of 100 points.
2. At a minimum, the IRO will annually test (as outlined in steps III.B.2 through 7 below) a minimum of 10%, but no less than 20, of the Company’s hospitals including at least 2/3 “higher risk” facilities and 1/3 randomly selected “lower risk” hospitals.

- a. The hospitals with the lowest combined scores from the risk profiling will be considered “higher risk.” (See attachment A for an example of the risk profile).
- b. The “lower risk” hospitals will be a random selection of the remaining hospitals not selected in step III. B.2.a.
- c. The number of hospitals to be tested may vary based on the fluctuation of the number of hospitals owned by the Company such that approximately the same percentage of facilities are considered “higher risk” and “lower risk” each year .

3. The IRO will:

- a. Read the Company’s Outpatient Laboratory risk profile and hospital controls assessment.
- b. Compare the information contained in these profiles for a minimum of 10%, but no less than 20, of the Company’s hospitals to source documents and recompute each hospital’s overall risk score.
- c. Compare the Company’s identification of the “higher” risk hospitals to the hospital sample population based on the computed risk score.
- d. Assess whether the Company's Outpatient Laboratory Risk Profile should be amended in light of industry and regulatory changes.

4. For the hospitals selected for detailed review in steps III. B. 1. and 2. above, the IRO will:

- a. Understand and analyze the hospital’s Outpatient Laboratory billing processes and controls by interviewing the hospital compliance officer, laboratory and billing directors and other key personnel.
- b. Read documentation at the hospital level that supports the process.
- c. Document the process and significant controls.
- d. Compare each hospital’s compliance process with the Company’s Plan and respective policies and procedures and identify variances.
- e. Understand each hospital’s process for complying with medical necessity requirements specific to HCFA’s National Coverage Limitations

and/or the FI's Local Medical Review Policies (LMRPs) as they pertain to Medicare Outpatient Laboratory billing and compare to the Company's Plan.

f. Compare the hospital's use of Outpatient Laboratory billing edits for application of the NCCI edits related to Medicare claims to the Company policies and Plan and identify any variances.

g. Compare the hospital's education and training efforts to the Company's Plan and verify key participant (Billers and Laboratory Staff) attendance at relevant training sessions.

5. Utilizing the Company's chargemaster exception reports, the IRO will compare each hospital's chargemaster to the HCA standard laboratory chargemaster and validate variances for the sample identified in step 2. above.

6. The Company and/or IRO will select a random Probe Sample of at least 30 Medicare claims at each selected hospital identified in step III. B. 2. above for a Claims Review (including detailed Outpatient Laboratory billing medical necessity review as specific in section III.B.4.e.). These tests will address key control points that were identified as critical for the sample selected. The procedures that will be performed for this sample are as follows:

- Compare the test ordered to the test performed
- Compare the test performed to the test billed
- Compare the test billed to the payment received
- Review the patient's medical record (if test performed on a hospital registered outpatient) and determine if the laboratory test(s) were medically necessary for the diagnosis and treatment of the patient's illness per HCFA's National Coverage Limitations and/or the FI's LMRPs.

Based on the results of this testing, the Company and/or IRO will determine whether a Full Sample is required to assess medical necessity and billing compliance as follows:

a. If the initial sample results indicate a gross financial error rate of 5% of the total amount reimbursed for those Medicare claims or less, no further testing will be performed in that annual audit.

b. If the initial sample results indicate a gross financial error rate of more than 5% of the total amount reimbursed for those Medicare claims, a Claims Review of a Full Sample will be performed.

c. For purposes of evaluating the testing results of the samples, an "overpayment" includes the following:

- A test performed that was not ordered but was billed for and resulted in an overpayment to the hospital.
- A test that was performed as ordered but was billed in a manner that resulted in an overpayment to the hospital.
- A test or panel of tests that was performed as ordered, but was determined to lack medical necessity per HCFA's National Coverage Limitations and/or the FI's LMRPs and for which the hospital received payment.
- An add-on test specified in the Risk Profile that was ordered as part of a chemistry, organ or disease, hematology, or blood gas panel that was determined to be medically unnecessary per HCFA's National Coverage Limitations and/or the FI's LMRPs and for which the hospital received payment.

d. If the Company performs the above testing, the IRO will review the testing and conclusions reached by the Company and confirm that the appropriate follow up steps occur. The IRO will also reperform the reviews on a random sample of a minimum of 10% of the claims reviewed by the Company.

IV. REPORTING

Upon completion of all testing, the Company will quantify the results and findings will be reported to the OIG. The Company's report will include the following:

- A. The information required for the Claims Review Report in Appendix A.
- B. Results of the assessment and testing of the Company's Outpatient Laboratory billing operations (including, but not limited to, the infrastructure, strengths and weaknesses of the plan and process, internal controls, effectiveness of the overall Outpatient Laboratory Billing compliance program).

- C. The Company's procedures to correct inaccurate Outpatient Laboratory billing and report to the Medicare, Medicaid, and other Federal health care programs.
- D. The steps the Company is taking to bring its operations into compliance and/or to correct problems identified by any of the reviews described above.

The IRO will read the Company's results and findings reported to the OIG and issue a report that enumerates their procedures performed and the findings for each procedure.

Attachment A

**HCA – The Healthcare Company.
OUTPATIENT LABORATORY RISK PROFILE**

The risk profile incorporates both statistical measures (S) and a process and controls assessment (C) with 100 points available. (The points available are subject to further refinement and negotiations with the OIG.)

Billing Policies

up to 32 points

Award up to 4 points semi-annually for accuracy rates for audits performed for the following policies: (S)

- GOS.LAB 002 Hematology Procedures
- GOS.LAB.003 Urinalysis Procedures
- GOS.LAB.004 Organ and Disease Panels
- GOS.LAB.006 Outpatient Specimen Collection

(semi-annual accuracy rate = total # of accounts audited per policy guidelines minus the total # errors identified / total # of accounts audited per policy guidelines)

- Accuracy rate 95-100% 4 points
- Accuracy rate 90- 94% 3 points
- Accuracy rate 75- 89% 2 points
- Accuracy rate 61- 74% 0 points
- Accuracy rate 60% or below deduct 2 points

Policy	Audit Performance					
	First 6 months			Second 6 months		
	# of accounts reviewed	# of errors	Accuracy Rate	# of accounts reviewed	# of errors	Accuracy Rate
Hematology Procedures GOS.LAB.002						
Urinalysis Procedures GOS.LAB.003						
Organ and Disease Panels GOS.LAB.004						
Outpatient Specimen Collection GOS.LAB.006						
TOTAL SCORE						

Standard Laboratory Chargemaster (CDM)

up to 12 points

Award up to 3 points per quarter as follows for adoption of Standard Laboratory Chargemaster, based on compliance rate from most current CDM Exception report. Compliance is measured by comparing the facility's procedure description, HCPCS codes and revenue code assignment to the Company standard. (S)

- 90- 100% compliance 3 points
- 80- 89% compliance 2 points
- 61- 79% compliance 0 points
- 60% or below compliance deduct 2 points

Medical Necessity

up to 21 points

1. Accuracy Rate (C): Award up to 6 points as follows for accuracy rate for policy GOS.GEN.002, Medicare Medical Necessity, for the quarter being reviewed. The Corporate office will choose the quarter to be reviewed and it will vary from year to year.

(quarter accuracy rate = total # of accounts audited per policy guidelines minus the total # errors identified / total # of accounts audited per policy guidelines)

- Accuracy rate 90- 100% 6 points
- Accuracy rate 75- 89% 3 points
- Accuracy rate 61- 74% 0 points
- Accuracy rate 60% or below deduct 2 points

2. Action Plans (C): Award 1 point if action plans were developed or were not required (i.e., accuracy rate = 100%). Deduct 2 points if action plans were required but were not developed.

Policy	Audit Performance						Accuracy Rate	Action Plan
	Month 1		Month 2		Month 3			
	# of accounts reviewed	# of errors	# of accounts reviewed	# of errors	# of accounts reviewed	# of errors		
Medicare Medical Necessity GOS.GEN.002							Y/N	

3. Award 2 points if facility discloses contents of lab panels on test order forms or other test ordering system and gives physicians the option of ordering each test individually. (Custom profiles disclosed in accordance with policy GOS.LAB.007 are considered disclosed.) (C)

4. Award 2 points if facility personnel review test orders through a manual or automated process prior to performing tests to ensure the services are medically necessary according to Medicare guidelines (i.e., Local Medical Review Policies (LMRP) and/or National Coverage Limitations (NCL). (C)
5. Award 2 points if facility personnel can demonstrate that a process is in place to determine that standing orders are valid, documented, medically necessary and monitored annually for appropriateness. (C)
6. Award 2 points if facility can demonstrate through a manual or automated process that non-medically necessary services for which an ABN is present are not billed to Medicare as covered services. (C)
7. Award 2 points if facility can demonstrate through a manual or automated process that non-medically necessary services for which an ABN is not present are not billed to Medicare or the patient. (C)
8. Award 2 points if facility can demonstrate through a manual or automated process that services which were ordered but not performed are not billed to Medicare or the patient. (C)
9. Award 2 points if facility can demonstrate through a manual or automated process that services which were not ordered by a physician or other authorized personnel but were performed are not billed to Medicare. (Medically necessary reflex testing in accordance with policy GOS.LAB.010 is considered ordered by authorized personnel.) (C)

Training

up to 12 points

Award up to 3 points for each of the following groups that have received initial and/or refresher Laboratory Billing Compliance training within the last 12 months. (C)

- A) Billing Staff
- B) Laboratory Staff
- C) Employed physicians who are involved in the ordering, performing, or monitoring of laboratory tests or services or the preparation of Outpatient claims containing laboratory tests or services.

Points will be awarded based on the number of trained employees compared to the number on staff in each area:

90- 100%	3 points
80- 89%	2 points
71- 79%	1 point
61- 70%	0 points
60% or below	deduct 2 points

Award 3 additional points if the facility can demonstrate that it has provided updated information regarding medical necessity and the ordering of laboratory tests and services to active staff physicians.. (C)

Potential Add-On Tests

up to 18 points

For the quarter in review, compare the volume of each of the following tests, Amylase (82150), Iron (83540), Magnesium (83735), Ferritin (82728) and TSH (84443), when they are billed with the following Organ and Disease Panels, 80048, 80049, 80053, 80054, to the total volume of those Organ and Disease Panels. Additionally, compare the volume of Carbon Monoxide (82375) when it is billed with the following Blood Gas Panels, 82803 and 82805, to the total volume of those blood gas panels. These add-on utilization rates will be compared to an industry benchmark based on the Medicare Standard Analytical File (SAF), exclusive of HCA hospitals. Tests selected for inclusion in the Risk Profile may be reviewed and revised annually based on new data.

Award 3 points for each test which is at or below the current SAF file industry benchmark. (S)

Billing Compliance Committee

up to 5 points

Award 5 points as follows based on the percentage of Billing Compliance Committee meetings held as required by current Company policy during the 12-month period being reviewed. Minutes of these meetings must be available. (C)

100%	5 points
90- 99%	4 points
75- 89%	3 points
50- 74%	1 point
25- 49%	0 points
24% or below	deduct 2 points

HCA PHYSICIAN RELATIONSHIPS WORKPLAN

I. INTRODUCTION

This workplan describes the physician relationships procedures that HCA–The Healthcare Company (the “Company”) and the Independent Review Organization (“IRO”) will follow with respect to physician relationships. A public accounting firm (the “PA IRO”) and/or a law firm (the “Legal IRO”), as appropriate, will perform the role of the IRO for physician relationships. References to the IRO in this document refer to either type of IRO unless specifically designated.

II. PHYSICIAN RELATIONSHIPS CORPORATE COMPLIANCE PROCESS

The Legal IRO will review all of the Company’s physician relationship policies and confirm that they cover and seek to ensure compliance with all applicable laws and regulations related to physician relationships, including but not limited to 42 U.S.C. §§ 1320a-7b(b) and 1395nn. The Legal IRO will, from time to time, recommend any new policies needed to address changes in the applicable statutes, regulations or case law.

III. PHYSICIAN RELATIONSHIPS FACILITY LEVEL COMPLIANCE PROCESS

A. UNDERSTAND THE FACILITY PHYSICIAN RELATIONSHIPS PROCESS AND CONTROLS

1. The Company, after consulting with the PA IRO, will select a sample of the greater of 25 facilities or 10% of the facilities for a review of its facility level process and controls (the Company will select the facilities randomly except that the Company may choose to select up to 10 facilities based on the IRO’s conclusion that such facilities are at relatively high risk for physician relationship issues – if facilities are chosen based on being high risk the criteria for such selection shall be reported to the OIG).
2. The Company’s Internal Audit Department (the “IAD”) will obtain an understanding of the compliance controls and processes with respect to Physician Relationships (as defined below) at the facility by:
 - a) Interviewing facility personnel;

- b) Reading documentation at the facility level that supports the process;
 - c) Verifying the use of various tools, forms and other materials provided to the facilities from Corporate; and
 - d) Documenting the process and significant control points in the workpapers.
3. The IAD will compare the facility process to the model process defined in the Company's policies and procedures. The IAD will identify any control gaps or points within the processes for the facilities selected that may result in non-compliance based on its documented understanding of the processes and controls at each facility selected.
 4. The IAD will validate the data contained in the Physician Receivables Database (as defined in Section III.B.1(a) below) and the property managers' reports (as defined in Section III.B.1(b) below) by comparing the information on site at the facility to the information contained in the database and the property managers' reports.
 5. The PA IRO will retest and validate the IAD's work performed pursuant to Sections III.A and III.B.1(c) for a random sample of the greater of (i) 5 facilities, or (ii) 10% of the facilities reviewed pursuant to Section III.A.1 above.

B. REVIEW OF OUTLIER PHYSICIAN CONTRACTS AND PAYMENTS

The Company will identify those physician relationships with the greatest risk of non-compliance with applicable law. The Company will do so by identifying and examining relationships that meet the following descriptions: i) loans and other physician accounts receivable which are past due; ii) leases of buildings where physicians have offices ("Medical Office Building" or "MOB" leases); and iii) personal services agreements (e.g., medical directorships and consultancies) and other payments to physicians (collectively, all of the above are referred to as "Physician Relationships"). In addition, the OIG may notify the Company that it should examine additional types of relationships. To implement a review of these outlier areas, the Company will take the following steps:

1. The Company will identify "outlier" Physician Relationships for further review as follows:
 - a) Physician Receivables Database – The Company will annually collect data regarding loans, leases, income guarantee repayments and other accounts owed by physicians to the Company and maintain this information in a corporate Physician Receivables database. Using this database, the Company will identify receivables that meet the following conditions : i) over 120 days

delinquent; and ii) have not been referred to outside counsel for collection within 30 days of becoming 120 days delinquent. The database will be compiled by the IAD. The IAD will send a copy of the database to the Legal Department for review and any necessary corrective action.

- b) **Property Manager Reports** – All medical office buildings will be managed by professional independent third-party managers. The property managers will certify annually that, except as noted: (1) all physician tenants have written leases, (2) the rent payable under the leases is consistent with fair market value (“FMV”) (for the purposes of this workplan, FMV must be determined without taking into account the volume or value of any referrals or other business generated between the parties), (3) all leases would be commercially reasonable even if no referrals were made between the parties, and (4) all rental payments are either current or appropriate collection activities are being pursued. The certificates will be collected by the Real Estate Department and forwarded to the IAD. Any MOB leases that are noted as exceptions to the certifications will be forwarded to the Legal Department for review and any necessary corrective action.
- c) **Internal Audits** – The IAD will perform a review of: (1) facility and regional level personal services agreements with physicians (including medical directorship agreements and consultation agreements); and (2) payments to physicians from facility, regional, and corporate levels (e.g., through accounts payable records) using the sample of the Company’s facilities selected in Section III.A.1 above and perform the following steps:
- i) Identify personal service agreements and/or payments to physicians with the following characteristics:
- Payments made to physicians inconsistent with the contract, without a contract, or without documentation of services rendered as required by the contract;
 - Personal service agreements (considering all agreements and arrangements with the physician)(excluding hospital-based physician agreements) providing for: (1) compensation of more than \$150 per hour (this amount may be renegotiated by the Company and the OIG in years after 2001 in order to adjust for inflation) without a FMV verification by an independent third party; or (2) providing for more than 40 hours per month to a physician without a FMV verification by an independent third party (unless the number of hours in excess of 40 hours per month set forth in the agreement is required by the applicable statute(s) and/or regulation(s));

- Multiple medical directorships at the same facility with the same apparent function where the physicians are not demonstrated co-directors;
- Leases of physician-owned property or equipment without a FMV verification by an independent third party; or
- Physician recruitment arrangements that: (1) do not meet the standards of 42 U.S.C. § 1395nn and the related regulations; (2) involve the recruitment of a physician with an active practice located within 25 miles of the facility; (3) involve a total payment/repayment (or forgiveness) period of more than 4 years; (4) involve "additional or different incentives to relocate" (as described in HCA's policy on physician recruitment agreements) totaling \$25,000 or more; (5) involve recruitment by an ASC or home health agency (rather than a hospital); or (6) are not supported by a certification from a CEO that there is a community need (as opposed to a hospital need) for the physician. In addition, a random sample of 20% of all arrangements involving recruitment to join a physician practice under which the facility is making payments shall be identified for further review.

ii) Items noted during the IAD reviews identified in step (i) as potential compliance issues will be sent to the Legal Department for review and any necessary corrective action. "Corrective action" as to the agreements listed in this Section III.B.1 (c) may mean enforcing the terms of the current agreement, creating a new written agreement where there was not a current agreement, amending a current written agreement, or terminating an agreement.

2. The Legal Department will review all Physician Relationships referred to it by the IAD as outlined above. The review shall include an examination of all relevant facts, e.g., the terms of the contract, adherence to those terms, the facility's need for the services described in the contract and those provided, all payments to the physician, the referral patterns of the physician, evidence of work actually performed by physician (e.g., contemporaneous time records), the FMV of the services provided by the physician, and the commercial reasonableness of the arrangement. Relevant facts in physician recruitment arrangements where the physician joins a group practice include: (1) the overhead and operating expenses included in the guarantee amount; (2) the marginal overhead and operating expenses associated with the recruited physician; (3) the ancillary revenues (e.g., labs, x-rays) associated with the recruited physician; and (4) the ancillary revenues reflected in the calculation of the net collectable revenues. The review shall include document review and in-person or telephone interviews with facility personnel where appropriate. After the review, the Legal Department shall take the following steps:

- a) Document its findings and conclusions for each relationship reviewed;
- b) Determine whether the relationships require corrective action;

- c) Prepare corrective action plans as appropriate;
- d) Prepare a disposition form for each outlier reviewed; and
- e) Prepare periodic reports on the status of all such corrective actions and submit to the Vice President, Legal Operations, for review.

The IAD will verify that the Legal Department has reviewed all relationships identified by the IAD or the Company as outliers and prepared a disposition form and corrective action plan where appropriate for each relationship.

3. The Legal IRO will reevaluate the appropriateness of the conclusions and corrective action plans, if applicable, prepared by the Legal Department for 10% of the issues identified as outliers. The outliers to be reevaluated shall be randomly selected. The Legal IRO shall also review the systems used by the Company for determining outliers as set forth in section III.B.1 to determine if they are appropriately identifying problematic matters.

IV. REPORTING

Upon completion of all testing of process controls and investigative procedures, the Company will report the following to the OIG in the appropriate Annual Reports (and earlier if so required under the CIA):

1. Physician Relationships which constitute Reportable Events as determined by either the Company (including the Legal Department and IAD) or the Legal IRO.
2. A description of all Physician Relationships for which the Company or the Legal IRO determines corrective action is necessary, and a description of the corrective action plan and its execution.
3. A summary of the findings of the Legal Department, IAD, and the IRO(s) resulting from their reviews (for the reviews of outlier physician contracts and payments described in Section III.B, the summary shall describe the relevant facts for each such outlier as set forth in Section III.B.2).
4. Material changes in the Company's physician relationship policies.
5. Material changes in the Company's physician relationship processes.

HCA - The Healthcare Company.
MEDICARE OUTPATIENT PROSPECTIVE PAYMENT SYSTEM (OPPS) WORKPLAN

I. INTRODUCTION

This Workplan describes the review process that HCA – The Healthcare Company (the “Company”) and the Independent Review Organization (“IRO”) will follow with respect to testing the Company’s acute care hospital-based Medicare Outpatient Prospective Payment System (“OPPS”) billing and coding processes.

The IRO will gain an understanding of the Company’s processes and controls that are designed to prevent and detect billing and coding errors on acute care hospital-based Medicare OPPS claims. The focus of the procedures will be on the Company’s acute care hospitals’ processes and controls designed to ensure compliance with OPPS billing and coding requirements.

II. OPPS CORPORATE COMPLIANCE PROCESS

The IRO will begin its understanding of the Company's OPPS billing and coding compliance by understanding the Corporate level OPPS processes. The focus will be on the Company's controls affecting the acute care hospitals. After gaining this understanding, the IRO and the Company will design agreed upon procedures that will allow the Company and the OIG to evaluate the effectiveness of the Corporate OPPS infrastructure. Focusing on the Company’s infrastructure, processes, controls and monitoring systems, the IRO will:

A. Understand Acute Care Hospital-Based Medicare OPPS Billing and Coding Processes

The IRO will obtain an understanding of the regulatory environment, of key assumptions underlying the acute care hospital-based Medicare OPPS process and how they impact the Company’s compliance risk. The IRO will understand how the Company establishes acute care hospital-based Medicare OPPS billing and coding procedures. The following interviews/reviews will be performed to understand the education, implementation and monitoring of acute care hospital-based Medicare OPPS:

1. Read organizational charts and understand OPPS infrastructure.
2. Interview the Corporate Ethics and Compliance Officer, VP Governmental Operations Support (GOS), VP Health Information Management Services (HIMS) and other key personnel to understand how acute care hospital-based Medicare OPPS billing and coding decisions are made.

3. Read policy and procedure manuals, training materials and other tools and resources.
4. Compare policy and procedure manuals, training materials, tools and resources, identify variations and determine if these variations differ from acute care hospital-based Medicare OPPS rules, regulations or program memoranda.
5. Understand how the Company monitors acute care hospital-based Medicare OPPS rules, regulations and program memoranda and how changes are integrated into the Company's policy and procedure manuals, training materials, tools and resources.
6. Understand the process used to notify acute care hospitals of changes in the Medicare OPPS rules, regulations, new or revised program memoranda and billing and coding requirements.
7. Read training materials developed at the corporate level and understand how they are implemented at the acute care hospital level. Identify critical areas not covered by such training.

B. Review Acute Care Hospital-Based Medicare OPPS Controls

The IRO will understand how the Company ensures that controls are in place to support appropriate acute care hospital-based Medicare OPPS billing and coding. Procedures to gain this understanding include:

1. Understand the use and role of the Medicare Outpatient Code Editor (OCE), APC Finder and Encoder through discussions with GOS VP, HIMS VP, Director, GOS Monitoring and other key personnel.
2. Understand the process for notifying acute care hospitals of the appropriate APC reimbursed chargemaster driven codes that are included in the acute care hospital's chargemaster.
3. Read a random sample of training programs and related materials to assess implementation and consistency with regulations.
4. Select a random sample of 10 acute care hospitals from the Corporate compliance training database and test for acute care hospital attendance/participation.
5. Understand the Company's efforts to keep abreast of new acute care hospital-based Medicare OPPS billing and coding rules and changes and understand how the Company informs its acute care hospitals to conform their billing and coding processes and controls to such a change(s).

6. Determine whether changes in or new acute care hospital Medicare OPPS billing and coding rules and requirements have been incorporated into the appropriate policies, resources and tools.

C. Understand Acute Care Hospital-Based Medicare OPPS Billing and Coding Monitoring Function

The IRO will understand how the Company measures, monitors and assesses compliance with acute care hospital-based Medicare OPPS rules and regulations through the following procedures:

1. Interview the Corporate Ethics and Compliance Officer, HIMS VP, GOS VP and other key personnel.
2. Identify the types of monitoring plans, tools and reports that are in place to identify, correct and prevent acute care hospital-based Medicare OPPS billing and coding errors.
3. Review a random sample of 10 results of monitoring activities, including corrective action plans. Compare the action taken to appropriate acute care hospital-based Medicare billing and coding rules and regulations and identify any non-conformance.
4. Compare plans, tools, and reports to rules, regulations and program memoranda, identify variances and make recommendations for additional tools to facilitate monitoring activities.

E. Summarize the Acute Care Hospital-Based Medicare OPPS Billing and Coding Compliance Process

The IRO will summarize its procedures and findings from sections II.A through C outlined above to allow the OIG and the Company to evaluate the following:

1. Whether the established acute care hospital-based Medicare OPPS infrastructure is successfully designed to comply with relevant regulations.
2. Whether the Company's existing processes, controls and monitoring activities address major areas of acute care hospital-based Medicare OPPS compliance risk.
3. Whether controls may not exist in certain areas to reduce risk to an appropriate level.

4. The IRO will review with and make recommendations to Company management for improvements to the infrastructure, including processes, controls, and monitoring activities.

III. MEDICARE OPPTS ACUTE CARE HOSPITAL LEVEL BILLING AND CODING COMPLIANCE PROCESS REVIEW

A. Test of Acute Care Hospital-Based Medicare OPPTS Billing and Coding Process Controls

1. For the purpose of this Workplan, the item(s) to be tested are those on a paid acute care hospital-based Medicare outpatient claim that result in an APC assignment.
2. As part of the Company's monitoring program, the Company will implement appropriate procedures and tools to ensure proper HCPCS/CPT coding and billing of acute care hospital-based Medicare OPPTS claims by performing the following procedures:
 - a. Apply HCFA's National Correct Coding Initiative (NCCI) edits and other edits included in the Outpatient Code Editor (OCE), APC Finder and/or Encoder to acute care hospital-based Medicare OPPTS claims.
 - b. Implement edits to prevent duplicate charges on the same claim.
 - c. Analyze and institute corrective action plans based on identified compliance issues.
 - d. Implement appropriate steps to ensure overpayments for APC reimbursed items are returned to Medicare.

B. Understand and Review the OPPTS Billing and Coding Compliance Process and Controls

1. The IRO and/or the Company will subject a sample of 10% of the Company's hospitals for detailed process and control testing.
2. For the acute care hospitals selected for detailed review in step 1 above, the Company and/or the IRO will:
 - a. Understand and analyze the acute care hospital's Medicare OPPTS billing and coding processes and controls by interviewing the hospital compliance officer, HIMS and billing directors and other key personnel.

- b. Read documentation at the acute care hospital level that supports the process.
 - c. Observe the use of various tools and materials provided to the acute care hospital from the Corporate Office.
 - d. Determine if the acute care hospital has met the Medicare OPPS billing and coding education and training requirements. Verify key participant (billers and coders) attendance at relevant training sessions.
 - e. Determine how the acute care hospital uses the system edit reports to correct claims before they are billed.
 - f. Document the process and significant controls.
3. The Company and/or IRO will select, for each hospital identified in step 1. above, a random sample of 50 acute care hospital-based Medicare OPPS claims that include at least one APC reimbursed line item for a detailed claims review. The procedures that will be performed for this sample are as follows:
- Compare the APC services ordered to the APC services performed
 - Compare the APC services performed to the APC services billed
 - Compare the APC services billed to the APC payment received
 - Validate the accuracy of the ICD-9-CM diagnosis codes for PHP services
 - Validate the accuracy of the HCPCS/CPT codes that result in APC assignment(s)
 - Validate the accuracy of the units billed that result in APC assignment(s)
 - Validate the accuracy of modifiers on HCPCS/CPT codes that impact APC assignment(s)
 - Validate the accuracy of condition codes that are present on the claim that pertain to acute care hospital-based Medicare OPPS

- Determine whether any modifiers or condition codes pertaining to acute care hospital-based Medicare OPPS that should be present on the claim are missing
 - Validate that the appropriate HCPCS/CPT codes and revenue codes have been assigned to approved APC pass through items
4. For purposes of evaluating the testing results of the sample, an “overpayment” includes the following:
 - An APC service performed that was not ordered but was billed for and resulted in an overpayment to the hospital.
 - An APC service that was performed as ordered but was billed in a manner that resulted in an overpayment to the hospital.
 5. The Company and/or IRO will summarize the results of these reviews.
 6. Based on the results of the review, the acute care hospital shall create an action plan that is appropriate to the findings. The hospital shall also promptly repay any APC overpayments to Medicare.
 7. Based upon the results of the review, the Company shall develop and implement, as appropriate, additional resources, training or tools to improve processes and/or correct identified deficiencies.
 8. If the Company performs the above testing, the IRO will:
 - a. Read the Company’s documentation regarding the review results and determine whether the appropriate reviews as defined in step 3. above were performed.
 - b. Reperform the reviews at 3 of the hospitals reviewed by the Company.
 - c. Review the testing and conclusions reached by the Company and confirm that the appropriate follow up steps occur.

IV. REPORTING

Upon completion of all testing, the Company will quantify the results and findings will be reported to the OIG. The Company’s report will include the following:

- A. Information on the results of acute care hospital-based Medicare OPPS claims review.

- B. Results of the assessment and testing of the Company's acute care hospital-based Medicare OPPS billing and coding operations (including, but not limited to, the infrastructure, strengths and weaknesses of processes and procedures, internal controls, and effectiveness of the overall OPPS compliance program.)**
- C. The Company's procedures to correct inaccurate acute care hospital-based Medicare OPPS billing and coding.**
- D. The steps the Company is taking to bring its operations into compliance and/or to correct problems identified by any of the reviews described above.**

The IRO will read the Company's results and findings reported to the OIG and issue a report as part of the Annual Report that enumerates their procedures performed and the findings for each procedure.

V. ANNUAL REVIEW OF THE MEDICARE OPPS WORKPLAN

Because of the recent implementation of OPPS, the Company shall review and/or revise this Workplan annually to incorporate new processes and procedures necessitated by acute care hospital-based Medicare OPPS rules, regulations or program memoranda. The Company may also revise this Workplan other than annually if additional clarifications about acute care hospital-based Medicare OPPS that impact the Company's procedures and processes become known. No revisions shall be made to the Workplan without OIG approval.