NAHC 2014 Annual Meeting: Phoenix, AZ
How to Stay the Course in Compliance and Ethics

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WHO IS SIMIONE?

• Team of home care and hospice experts with focus on solutions
  o Organizational
    • Operational Assessment, Strategic Planning, Interim Management, Clinical Operations, Compliance & Risk: Assessments, Audits, Ethics Consulting and Compliance Program Development
  o Financial
    • Cost Reporting, Compliance, Revenue Cycle
  o Sales & Marketing
    • Assessment & Analysis, Referral Management, Training Resources, “Sales Boot Camp”
  o Technology
    • Assessment & Analysis, Guided System Search, Implementation Support, Process Engineering
  o Mergers & Acquisitions
    • Due Diligence & Compliance Audits, Business Valuation, Market Assess
• Strategic Planning, Executive Support, Process Engineering, and Simione Financial Monitor offered in all 5 core challenge areas
PURPOSE OF PRESENTATION

• The objectives should assist agencies to:
  → Identify laws and initiatives applicable to the government’s fight against fraud and abuse in the healthcare industry
  → Identify the seven elements of an effective Compliance and Ethics Program
  → Explain how auditing practices reduce risk
  → State at least one lesson learned from a CIA

WHO, WHAT, WHERE, WHEN …

• **Who**: All Medicare Certified & Medicaid providers
  → Hospitals, Physician Offices, DME, **Home Health & Hospice Agency Providers**, Skilled Nursing Facilities, Ambulance, Pharmacies, Clinical Laboratories, other

• **What**: More government oversight and enforcement
  → HHS Centers for Medicare (CMS) and Office of Inspector General (OIG) compliance mandates & monitoring; investigations & enforcement actions; MACs, RACs, ZPICS state laws & Medicaid fraud units; Department of Justice (DOJ)

• **Where**: Everywhere
  → All regions across the United States

• **When**: Past, Present & Future
AND WHY?

• **Why**: Government is on watch for fraud, abuse and waste in health care
  → Medicare spends billions of dollars each year paying health care providers (billions alone for Hospice/HH)
  → The Government has confirmed many reports of fraud, abuse and waste in all areas of healthcare resulting in settlements for millions of dollars every year...
    • Roadmaps: OIG reports & Work Plans, fraud alerts, Corporate Integrity Agreement (CIAs)
  → New regulations dictate new compliance practices
  → Media on healthcare government spending
  → See government enforcement actions (Department of Justice)

BRIEF HISTORY: FRAUD, ABUSE AND WASTE

• Operations Restore Trust (ORT) Pilot 1995
  → Successful recoveries in 5 states
    • 42.3 million
  → 35 Criminal convictions
  → 18 Civil settlements
ANTI-KICKBACK STATUTE

- Focus on Federal Anti-Kickback Statute (Criminal)
  → Statute: 42 U.S.C. Sec. 1320a-7b: “Whoever knowingly and willingly solicits or receives any remuneration directly or indirectly, overtly or covertly, in cash or in kind, …”
  - Kickbacks, bribes, rebates, gifts, other
    - Established the “one purpose” test

ANTI-KICKBACK SANCTIONS

- Federal law sanctions include but may not be limited to:
  → Single violation can be $25,000 and up to five years in prison, exclusion for certified and Federal programs
  → Civil sanctions may be applied for treble damages
- Safe Harbors may be applicable
- State Anti-Kickback Statutes
- Stark laws:
  → Prohibits physician self-referrals…
FEDERAL AND STATE FALSE CLAIMS

• Federal False Claims Act (FCA)
  → 1) Actual knowledge; 2) Deliberate ignorance; 3) Reckless disregard
  → State False Claims laws

• FCA contains provision for Whistleblower (Qui Tam) Actions

WHISTLEBLOWER PROTECTION ACT 1989

• Seventy percent of FCA actions are initiated by whistleblowers
• Person can file an action on behalf of government
• 15-25% of recovered claims go to person who brought action (Government decides each case)
• 35 Billion has been recovered under FCA between 1987-2012;
  → 24 billion by qui tam actions
WHY A COMPLIANCE & ETHICS PROGRAM?

- Patient Protection & Affordable Care Act (PPACA) also known as ACA 2010 (Obama Care)
  - Requires all certified Medicare providers to establish and implement a compliance program that contains….core elements established by…HHS CMS (Section 6401 (a) (7))
- CMS is charged with drafting and implementing regulations
  - waiting for CMS… but likely modeled after voluntary guidance and Corporate Integrity Agreement (CIA) content and structure

OIG COMPLIANCE PROGRAM GUIDANCE

  - History of OIG voluntary guidance
    - Supplemental 70 Fed. Reg. 4858; January 31, 2005
    - Hospice: 64 Fed. Reg. 54031; October 5, 1999
    - Clinical lab; ambulance, physician practices; other…
MORE ON: WHY COMPLIANCE PROGRAM

- Programs may allow providers to mitigate risk and negotiate a more favorable outcome if OIG investigation implicates providers or provider self-reports
- Corporate Integrity Agreements (CIA) mandate compliance plan (See handouts)
  → Elements of CIAs (see [www.oig.hhs.gov](http://www.oig.hhs.gov))
  - Common elements
  - Five year requirements for Independent Review Organizations (IRO)
  - Must establish a company compliance and ethics plan or enhance plan
  - Annual Audits

MANDATORY COMPLIANCE REQUIREMENTS

- CMS Conditions of Participation (CoPs)
- Medicare Administrative Contractors (MACs)
- ZPIC (Zone Program Integrity Contractors)
- CMS Regulations, Notices, Transmittals, other
- Self Disclosure Protocol (revised April 2013)
- Case Law
  - Jimmo v. Sebelius Settlement Agreement-Program Manual Clarifications (Fact Sheet)
- State laws regarding background checks/Medicaid fraud/Other
HIGH RISK AREAS

- Common areas for high risk:
  - Marketing, Billing, Human Resources, Quality Management/QAP

HOW TO IDENTIFY HIGH RISK COMPLIANCE AREAS

- Each Medicare provider type has its own high risk areas that must be addressed
- CMS New Regulations & Rules
- CMS Transmittals & Change Requests
- Regularly review CMS/OIG websites, CIAs, Enforcement Actions
- Annually review OIG Work Plans
  - 2013
  - 2014
EXAMPLE OF GOVERNMENT OVERSIGHT FOR HH

- 2013-2014 OIG Work Plan (www.oig.hhs.gov/reports)
  - Face to face encounters
  - Employment of home health aides (HHA) with criminal convictions
  - OASIS
  - MAC: Claims oversight
  - Home health PPS requirements
  - State survey and Certification/Quality
  - Trends in expenses and revenues
    - Cost report analysis

EXAMPLE OF GOVERNMENT OVERSIGHT FOR HOSPICE

- 2013-2014 OIG Work Plan (www.oig.hhs.gov/reports)
  - Marketing practices
  - Financial relationships with nursing facilities
    - Mandatory contract language
  - Hospice in Assisted Living Facilities
  - General Inpatient Care (GIP) services
    - Services billed but not received
    - Increase utilization
CORE ELEMENTS OF AN ETHICS & COMPLIANCE PLAN

1. Written policies and procedures to include written standards/code of conduct; policies must cover high risk areas of practice; include anti-kickback, conflicts…
2. Effective oversight by provider/company compliance officer & governing body & compliance committee
3. Effective development and implementation of regular, applicable education and training for all affected employees;

ELEMENTS OF A COMPLIANCE PROGRAM

4. An effective reporting system such as a hotline to receive complaints and to ensure effective communication between the compliance officer and employees. Option for anonymity.
   - Most Common: Telephone
   - Other:
     → Email
     → Mail
ELEMENTS OF AN ETHICS & COMPLIANCE PLAN

5. Use of audits and or other systemic practices to monitor compliance, identify problem areas, and implement corrective action measures: contracts; pre-billing checks, high risk areas per provider type, internal & external compliance audits, etc.;

6. Establish disciplinary measures to enforce standards of conduct, address violation and apply applicable sanctions;

7. Effective policies that ensure prompt investigations, reporting and corrective actions;


IS THERE A READY MADE COMPLIANCE PLAN?

• One size does not fit all
• Compliance plans evolve and change
NO COMPLIANCE PROGRAM? DO NOT DESPAIR

- Take inventory of compliance measures your clients already have in place

ASSESS CLIENT COMPLIANCE MEASURES

- Assess programs/processes already in place:
  - Clinical policies and procedures
    - Written manuals or computer accessible?
    - Current and up-to-date?
    - Accessible to all clinical staff/other staff?
    - Reviewed/revised annually?
  - Billing and Claims submission policies/processes
    - Written manuals or computer accessible
    - Pre-billing checks
    - Special training and education for billing personnel: on-hire and annually?
ASSESS COMPLIANCE MEASURES

→ Effective Quality Assessment and Performance Improvement (QAPI) Committee?
  • Dashboard? Agency management team put together for what your agency wants to measure.
  • Analysis of data? Action Plans?
  • Ongoing auditing and monitoring?

→ Electronic Medical Records
  • Compliance measures in place to capture regulatory requirements? Clinical people working w/vendor?

→ Human Resource Function
  • Employee Handbook? Standard of Conduct?
  • Written progressive disciplinary procedures all levels management? Just culture? Use term “Ethics” in title

ASSESS, AUDIT, MEASURE & MONITOR & AGAIN

• DO THIS: to AVOID this:
EXAMPLE: ENFORCEMENT ACTION

- Department of Justice
- Office of Public Affairs
- FOR IMMEDIATE RELEASE
- Tuesday, January 7, 2014
- Medical Clinic Owner and Other Patient Recruiters Plead Guilty in Miami for Roles in $8 Million Health Care Fraud Scheme

Several patient recruiters, including a medical clinic owner, pleaded guilty today in connection with a health care fraud scheme involving Flores Home Health Care Inc., a defunct home health care company.


At a hearing held before U.S. District Judge Ursula Ungaro of the Southern District of Florida, Lerida Labrada, 59, of Miami, pleaded guilty to conspiracy to commit health care fraud, which carries a maximum penalty of 10 years in prison, and Mayra Flores, 49, and German Martinez, 36, both of Miami, pleaded guilty to conspiracy to defraud the United States and receive health care kickbacks, which carries a maximum penalty of five years in prison.

Sentencing has been scheduled for March 14, 2014.

According to court documents, the defendants worked as patient recruiters for the owners and operators of Flores Home Health, a Miami home health care agency that purported to provide home health and physical therapy services to Medicare beneficiaries. Labrada also owned and operated a Miami medical clinic that provided fraudulent prescriptions to patient recruiters and to the owners and operators of Flores Home Health.

Flores Home Health was operated for the purpose of billing the Medicare program for, among other things, expensive physical therapy and home health care services that were not medically necessary and/or were not provided.

The defendants would recruit patients for Flores Home Health and would solicit and receive kickbacks and bribes from the owners and operators of Flores Home Health in return for allowing the agency to bill the Medicare program on behalf of the recruited Medicare patients. These Medicare beneficiaries were billed for home health care and therapy services that were not medically necessary and/or not provided.

CORPORATE INTEGRITY AGREEMENTS

- Read CIAs (www.oig.hhs.gov)
  → A good approach to learning what government is investigating and penalizing
CORPORATE INTEGRITY AGREEMENTS

• Example provided of Home Health & Hospice CIA
  → CIA False Claims Act Activity
  → More criminal charges in home health activity than hospice
  → Medicaid Enforcement increasing
    • December 2013 NY AG Fraud Unit: 2.5 million settlement included false billings and uncertified HH aides...
  → Other

CIA DISCUSSION

• KAI Heart, Inc. D/B/A Kai Heart Home Health Care
  → Highlights of CIA
    • Board Obligations
    • Implement written policies and procedures reimbursement requirements for home health services
    • Training and Education on: medical necessity, accurate coding, timely assessments, OASIS data collection, other
    • IRO Claims review
GOVERNMENT RESOURCES

- MAC websites
- www.cms.gov
  → Medicare
  → Provider Type
    - Date
    - Transmittals
    - Regulations and Notices

GOVERNMENT RESOURCES (OIG)

- www.oig.hhs.gov
  → Compliance Guidance
  → Compliance Tool Kits (toolkit for Boards)
  → OIG Compliance Audit Tool for Hospice
  → Corporate Integrity Agreements (CIA)
  → Latest enforcement actions with link to the Department of Justice (DOJ)
  → Self Disclosure Protocol (SDP)—April 17, 2013
  → Internal Review Organizations (IRO)
QUESTIONS?

EDUCATION PURPOSES

• This presentation is for education purposes only and should not be construed as providing legal advice.
THANK YOU!

• Thank you for your time and attention; we know you are busy!
• For additional questions or inquiries please contact:
  
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Note: This notice, issued on April 17, 2013, updates the Provider Self-Disclosure Protocol.
Updated OIG’s Provider Self-Disclosure Protocol

SUMMARY: This notice, issued on April 17, 2013, updates the Provider Self-Disclosure Protocol.

FOR FURTHER INFORMATION CONTACT: Patrice S. Drew, Department of Health and Human Services, Office of Inspector General, Congressional and Regulatory Affairs, at (202) 619-1368.

I. Background

In 1998, the Office of Inspector General (OIG) of the United States Department of Health and Human Services (HHS) published the Provider Self-Disclosure Protocol (the SDP) at 63 Fed Reg. 58399 (October 30, 1998) to establish a process for health care providers to voluntarily identify, disclose, and resolve instances of potential fraud involving the Federal health care programs (as defined in section 1128B(f) of the Social Security Act (the Act), 42 U.S.C. 1320a–7b(f)). The SDP provides guidance on how to investigate this conduct, quantify damages, and report the conduct to OIG to resolve the provider’s liability under OIG’s civil monetary penalty (CMP) authorities. Over the past 15 years, we have resolved over 800 disclosures, resulting in recoveries of more than $280 million to the Federal health care programs.

Since the original publication, we identified areas where additional guidance would be beneficial to the health care community and would improve the efficient resolution of SDP matters. To that end, we issued three Open Letters to Health Care Providers in 2006, 2008, and 2009. Since the last Open Letter, we continued to evaluate our SDP process. We also solicited comments about the SDP on June 18, 2012, and we received numerous helpful comments from the public. On the basis of our experience and the comments we received, we have decided to revise the SDP in its entirety at this time. This revised SDP supersedes and replaces the 1998 Federal Register Notice and the Open Letters, as described below.

A. Why Disclosure Is Important

For many years, OIG has emphasized the importance of dealing with the Federal health care programs with integrity. All members of the health care industry have a legal and ethical duty to do so. This duty includes an obligation to take measures to detect and prevent fraudulent and abusive activities, including implementing specific procedures and mechanisms to investigate and resolve instances of potential fraud involving the Federal health care programs. Whether as a result of voluntary self-assessment or in response to external forces, participants in the health care industry must be prepared
to investigate such instances, assess the potential losses suffered by the Federal health care programs, and make full disclosure to the appropriate authorities.

B. Benefits of Disclosure

We recognize that whether to disclose potential fraud to OIG is a significant decision. However, there are significant benefits to disclosing potential fraud to OIG that should make that decision easier.

First, we believe that good faith disclosure of potential fraud and cooperation with OIG’s review and resolution process are typically indications of a robust and effective compliance program. As a result, we have instituted a presumption against requiring integrity agreement obligations in exchange for a release of OIG’s permissive exclusion authorities in resolving an SDP matter. Since 2008, we have resolved 235 SDP cases through settlements. In all but one of these cases, we have released the disclosing parties from permissive exclusion without requiring any integrity measures.

Second, we believe that individuals or entities that use the SDP and cooperate with OIG during the SDP process deserve to pay a lower multiplier on single damages than would normally be required in resolving a Government-initiated investigation. The specific multiplier that we accept may vary depending on the facts of each case. OIG’s general practice in CMP settlements of SDP matters is to require a minimum multiplier of 1.5 times the single damages, although we determine in each individual case whether a higher multiplier may be warranted.

Third, we believe that using the SDP may mitigate potential exposure under section 1128J(d) of the Act, 42 U.S.C. 1320a-7k(d). Section 1128J(d)(2) of the Act requires that a Medicare or Medicaid overpayment be reported and returned by the later of (1) the date that is 60 days after the date on which the overpayment was identified or (2) the date any corresponding cost report is due, if applicable. Any overpayment retained by a "person," as defined in section 1128J(d)(4)(C) of the Act after this deadline may create liability under the Civil Monetary Penalties Law (CMPL), section 1128A of the Act, and the False Claims Act (FCA), 31 U.S.C. 3729. In its Notice of Proposed Rulemaking, 77 Fed. Reg. 9179-9187 (February 16, 2012), the Centers for Medicare & Medicaid Services (CMS) propose to suspend the obligation to report overpayments under section 1128J(d) when OIG acknowledges receipt of a submission to the SDP so long as the submission is timely made. CMS also proposes to suspend the obligation to return overpayments until a settlement agreement is entered into, or the provider or supplier withdraws or is removed from the SDP. As necessary, we will provide additional guidance on OIG’s web site concerning section 1128J of the Act and the SDP after CMS issues its final rule.

Finally, we commit to working with individuals and entities that use the SDP in good faith and cooperate with OIG’s review and resolution process. OIG created the SDP to provide a specific and detailed process that can be relied upon by all participants in the
health care industry as one that OIG will consistently follow. As part of this commitment, we streamlined our internal process to reduce the average time a case is pending with OIG to less than 12 months from acceptance into the SDP. To further facilitate timely resolutions of SDP matters, we are changing the timeframe to submit the findings of the completed internal investigation and damages calculation from 90 days from acceptance into the SDP to 90 days from the date of the initial submission.

II. Eligibility Criteria and Guidance

This section explains the eligibility criteria for the SDP, including who may use the SDP and what conduct is and is not eligible for acceptance into the SDP.

A. Who May Use the SDP

All health care providers, suppliers, or other individuals or entities who are subject to OIG’s CMP authorities found at 42 C.F.R. Part 1003 are eligible to use the SDP. The SDP is not limited to any particular industry, medical specialty, or type of service. For example, a pharmaceutical or medical device manufacturer may use the SDP to disclose potential violations of the Federal anti-kickback statute (AKS), section 1128B(b) of the Act, because such violations trigger CMP liability under section 1128A(a)(7) of the Act, a provision of the CMPL. For purposes of the SDP, we refer to all individuals or entities that make a submission to the SDP as “disclosing parties.” The disclosing party should disclose conduct for which it may be liable, including potential successor liability based on its purchase of another entity. For example, a disclosing party could have liabilities as the result of a merger or an acquisition. However, disclosing parties should not use the SDP to disclose conduct of another, unrelated party. OIG’s hotline should be used to report potential misconduct of other parties (1-800-HHS-TIPS or https://oig.hhs.gov/fraud/report-fraud/index.asp).

Disclosing parties already subject to a Government inquiry (including investigations, audits, or other oversight activities) are not automatically precluded from using the SDP. The disclosure, however, must be made in good faith and must not be an attempt to circumvent any ongoing inquiry. Disclosing parties under Corporate Integrity Agreements (CIA) with OIG may also use the SDP in addition to making any reports required in the CIA.

B. Conduct Eligible for the SDP

The SDP is available to facilitate the resolution of matters that, in the disclosing party’s reasonable assessment, potentially violate Federal criminal, civil, or administrative laws for which CMPs are authorized. In making a disclosure, a disclosing party must acknowledge that the conduct is a potential violation. Disclosing parties must explicitly identify the laws that were potentially violated and should not refer broadly to, for example, "Federal laws, rules, and regulations” or “the Social Security Act.” OIG has
found that disclosing parties who avoid acknowledging that there is a potential violation are more likely to have unclear or incomplete submissions or unrealistic expectations about resolutions, which result in a lengthier review and resolution process. In addition, statements such as "the Government may think there is a violation, but we disagree" raise questions about whether the matter is appropriate for the SDP. The resulting back-and-forth over these issues can create unnecessary delays in reaching a resolution and may result in the disclosing party’s removal from the SDP.

C. Conduct Ineligible for the SDP

First, the SDP is not available for a matter that does not involve potential violations of Federal criminal, civil, or administrative law for which CMPs are authorized, such as one exclusively involving overpayments or errors. In this situation, the matter should be disclosed directly to the appropriate CMS or other responsible contractor under the payor’s voluntary refund process.

Second, the SDP is not available to request an opinion from OIG regarding whether an actual or potential violation has occurred. For example, a disclosure that broadly describes a business arrangement and requests a determination from OIG regarding whether the arrangement violates the AKS is not appropriate for the SDP. The Advisory Opinion process is the only vehicle to obtain an OIG opinion, as described at https://oig.hhs.gov/compliance/advisory-opinions/index.asp.

Third, the SDP is not available for disclosure of an arrangement that involves only liability under the physician self-referal law, section 1877 of the Act (the Stark Law), without accompanying potential liability under the AKS for the same arrangement. Disclosing parties must analyze each arrangement involving a physician to determine whether it raises potential liability under the AKS, the Stark Law, or both laws. Stark-only conduct should be disclosed to CMS through its Self-Referral Disclosure Protocol (SRDP), which can be found at: http://www.cms.gov/PhysicianSelfReferral/. OIG reserves the right to determine whether an arrangement is appropriate for resolution in the SDP.

D. Tolling the Statute of Limitations

As described above, one of the benefits of disclosure is that CMS has proposed that the time for repayment of an identified overpayment under section 1128J(d) of the Act will be tolled for the disclosing party. To preserve the rights of the parties while the matter is being resolved through the SDP, OIG expects disclosing parties to disclose with a good faith willingness to resolve all liability within the CMPL’s six year statute of limitations as described in section 1128A(c)(1) of the Act. Accordingly, the disclosing party agrees, as a condition precedent to the OIG’s acceptance into the SDP, to waive and not to plead statute of limitations, laches, or any similar defenses to any administrative action filed by OIG relating to the disclosed conduct, except to the extent
that such defenses would have been available to the disclosing party had an administrative action been filed on the date of submission.

E. Corrective Action

Prior to disclosure, the disclosing party should ensure that the conduct has ended or, at least, in the case of an improper kickback arrangement, that corrective action will be taken and the improper arrangement will be terminated within 90 days of submission to the SDP. Additionally, all other necessary corrective action should be complete and effective at the time of disclosure.

III. Submission Content

To be considered for admission into the SDP, the disclosing party must include the following information in its submission:

A. Requirements for All Disclosures

The disclosing party is expected to conduct an internal investigation and report its findings to OIG in its submission. If the disclosing party is unable to complete its internal investigation before sending its submission, the disclosing party must certify in its submission that it will complete the internal investigation within 90 days of the date of its initial submission.

Disclosures may be submitted through OIG’s Web site at https://oig.hhs.gov/compliance/self-disclosure-info/index.asp. Disclosures may also be submitted by mail to the Chief of the Administrative and Civil Remedies Branch, Office of Counsel to the Inspector General, Office of Inspector General, Department of Health and Human Services, 330 Independence Avenue, SW, Cohen Building, Room 5527, Washington, DC 20201. Submissions by facsimile or other means will not be accepted. The narrative submission must include:

1. The name, address, type of health care provider, provider identification number(s), and tax identification number(s) of the disclosing party and the Government payors (including Medicare contractors) to which the disclosing party submits claims or a statement that the disclosing party does not submit claims.

2. If the disclosing party is an entity that is owned or controlled by or is otherwise part of a system or network, an organizational chart, a description or diagram describing the pertinent relationships; the names and addresses of any related entities; and any affected corporate divisions, departments, or branches.
3. The name, street address, phone number, and email address of the disclosing party’s designated representative for purposes of the voluntary disclosure.

4. A concise statement of all details relevant to the conduct disclosed, including, at minimum, the types of claims, transactions, or other conduct giving rise to the matter; the period during which the conduct occurred; and the names of entities and individuals believed to be implicated, including an explanation of their roles in the matter.

5. A statement of the Federal criminal, civil, or administrative laws that are potentially violated by the disclosed conduct.

6. The Federal health care programs affected by the disclosed conduct.

7. An estimate of the damages, as described in the applicable section below, to each Federal health care program relevant to the disclosed conduct, or a certification that the estimate will be completed and submitted to OIG within 90 days of the date of submission. When a disclosing party can determine the amount of actual damages to Federal health care programs, the actual damages amount must be provided instead of an estimate.

8. A description of the disclosing party’s corrective action upon discovery of the conduct.

9. A statement of whether the disclosing party has knowledge that the matter is under current inquiry by a Government agency or contractor. If the disclosing party has knowledge of a pending inquiry, it must identify any involved Government entity and its individual representatives. The disclosing party must also disclose whether it is under investigation or other inquiry for any other matters relating to a Federal health care program and provide similar information relating to those other matters.

10. The name of an individual authorized to enter into a settlement agreement on behalf of the disclosing party.

11. A certification by the disclosing party, or, in the case of an entity, an authorized representative on behalf of the disclosing party, stating that to the best of the individual’s knowledge, the submission contains truthful information and is based on a good faith effort to bring the matter to the Government’s attention for the purpose of resolving potential liability to the Government and to assist OIG in its resolution of the disclosed matter.
B. Requirements for Conduct Involving False Billing

When a disclosure involves the submission of improper claims to Federal health care programs, the disclosing party must conduct a review to estimate the improper amount paid by the Federal health care programs (referred to as “damages”) and prepare a report of its findings that follows the requirements in this section. OIG will verify a disclosing party’s calculation of damages.

The disclosing party’s estimation of damages must consist of a review of either: (1) all the claims affected by the disclosed matter or (2) a statistically valid random sample of the claims that can be projected to the population of claims affected by the matter. A disclosing party may not extend the time to resubmit claims to Federal health care programs through the SDP; therefore, the damages estimation must not include a reduction, or “netting” for any underpayments discovered in the review.

When using a sample to estimate damages, the disclosing party must use a sample of at least 100 items and use the mean point estimate to calculate damages. If a probe sample was used, those claims may be included in the 100-item sample if statistically appropriate. To avoid unreasonably large sample sizes, the SDP does not require a minimum precision level for the review of claims. As a result, the disclosing party may select an appropriate sample size to estimate damages as long as the sample size is at least 100 items. As a general rule, smaller sample sizes (closer to 100) will suffice where the population has a high level of homogeneity, and larger sample sizes will be necessary where the population contains a more diverse mixture of claim types. The disclosing party should keep in mind that a careful and complete definition of the population will assist in making accurate findings.

The disclosing party’s report must include, at a minimum, the following information:

1. **Review Objective**: A statement clearly articulating the objective of the review.

2. **Population**: A description of the group of claims about which information is needed, an explanation of the methodology used to develop the population, and the basis for this determination.

3. **Sources of Data**: A full description of the source of the data reviewed and the information upon which the review was based, including the sources of payment data, and the documents that were relied upon.

4. **Personnel Qualifications**: The names and titles of the individuals who conducted the review. The review should be conducted by qualified individuals, e.g., statisticians, accountants, auditors,
consultants, and medical reviewers, and the review report should describe their qualifications.

5. **Characteristics Measured**: The review report should identify the characteristics used for testing each item. For example, in a review designed to estimate the value of overpayments due to duplicate payments, the characteristics used are those that must exist for an item to be a duplicate. The amount of the duplicate payment is the measurement of the overpayment. The report must also explain the method for determining whether an item entirely or partially meets the criterion for having the characteristics measured.

If the financial review was based upon a sample, the review report must also include the Sampling Plan that was followed. At a minimum, this includes:

1. **Sampling Unit**: Any of the designated elements that constitute the population of interest.

2. **Sampling Frame**: The totality of the sampling units from which the sample was selected and the way in which the audit population differs from the sampling frame (and the effect this difference has on conclusions reached as a result of the audit).

3. **Sample Size**: The size of the sample reviewed to reach the estimate of the damages. The sample size must be at least 100 claims.

4. **Source of Random Numbers**: The sample must be selected through random numbers. The source of the random numbers used must be shown in the report. We strongly recommend the use of OIG’s Statistical Sampling Software, also known as “RAT-STATS,” which is currently available free of charge at https://oig.hhs.gov/compliance/rat-stats/index.asp.

5. **Method of Selecting Sampling Units**: The method for selecting the sample units.

6. **Sample Design**: Unless the disclosing party demonstrates the need to use a different sample design, the review should use simple random sampling. If necessary, the disclosing party may use stratified or multistage sampling. Details about the strata, stages, and clusters should be included in the review report.

7. **Missing Sample Items and Other Evidence**: If the review was based on a sample, missing sample items should be treated as errors, pursuant to Federal health care program rules requiring the retention of supporting information for submitted claims. Missing sample items should be noted
in the report. The report must also describe any evidence, other than the sample results, that was considered in arriving at the review results.

8. **Estimation Methodology:** If the review was based on a sample, because the general purpose of the review is to estimate the monetary losses to the Federal health care programs, the methodology to be used must be variables sampling (treating each individual item in the population as a sampling unit) using the difference estimator (estimates of the total errors in the population are made from the sample differences by multiplying the average audited difference by the number of units in the population).

C. **Requirements for Conduct Involving Excluded Persons**

Many SDP submissions disclose the employment of, or contracting with, individuals who appear on OIG’s List of Excluded Individuals and Entities (LEIE) (available online at https://exclusions.oig.hhs.gov). We are providing additional guidance here to help disclosing parties gather the necessary information for a complete disclosure.

**Specific Information**

In addition to providing the general information required by section III.A, the disclosure must provide the following information:

1. The identity of the excluded individual and any provider identification number.
2. The job duties performed by that individual.
3. The dates of the individual’s employment or contractual relationship.
4. A description of any background checks that the disclosing party completed before and/or during the individual’s employment or contract.
5. A description of the disclosing party’s screening process (including any policy or procedure that was in place) and any flaw or breakdown in that process that led to the hiring or contracting with the excluded individual.
6. A description of how the conduct was discovered.
7. A description of any corrective action (including a copy of any revised policy or procedure) implemented to prevent future hiring of excluded individuals.

In addition, before disclosing the employment of an excluded individual, a disclosing party must screen all current employees and contractors against the LEIE. Once this has been done, the disclosing party should disclose all excluded persons in one submission.
Calculating Damages

Federal health care programs may not pay, directly or indirectly, for items or services furnished, ordered, or prescribed by excluded individuals or entities. If a disclosing party employed or contracted with an excluded person who was a direct provider, such as a physician or a pharmacist, and the items or services furnished, ordered, or prescribed by that person were separately billed to Federal health care programs, the disclosure must include the total amounts claimed and paid by the Federal health care programs for those items or services.

We understand that when an excluded individual provided items or services that are not billed separately to Federal health care programs, such as many items or services furnished by nurses, respiratory therapists, and billing and other administrative personnel, the damages amounts can be difficult to quantify. For purposes of resolving SDP matters involving such non-separately-billable items or services, we use the disclosing party’s total costs of employment or contracting during the exclusion to estimate the value of the items and services provided by that excluded individual. The costs of employment or contracting include, but are not limited to, all salary and benefits and other money or items of value, health insurance, life insurance, disability insurance, and employer taxes paid related to employment of the individual (e.g., employer’s share of FICA and Medicare taxes). This total amount should be multiplied by the disclosing party’s revenue-based Federal health care program payor mix for the relevant time period. (If a disclosing party can measure the Federal payor mix for the department or unit in which the excluded person worked, it is appropriate to apply that payor mix. If the departmental payor mix cannot reasonably be measured, the disclosing party must apply the payor mix for the whole entity.) The resulting amount will be used, for purposes of compromising OIG’s CMP authorities in a settlement, as a proxy for the amount paid and the single damages to the Federal health care programs resulting from the employment of the excluded individual. When the disclosing party is using a Federal payor mix, the disclosure must include a separate calculation for each Federal health care program. For example, if the disclosing party’s Federal payor mix is 60 percent, the disclosure should break down how the Federal health care programs make up that 60 percent, such as 40 percent Medicare, 10 percent Medicaid State A, 5 percent Medicaid State B, and 5 percent TRICARE.

D. Requirements for Conduct Involving the Anti-Kickback Statute and Physician Self-Referral Law

Another large category of SDP submissions relates to potential violations of the AKS (including conduct that violates both the AKS and the Stark Law). This section provides further guidance to help disclosing parties gather the necessary information for complete disclosure.
Specific Information

In this section, we provide additional guidance on submitting the information described in section III.A. Any disclosure must clearly acknowledge that in the disclosing party’s reasonable assessment of the information available at the time of the disclosure, the subject arrangement(s) constitute potential violations of the AKS and, if applicable, the Stark Law. In the past, some disclosing parties have failed to include this acknowledgment in their submissions to the SDP while others have phrased their acknowledgments as suggestions that OIG could view the disclosed conduct as potential violations. OIG will not accept any disclosing party into the SDP that fails to acknowledge clearly that the disclosed arrangement constitutes a potential violation of the AKS and, if applicable, the Stark Law.

As with other self-disclosed conduct, OIG needs to understand the precise nature of the disclosed conduct that creates potential AKS liability or both AKS and Stark Law liability. Therefore, the disclosing party must include in its narrative submission (not by reference to attachments or other documents) a concise statement of all details directly relevant to the disclosed conduct and a specific analysis of why each disclosed arrangement potentially violates the AKS and Stark Laws. The description should include the participants’ identities, their relationship to one another to the extent that the relationship affects their potential liability (e.g., hospital-landlord, referring physician-tenant); the payment arrangements; and the dates during which each suspect arrangement occurred. Further, the disclosure should explain the relevant context and the features of the arrangement that raise potential AKS or both AKS and Stark Law liability.

Below are several examples of the type of information OIG finds helpful in assessing and resolving disclosed conduct involving potential AKS and, if applicable, Stark Law violations. These illustrations are by no means comprehensive or exclusive; rather, they reflect some common issues that have arisen in SDP submissions. For example:

1. How fair market value was determined and why it is now in question.

2. Why required payments from referral sources, under leases or other contracts, were not timely made or collected or did not conform to the negotiated agreement and how long such lapses existed.

3. Why the arrangement was arguably not commercially reasonable (e.g., lacked a reasonable business purpose).

4. Whether payments were made for services not performed or documented and, if so, why.
5. Whether referring physicians received payments from Designated Health Service entities that varied with, or took into account, the volume or value of referrals without complying with a Stark Law exception.

Finally, the submission must describe the corrective action taken to remedy the suspect arrangement(s), as well as any safeguards implemented by the disclosing party to prevent the conduct from reoccurring.

Calculating Damages

AKS compliance is a condition of payment of the Federal health care programs. Under section 1128B(g) of the Act, claims that include items or services resulting from an AKS violation constitute false or fraudulent claims for purposes of the FCA. Stark Law compliance is also a condition of payment under section 1877 of the Act. Thus, a disclosing party must submit an estimate of the amount paid by Federal health care programs for the items or services associated with potential violations of the AKS and, if applicable, the Stark Law. A disclosing party may use the methodology in section III.B to calculate the estimate. Alternatively, a disclosing party may identify another reliable methodology to calculate this claims-based estimate and explain that methodology in its submission.

Consistent with OIG’s CMPL authorities, a disclosing party must include the total amount of remuneration involved in each arrangement without regard to whether the disclosing party believes a portion of the total remuneration was offered, paid, solicited, or received for a lawful purpose. A disclosing party may also explain what it believes is the value of the financial benefit conferred under the arrangement and whether it believes any portion of the total remuneration should not be considered by OIG in determining an appropriate settlement of OIG’s CMP authorities. Given the various legal authorities at issue, OIG has broad discretion in determining an appropriate resolution in these cases. For purposes of resolving SDP matters, we generally exercise this discretion by compromising our CMP authorities for an amount based upon a multiplier of the remuneration conferred by the referral recipient to the individual or entity making the referral. While this is our general approach, OIG’s determination of the appropriate settlement amount depends on the facts and circumstances of each matter. We generally use this remuneration-based methodology in the SDP as an incentive to encourage disclosure of potential AKS violations. OIG’s use of a remuneration-based methodology in the SDP settlement context does not govern OIG’s position in other situations, such as Government-initiated investigations, in which the Government may use any legally supportable measure of damages, multipliers, and penalties.
IV. Resolution

Resolution of a matter in the SDP depends on cooperation, realistic expectations, and clear communication between OIG and the disclosing party. This section provides some basic information about successful resolution of SDP matters.

A. Cooperation Is Essential

The benefits of self-disclosure, such as a speedy resolution, lower multiplier, and an exclusion release without integrity agreement obligations, depend on the disclosing party’s willingness to work cooperatively with OIG throughout the process. Cooperation includes, for example, conducting a thorough investigation, submitting all necessary information, communicating through a consistent point of contact, being responsive to OIG requests for additional information, and being willing to pay a penalty or multiplier of damages for self-disclosed conduct. Disclosing parties who fail to cooperate with OIG in good faith will be removed from the SDP.

B. OIG Coordination With DOJ on Civil Matters

OIG will coordinate with the Department of Justice (DOJ) on in resolving SDP matters. If OIG is the sole agency representing the Federal Government, the matter will be settled under OIG’s applicable CMP authorities. In some cases, disclosing parties may request release under the FCA, and in other cases, DOJ may choose to participate in the settlement of the matters. If DOJ participates in the settlement, the matter will be resolved as DOJ determines is appropriate consistent with its resolution of FCA cases, which could include a calculation of damages resulting from violations of the AKS based on paid claims. OIG will advocate that the disclosing party receive a benefit from disclosure under the SDP and the matter be resolved consistent with OIG’s approach in similar cases. However, DOJ determines the approach in cases in which it is involved.

C. OIG Coordination With DOJ on Criminal Matters

OIG encourages disclosing parties to disclose potential criminal conduct though the SDP process. OIG’s Office of Investigations investigates criminal matters, and any disclosure of criminal conduct through the SDP will be referred to DOJ for resolution. As in civil cases referred to DOJ, OIG will advocate that the disclosing parties receive a benefit from disclosure under the SDP.

D. OIG Coordination With the SRDP

Disclosing parties need to decide whether OIG’s SDP or CMS’s SRDP is the appropriate protocol to disclose potential Stark Law violations. Both protocols should not be used
for the same arrangement. As stated above, disclosing parties must analyze each arrangement to determine whether the arrangement raises potential violations of the AKS, the Stark Law, or both. If the arrangement raises a potential violation of only the AKS or of both the AKS and the Stark Law, the arrangement should be disclosed to OIG under the SDP. If the arrangement raises a potential violation of only the Stark Law, the arrangement should be disclosed to CMS under the SRDP. OIG coordinates with CMS on the review and resolution of matters disclosed to either agency as appropriate. However, OIG does not participate in SRDP settlements.

E. Minimum Settlement Amounts

While OIG does not demand an admission of liability in settlement agreements, disclosing parties should expect to pay above single damages for disclosed conduct that potentially violates Federal law. OIG’s general practice is to require a minimum multiplier of 1.5 times the single damages, although in each case, we determine whether a higher multiplier is appropriate. As a general practice, for purposes of settlement in the SDP, OIG applies this multiplier to the amount paid by Federal health care programs, not the amount claimed.

To better allocate disclosing party and OIG resources in resolving matters through the SDP and to promote transparency and realistic expectations in the SDP process, we require minimum settlement amounts for self-disclosed matters. For kickback-related submissions accepted into the SDP, OIG will require a minimum $50,000 settlement amount to resolve the matter. This minimum amount is consistent with OIG’s statutory authority to impose a penalty of up to $50,000 for each such transaction and an assessment of up to three times the total remuneration. See section 1128A(a)(7) of the Act. For all other matters accepted into the SDP, OIG will require a minimum $10,000 settlement amount to resolve the matter. This minimum amount is consistent with OIG’s statutory authority to impose a penalty of at least up to $10,000 for each improper claim submitted as described in the CMPL, section 1128A(a) of the Act. These minimum amounts account for Federal health care program damages and any relevant multiplier.

In the unusual instance when OIG determines that no potential fraud liability exists for conduct disclosed under the SDP, OIG will refer the matter to the appropriate payor for acceptance of the overpayment and no CMP release will be provided.

F. Financial Inability To Pay

In some situations, disclosing parties may be unable to pay otherwise appropriate settlement amounts. In preparing the disclosure, disclosing parties should determine whether an inability to pay may be an issue. If a disclosing party asserts that it cannot pay a proposed settlement amount (i.e., damages plus a multiplier or penalty amount), OIG will require extensive financial information, including audited financial statements,
Disclosing parties must certify to the truthfulness and completeness of the financial disclosure. In addition to submitting the financial forms, disclosing parties should include an assessment of how much they believe they can afford to pay.

Disclosing parties should raise potential inability-to-pay issues at the earliest possible time, preferably in the SDP submission. Doing so enables OIG to promptly send the disclosing party the financial disclosure forms and consider that information in determining an appropriate resolution.

G. Overpayment Reconciliation

If, prior to resolving an SDP matter, a disclosing party refunds an overpayment related to the same conduct disclosed under the SDP, OIG will credit the amount paid toward the ultimate settlement amount. However, OIG is not bound by any amount that is repaid outside the SDP process. OIG may question the methodology of the overpayment calculation, particularly if the disclosing party estimated the overpayment amount by some method other than as described in the SDP. If OIG disputes the methodology used to calculate the overpayment, OIG may require the disclosing party to redo the review or conduct an independent damages review, which may result in a damages or overpayment amount that is higher than the disclosing party’s estimate. Moreover, even if OIG agrees with the methodology used to calculate the overpayment, the disclosing party should expect to pay a multiplier on the damages under the SDP.

H. FOIA Implications of Disclosure

Disclosing parties should clearly identify any portion of their submissions that they believe are trade secrets or are commercial, financial, privileged, or confidential and therefore potentially exempt from disclosure under the Freedom of Information Act (FOIA), 5 U.S.C. § 552. Information identified as exempt must meet the criteria for exemption from disclosure under FOIA as determined by an OIG FOIA officer. Consistent with the Department of Health and Human Services’ FOIA procedures, set forth in 45 C.F.R. Part 5, OIG will make a reasonable effort to notify a disclosing party prior to any release by OIG of information submitted by a disclosing party and identified upon submission by a disclosing party as trade secrets or as commercial, financial, privileged, or confidential under the FOIA rules. With respect to such releases, a disclosing party will have the rights set forth at 45 C.F.R. § 5.65(d).
Corporate Integrity Agreement  1  Hospice of the Comforter, Inc.
b. all contractors, subcontractors, agents, and other persons who provide patient care items or services or who perform billing or coding functions on behalf of HOTC, excluding vendors whose sole connection with HOTC is selling or otherwise providing medical supplies, equipment, medications, or biologicals to HOTC and who do not bill the Federal health care programs for such medical supplies, equipment, medications, or biologicals.

c. all physicians and other non-physician practitioners who are members of HOTC’s active medical staff.

Notwithstanding the above, this term does not include part-time or per diem employees, contractors, subcontractors, agents, and other persons 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. “Relevant Covered Persons” includes all Covered Persons whose job responsibilities involve (either directly or in a supervisory role) determining whether HOTC patients meet the requirements for any and all hospice services including, but not limited to, hospice administrators, patient care managers and interdisciplinary care team members such as hospice physicians, hospice nurses, hospice aides, nursing assistants, social workers, chaplains and bereavement counselors.

3. “Long Length of Stay” means an HOTC patient who during a Reporting Period received uninterrupted services from HOTC for 270 days or more.

III. CORPORATE INTEGRITY OBLIGATIONS

HOTC shall establish and maintain a Compliance Program that includes the following elements:
A. Compliance Officer and Committee

1. Compliance Officer. Within 90 days after the Effective Date, HOTC shall appoint a Covered Person to serve as its Compliance Officer and shall maintain a Compliance Officer for the term of the CIA. The Compliance Officer shall be responsible for developing and implementing policies, procedures, and practices designed to ensure compliance with the requirements set forth in this CIA and with Federal health care program requirements. The Compliance Officer shall be a member of senior management of HOTC, shall report directly to the Chief Executive Officer of HOTC, shall make periodic (at least quarterly) reports regarding compliance matters directly to the Board of Directors of HOTC, and shall be authorized to report on such matters to the Board of Directors at any time. The Compliance Officer shall not be or be subordinate to the General Counsel or Chief Financial Officer. The Compliance Officer shall be responsible for monitoring the day-to-day compliance activities engaged in by HOTC as well as for any reporting obligations created under this CIA. Any noncompliance job responsibilities of the Compliance Officer shall be limited and must not interfere with the Compliance Officer’s ability to perform the duties outlined in this CIA.

HOTC shall report to OIG, in writing, any change in the identity of the Compliance Officer, or any actions or changes that would affect the Compliance Officer’s ability to perform the duties necessary to meet the obligations in this CIA, within five days after such a change.

2. Compliance Committee. Within 90 days after the Effective Date, HOTC shall appoint a Compliance Committee. The Compliance Committee shall, at a minimum, include the Compliance Officer and other members of senior management necessary to meet the requirements of this CIA (e.g., senior executives of relevant departments, such as billing, clinical, human resources, audit, and operations). The Compliance Officer shall chair the Compliance Committee and the Committee shall support the Compliance Officer in fulfilling his/her responsibilities (e.g., shall assist in the analysis of the HOTC’s risk areas and shall oversee monitoring of internal and external audits and investigations). The Compliance Committee shall meet at least quarterly.

HOTC shall report to OIG, in writing, any changes in the composition of the Compliance Committee, or any actions or changes that would affect the Compliance
Committee’s ability to perform the duties necessary to meet the obligations in this CIA, within 15 days after such a change.

3. **Board of Directors Compliance Obligations.** The Board of Directors (or a committee of the Board) of HOTC (Board) shall be responsible for the review and oversight of matters related to compliance with Federal health care program requirements and the obligations of this CIA. The Board must include independent (i.e., non-executive) members.

The Board shall, at a minimum, be responsible for the following:

a. meeting at least quarterly to review and oversee HOTC’s Compliance Program, including but not limited to the performance of the Compliance Officer and Compliance Committee;

b. for each Reporting Period of the CIA, adopting a resolution, signed by each member of the Board summarizing its review and oversight of HOTC’s compliance with Federal health care program requirements and the obligations of this CIA.

At minimum, the resolution shall include the following language:

“The Board of Directors has made a reasonable inquiry into the operations of HOTC’s Compliance Program including the performance of the Compliance Officer and the Compliance Committee. Based on its inquiry and review, the Board has concluded that, to the best of its knowledge, HOTC has implemented an effective Compliance Program to meet Federal health care program requirements and the obligations of the CIA.”

If the Board is unable to provide such a conclusion in the resolution, the Board shall include in the resolution a written explanation of the reasons why it is unable to provide the conclusion and the steps it is taking to implement an effective Compliance Program at HOTC.

HOTC shall report to OIG, in writing, any changes in the composition of HOTC’s Corporate Integrity Agreement.
Board, or any actions or changes that would affect the Board’s ability to perform the
duties necessary to meet the obligations in this CIA, within 15 days after such a change.

B. **Written Standards**

1. **Code of Conduct.** Within 90 days after the Effective Date, HOTC shall develop, implement, and distribute a written Code of Conduct to all Covered Persons. HOTC shall make the promotion of, and adherence to, the Code of Conduct an element in evaluating the performance of all employees. The Code of Conduct shall, at a minimum, set forth:

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

   b. HOTC’s requirement that all of its Covered Persons shall be expected to comply with all Federal health care program requirements and with HOTC’s own Policies and Procedures;

   c. the requirement that all Covered Persons shall be expected to report to the Compliance Officer, or other appropriate individual designated by HOTC, suspected violations of any Federal health care program requirements or of HOTC’s own Policies and Procedures; and

   d. the right of all individuals to use the Disclosure Program described in Section III.E, and HOTC’s commitment to nonretaliation and to maintain, as appropriate, confidentiality and anonymity with respect to such disclosures.

Within 90 days after the Effective Date, each Covered Person shall certify, in writing or in electronic form, that he or she has received, read, understood, and shall abide by HOTC’s Code of Conduct. New Covered Persons shall receive the Code of Conduct and shall complete the required certification within 30 days after becoming a Covered Person or within 90 days after the Effective Date, whichever is later.
HOTC shall periodically review the Code of Conduct to determine if revisions are appropriate and shall make any necessary revisions based on such review. The Code of Conduct shall be distributed at least annually to all Covered Persons.

2. **Policies and Procedures.** Within 90 days after the Effective Date, HOTC shall implement written Policies and Procedures regarding the operation of its compliance program, including the compliance program requirements outlined in this CIA and Provider’s compliance with Federal health care program requirements. At a minimum, the Policies and Procedures shall address:

   a. the subjects relating to the Code of Conduct identified in Section III.B.1;
   
   b. the OIG’s Compliance Program Guidance for Hospice;
   
   c. Federal health care program requirements relating to the coverage of hospice services and the eligibility requirements for such coverage, including requirements relating to the initial admission of patients, eligibility of Long Length of Stay patients, crisis care, respite care, inpatient care; and
   
   d. Federal health care program requirements relating to the documentation of eligibility for hospice services and the services provided, and relating to the preparation and submission of accurate claims for such services.

Within 90 days after the Effective Date, the Policies and Procedures shall be distributed to all Covered Persons. Appropriate and knowledgeable staff shall be available to explain the Policies and Procedures.

At least annually (and more frequently, if appropriate), HOTC shall assess and update, as necessary, the Policies and Procedures. Within 30 days after the effective date of any revisions, a description of the revisions shall be communicated to all affected Covered Persons and any revised Policies and Procedures shall be distributed to all Covered Persons.
C. Training and Education

1. General Training. Within 90 days after the Effective Date, HOTC shall provide at least two hours of General Training to each Covered Person. This training, at a minimum, shall explain HOTC’s:

   a. CIA requirements; and

   b. HOTC’s Compliance Program, including the Code of Conduct.

   New Covered Persons shall receive the General Training described above within 30 days after becoming a Covered Person or within 90 days after the Effective Date, whichever is later. After receiving the initial General Training described above, each Covered Person shall receive at least one hour of General Training in each subsequent Reporting Period.

2. Specific Training. Within 90 days after the Effective Date, each Relevant Covered Person shall receive at least three hours of Specific Training in addition to the General Training required above. This Specific Training shall include a discussion of:

   a. the Federal health care program requirements regarding the hospice benefit, including requirements relating to the initial admission of patients, recertification of patients, eligibility of Long Length of Stay patients, and proper use of crisis care, respite care, inpatient care;

   b. policies, procedures, and other requirements applicable to the documentation of hospice medical records;

   c. the personal obligation of each individual involved in the certification and claims submission process to ensure that such claims are accurate;
d. applicable hospice reimbursement statutes, regulations, and program requirements and directives;

e. the legal sanctions for violations of the Federal health care program requirements; and

f. examples of proper and improper claims submission and patient eligibility assessment practices.

New Relevant Covered Persons shall receive this training within 30 days after the beginning of their employment or becoming Relevant Covered Persons, or within 90 days after the Effective Date, whichever is later.

After receiving the initial Specific Training described in this section, each Relevant Covered Person shall receive at least two hours of Specific Training, in addition to the General Training, in each subsequent Reporting Period.

3. 

3. **Board Member Training.** Within 90 days after the Effective Date, HOTC shall provide at least two hours of training to each member of the Board of Directors, in addition to the General Training. This training shall address the responsibilities of board members and corporate governance.

New members of the Board of Directors shall receive the Board Member Training described above within 30 days after becoming a member or within 90 days after the Effective Date, whichever is later.

4. **Certification.** Each individual who is required to attend training shall certify, in writing or in electronic form, that he or she has received the required training. The certification shall specify the type of training received and the date received. The Compliance Officer (or designee) shall retain the certifications, along with all course materials.

5. **Qualifications of Trainer.** Persons providing the training shall be knowledgeable about the subject area.
6. **Update of Training.** HOTC shall review the training annually, and, where appropriate, update the training to reflect changes in Federal health care program requirements, any issues discovered during internal audits or the Eligibility Reviews and any other relevant information.

7. **Computer-Based Training.** HOTC may provide the training required under this CIA through appropriate computer-based training approaches. If HOTC chooses to provide computer-based training, it shall make available appropriately qualified and knowledgeable staff or trainers to answer questions or provide additional information to the individuals receiving such training.

D. **Review Procedures**

1. **General Description**

   a. **Engagement of Independent Review Organization.** Within 90 days after the Effective Date, HOTC shall engage an entity (or entities), such as an accounting, auditing, or consulting firm (hereinafter “Independent Review Organization” or “IRO”), to perform the reviews listed in this Section III.D. The applicable requirements relating to the IRO are outlined in Appendix A to this CIA, which is incorporated by reference.

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

2. **Eligibility Review.** The IRO shall conduct the “Eligibility Review” to determine whether Medicare beneficiaries meet hospice eligibility criteria and shall include a review of (1) initial admissions (Admission Review) and (2) the most recent recertification period for Long Length of Stay patients (Long Length of Stay Review).

The applicable definitions, procedures, and reporting requirements are outlined in Appendix B to this CIA, which is incorporated by reference.
3. **Eligibility Review Report.** The IRO shall prepare a report based upon the Eligibility Review performed (Eligibility Review Report). Information to be included in the Eligibility Review Report is described in Appendix B to this CIA.

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

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

6. **Validation Review.** In the event OIG has reason to believe that: (a) HOTC’s Eligibility Review or Unallowable Cost Review fails to conform to the requirements of this CIA; or (b) the IRO’s findings or Eligibility Review or Unallowable Cost Review results are inaccurate, OIG may, at its sole discretion, conduct its own review to determine whether the Eligibility Review or Unallowable Cost Review complied with the requirements of the CIA and/or the findings or Eligibility Review or
Unallowable Cost Review results are inaccurate (Validation Review). HOTC shall pay for the reasonable cost of any such review performed by OIG or any of its designated agents. Any Validation Review of Reports submitted as part of HOTC’s final Annual Report shall be initiated no later than one year after HOTC’s final submission (as described in Section II) is received by OIG.

Prior to initiating a Validation Review, OIG shall notify HOTC of its intent to do so and provide a written explanation of why OIG believes such a review is necessary. To resolve any concerns raised by OIG, HOTC may request a meeting with OIG to: (a) discuss the results of any Eligibility Review or Unallowable Cost Review submissions or findings; (b) present any additional information to clarify the results of the Claims Review or Unallowable Cost Review or to correct the inaccuracy of the Eligibility Review or Unallowable Cost Review; and/or (c) propose alternatives to the proposed Validation Review. HOTC agrees to provide any additional information as may be requested by OIG under this Section III.D.5 in an expedited manner. OIG will attempt in good faith to resolve any Eligibility Review or Unallowable Cost Review issues with HOTC prior to conducting a Validation Review. However, the final determination as to whether or not to proceed with a Validation Review shall be made at the sole discretion of OIG.

7. Independence and Objectivity Certification. The IRO shall include in its report(s) to HOTC a certification that the IRO has (a) evaluated its professional independence and objectivity with respect to the reviews conducted under this Section III.D and (b) concluded that it is, in fact, independent and objective, in accordance with the requirements specified in Appendix A to this CIA.

E. Disclosure Program

Within 90 days after the Effective Date, HOTC shall establish a Disclosure Program that includes a mechanism (e.g., a toll-free compliance telephone line) to enable individuals to disclose, to the Compliance Officer or some other person who is not in the disclosing individual’s chain of command, any identified issues or questions associated with HOTC’s policies, conduct, practices, or procedures with respect to a Federal health care program believed by the individual to be a potential violation of criminal, civil, or administrative law. HOTC shall appropriately publicize the existence of the disclosure
mechanism (e.g., via periodic e-mails to employees or by posting the information in prominent common areas).

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

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

F. **Ineligible Persons**

1. **Definitions.** For purposes of this CIA:

a. an “Ineligible Person” shall include an individual or entity who:

   i. is currently excluded, debarred, suspended, or otherwise ineligible to participate in the Federal health care programs or in Federal procurement or nonprocurement programs; or

   ii. has been convicted of a criminal offense that falls within the scope of 42 U.S.C. § 1320a-7(a), but has not yet
been excluded, debarred, suspended, or otherwise declared ineligible.

b. “Exclusion Lists” include:
   i. the HHS/OIG List of Excluded Individuals/Entities (available through the Internet at http://www.oig.hhs.gov); and
   ii. the General Services Administration’s System for Award Management (available through the Internet at http://www.sam.gov).

2. Screening Requirements. HOTC shall ensure that all prospective and current Covered Persons are not Ineligible Persons, by implementing the following screening requirements.

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

   b. HOTC shall screen all Covered Persons against the Exclusion Lists within 90 days after the Effective Date and on a monthly basis thereafter.

   c. HOTC shall implement a policy requiring all Covered Persons to disclose immediately any debarment, exclusion, suspension, or other event that makes that person an Ineligible Person.

   Nothing in Section III.F affects HOTC’s responsibility to refrain from (and liability for) billing Federal health care programs for items or services furnished, ordered, or prescribed by excluded persons. HOTC understands that items or services furnished by excluded persons are not payable by Federal health care programs and that HOTC

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may be liable for overpayments and/or criminal, civil, and administrative sanctions for employing or contracting with an excluded person regardless of whether HOTC meets the requirements of Section III.F.

3. **Removal Requirement.** If HOTC has actual notice that a Covered Person has become an Ineligible Person, HOTC shall remove such Covered Person from responsibility for, or involvement with, HOTC’s business operations related to the Federal health care programs and shall remove such Covered Person from any position for which the Covered Person’s compensation or the items or services furnished, ordered, or prescribed by the Covered Person are paid in whole or part, directly or indirectly, by Federal health care programs or otherwise with Federal funds at least until such time as the Covered Person is reinstated into participation in the Federal health care programs.

4. **Pending Charges and Proposed Exclusions.** If HOTC has actual notice that a Covered Person is charged with a criminal offense that falls within the scope of 42 U.S.C. §§ 1320a-7(a), 1320a-7(b)(1)-(3), or is proposed for exclusion during the Covered Person’s employment or contract term, or during the term of a physician’s or other practitioner’s medical staff privileges, HOTC shall take all appropriate actions to ensure that the responsibilities of that Covered Person have not and shall not adversely affect the quality of care rendered to any beneficiary, patient, or resident, or any claims submitted to any Federal health care program.

G. **Notification of Government Investigation or Legal Proceedings**

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

1. Definition of Overpayments. For purposes of this CIA, an “Overpayment” shall mean the amount of money HOTC has received in excess of the amount due and payable under any Federal health care program requirements.

2. Repayment of Overpayments

a. If, at any time, HOTC identifies or learns of any Overpayment, HOTC shall repay the Overpayment to the appropriate payor (e.g., Medicare fiscal intermediary or carrier) within 60 days after identification of the Overpayment and take remedial steps within 90 days after identification (or such additional time as may be agreed to by the payor) to correct the problem, including preventing the underlying problem and the Overpayment from recurring. If not yet quantified, within 60 days after identification, HOTC 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 payor shall be done in accordance with the payor’s policies.

b. Notwithstanding the above, notification and repayment of any Overpayment amount that routinely is reconciled or adjusted pursuant to policies and procedures established by the payor should be handled in accordance with such policies and procedures.

I. Reportable Events

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

a. a substantial Overpayment;
b. a matter that a reasonable person would consider a probable violation of criminal, civil, or administrative laws applicable to any Federal health care program for which penalties or exclusion may be authorized;

c. the employment of or contracting with a Covered Person who is an Ineligible Person as defined by Section III.F.1.a; or

d. the filing of a bankruptcy petition by HOTC.

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

2. Reporting of Reportable Events. If HOTC determines (after a reasonable opportunity to conduct an appropriate review or investigation of the allegations) through any means that there is a Reportable Event, HOTC shall notify OIG, in writing, within 30 days after making the determination that the Reportable Event exists.

3. Reportable Events under Section III.I.1.a. For Reportable Events under Section III.I.1.a, the report to OIG shall be made within 30 days of the identification of the Overpayment, and shall include:

a. a description of the steps taken by HOTC to identify and quantify the Overpayment;

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

c. a description of HOTC’s actions taken to correct the Reportable Event; and

d. any further steps HOTC plans to take to address the Reportable Event and prevent it from recurring.
Within 60 days of identification of the Overpayment, HOTC shall provide OIG with a copy of the notification and repayment to the payor required in Section III.H.2.

4. **Reportable Events under Section III.I.1.b and c.** For Reportable Events under Section III.I.1.b and III.I.1.c, the report to OIG shall include:

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

   b. a description of HOTC’s actions taken to correct the Reportable Event;

   c. any further steps HOTC plans to take to address the Reportable Event and prevent it from recurring; and

   d. if the Reportable Event has resulted in an Overpayment, a description of the steps taken by HOTC to identify and quantify the Overpayment.

5. **Reportable Events under Section III.I.1.d.** For Reportable Events under Section III.I.1.d, the report to the OIG shall include documentation of the bankruptcy filing and a description of any Federal health care program authorities implicated.

6. **Reportable Events Involving the Stark Law.** Notwithstanding the reporting requirements outlined above, any Reportable Event that involves only a probable violation of section 1877 of the Social Security Act, 42 U.S.C. §1395nn (the Stark Law) should be submitted by HOTC to the Centers for Medicare & Medicaid Services (CMS) through the self-referral disclosure protocol (SRDP), with a copy to the OIG. The requirements of Section III.H.2 that require repayment to the payor of any identified Overpayment within 60 days shall not apply to any Overpayment that may result from a probable violation of only the Stark Law that is disclosed to CMS pursuant to the SRDP. If HOTC identifies a probable violation of the Stark Law and repays the applicable Overpayment directly to the CMS contractor, then HOTC is not required by this Section III.I to submit the Reportable Event to CMS through the SRDP.
IV. **SUCCESSOR LIABILITY; CHANGES TO BUSINESS UNITS OR LOCATIONS**

A. **Sale of Business, Business Unit or Location.**

In the event that, after the Effective Date, HOTC proposes to sell any or all of its business, business units or locations (whether through a sale of assets, sale of stock, or other type of transaction) that are subject to this CIA, HOTC shall notify OIG of the proposed sale at least 30 days prior to the sale of its business, business unit or location. This notification shall include a description of the business, business unit or location to be sold, a brief description of the terms of the sale, and the name and contact information of the prospective purchaser. This CIA shall be binding on the purchaser of the business, business unit or location, unless otherwise determined and agreed to in writing by the OIG.

B. **Change or Closure of Business, Business Unit or Location**

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

C. **Purchase or Establishment of New Business, Business Unit or Location**

In the event that, after the Effective Date, HOTC purchases or establishes a new business, business unit or location related to the furnishing of items or services that may be reimbursed by Federal health care programs, HOTC shall notify OIG at least 30 days prior to such purchase or the operation of the new business, business unit or location. This notification shall include the address of the new business, business unit or location, phone number, fax number, the location’s Medicare and state Medicaid program provider number and/or supplier number(s); and the name and address of each Medicare and state Medicaid program contractor to which HOTC currently submits claims. Each new business, business unit or location and all Covered Persons at each new business, business unit or location shall be subject to the applicable requirements of this CIA, unless otherwise agreed to in writing by the OIG.
V. IMPLEMENTATION AND ANNUAL REPORTS

A. Implementation Report

Within 120 days after the Effective Date, HOTC shall submit a written report to OIG summarizing the status of its implementation of the requirements of this CIA (Implementation Report). The Implementation Report shall, at a minimum, include:

1. the name, address, phone number, and position description of the Compliance Officer required by Section III.A, and a summary of other noncompliance-related job responsibilities the Compliance Officer may have;

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

3. the names of the Board members who are responsible for satisfying the Board of Directors compliance obligations described in Section III.A.3;

4. a copy of HOTC’s Code of Conduct required by Section III.B.1;

5. the number of individuals required to complete the Code of Conduct certification required by Section III.B.1, the percentage of individuals who have completed such certification, and an explanation of any exceptions (the documentation supporting this information shall be available to OIG upon request);

6. a summary of all Policies and Procedures required by Section III.B (copies of the Policies and Procedures shall be made available to OIG upon request);

7. the following information regarding each type of training required by Section III.C:

   a. a description of such training, including a summary of the topics covered, the length of sessions, and a schedule of training sessions; and
b. the number of individuals required to be trained, percentage of individuals actually trained, and an explanation of any exceptions.

A copy of all training materials and the documentation supporting this information shall be made available to OIG upon request.

8. a description of the Disclosure Program required by Section III.E;

9. the following information regarding the IRO(s): (a) identity, address, and phone number; (b) a copy of the engagement letter; (c) information to demonstrate that the IRO has the qualifications outlined in Appendix A to this CIA; (d) a summary and description of any and all current and prior engagements and agreements between HOTC and the IRO; and (e) a certification from the IRO regarding its professional independence and objectivity with respect to HOTC;

10. a description of the process by which HOTC fulfills the requirements of Section III.F regarding Ineligible Persons;

11. a list of all of HOTC’s locations (including locations and mailing addresses); the corresponding name under which each location is doing business; the corresponding phone numbers and fax numbers; each location’s Medicare and state Medicaid program provider number and/or supplier number(s); and the name and address of each Medicare and state Medicaid program contractor to which HOTC currently submits claims;

12. a description of HOTC’s corporate structure, including identification of any HOTC and sister companies, subsidiaries, and their respective lines of business; and

13. the certifications required by Section V.C.
B. Annual Reports

HOTC shall submit to OIG annually a report with respect to the status of, and findings regarding, HOTC’s compliance activities for each of the five Reporting Periods (Annual Report). Each Annual Report shall include, at a minimum:

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

2. the Board resolution required by Section III.A.3;

3. a summary of any changes or amendments to HOTC’s Code of Conduct required by Section III.B.1 and the reason for such changes, along with a copy of the revised Code of Conduct;

4. the number of individuals required to complete the Code of Conduct certification required by Section III.B.1, the percentage of individuals who have completed such certification, and an explanation of any exceptions (the documentation supporting this information shall be made available to OIG upon request);

5. a summary of any significant changes or amendments to the Policies and Procedures required by Section III.B and the reasons for such changes (e.g., change in contractor policy);

6. the following information regarding each type of training required by Section III.C:

   a. a description of the initial and annual training, including a summary of the topics covered, the length of sessions, and a schedule of training sessions; and

   b. the number of individuals required to complete the initial and annual training, the percentage of individuals who actually completed the initial and annual training, and an explanation of any exceptions.
A copy of all training materials and the documentation to support this information shall be made available to OIG upon request.

7. a complete copy of all reports prepared pursuant to Section III.D, along with a copy of the IRO’s engagement letter;

8. HOTC’s response to the reports prepared pursuant to Section III.D, along with corrective action plan(s) related to any issues raised by the reports;

9. a summary and description of any and all current and prior engagements and agreements between HOTC and the IRO (if different from what was submitted as part of the Implementation Report);

10. a certification from the IRO regarding its professional independence and objectivity with respect to HOTC;

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

12. a report of the aggregate Overpayments that have been returned to the Federal health care programs. Overpayment amounts shall be broken down into the following categories: inpatient Medicare, outpatient Medicare, Medicaid (report each applicable state separately, if applicable), and other Federal health care programs. Overpayment amounts that are routinely reconciled or adjusted pursuant to policies and procedures established by the payor do not need to be included in this aggregate Overpayment report;

13. a summary of the disclosures in the disclosure log required by Section III.E that relate to Federal health care programs (the complete disclosure log shall be made available to OIG upon request);

14. any changes to the process by which HOTC fulfills the requirements of Section III.F regarding Ineligible Persons;
15. a summary describing any ongoing investigation or legal proceeding required to have been reported pursuant to Section III.G. The summary shall include a description of the allegation, the identity of the investigating or prosecuting agency, and the status of such investigation or legal proceeding;

16. a description of all changes to the most recently provided list of HOTC’s locations (including addresses) as required by Section V.A.11; the corresponding name under which each location is doing business; the corresponding phone numbers and fax numbers; each location’s Medicare and state Medicaid program provider number(s) and/or supplier number(s); and the name and address of each Medicare and state Medicaid program contractor to which HOTC currently submits claims; and

17. the certifications required by Section V.C.

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

C. Certifications

The Implementation Report and each Annual Report shall include a certification by the Compliance Officer that:

1. to the best of his or her knowledge, except as otherwise described in the report, HOTC is in compliance with all of the requirements of this CIA;

2. he or she has reviewed the report and has made reasonable inquiry regarding its content and believes that the information in the report is accurate and truthful; and

3. to the best of his or her knowledge, HOTC has complied with its obligations under the Settlement Agreement: (a) not to resubmit to any Federal health care program payors any previously denied claims related to the Covered Conduct addressed in the Settlement Agreement, and not to appeal any such denials of claims; (b) not to charge to or otherwise seek payment from federal or state payors for unallowable claims; and

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costs (as defined in the Settlement Agreement); and (c) to identify and adjust any past charges or claims for unallowable costs.

D. Designation of Information

HOTC shall clearly identify any portions of its submissions that it believes are trade secrets, or information that is commercial or financial and privileged or confidential, and therefore potentially exempt from disclosure under the Freedom of Information Act (FOIA), 5 U.S.C. § 552. HOTC shall refrain from identifying any information as exempt from disclosure if that information does not meet the criteria for exemption from disclosure under FOIA.

VI. NOTIFICATIONS AND SUBMISSION OF REPORTS

Unless otherwise stated in writing after the Effective Date, all notifications and reports required under this CIA shall be submitted to the following entities:

OIG:

Administrative and Civil Remedies Branch
Office of Counsel to the Inspector General
Office of Inspector General
U.S. Department of Health and Human Services
Cohen Building, Room 5527
330 Independence Avenue, S.W.
Washington, DC 20201
Telephone: 202.619.2078
Facsimile: 202.205.0604
HOTC:

Jeff White
Hospice of the Comforter
Chief Compliance Officer
480 W. Central Parkway
Altamonte Springs, Florida 32714

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. Upon request by OIG, HOTC may be required to provide OIG with an electronic copy of each notification or report required by this CIA in searchable portable document format (pdf), in addition to a paper copy.

VII. OIG INSPECTION, AUDIT, AND REVIEW RIGHTS

In addition to any other rights OIG may have by statute, regulation, or contract, OIG or its duly authorized representative(s) may examine or request copies of HOTC’s books, records, and other documents and supporting materials and/or conduct on-site reviews of any of HOTC’s locations for the purpose of verifying and evaluating: (a) HOTC’s compliance with the terms of this CIA; and (b) HOTC’s compliance with the requirements of the Federal health care programs. The documentation described above shall be made available by HOTC 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 HOTC’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. HOTC shall assist OIG or its duly authorized representative(s) in contacting and arranging interviews with such individuals upon OIG’s request. HOTC’s employees may elect to be interviewed with or without a representative of HOTC present.
VIII. DOCUMENT AND RECORD RETENTION

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

IX. DISCLOSURES

Consistent with HHS’s FOIA procedures, set forth in 45 C.F.R. Part 5, OIG shall make a reasonable effort to notify HOTC prior to any release by OIG of information submitted by HOTC pursuant to its obligations under this CIA and identified upon submission by HOTC as trade secrets, or information that is commercial or financial and privileged or confidential, under the FOIA rules. With respect to such releases, HOTC shall have the rights set forth at 45 C.F.R. § 5.65(d).

X. BREACH AND DEFAULT PROVISIONS

HOTC 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, HOTC and OIG hereby agree that failure to comply with certain obligations as set forth in this CIA may lead to the imposition of the following monetary penalties (hereinafter referred to as “Stipulated Penalties”) in accordance with the following provisions.

1. A Stipulated Penalty of $2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day HOTC fails to establish and implement any of the following obligations as described in Section III:
   a. a Compliance Officer;
   b. a Compliance Committee;
   c. the Board of Directors compliance obligations;
d. a written Code of Conduct;

e. written Policies and Procedures;

f. the training of Covered Persons, Relevant Covered Persons, and Board Members;

g. a Disclosure Program;

h. Ineligible Persons screening and removal requirements;

i. notification of Government investigations or legal proceedings; and

j. reporting of Reportable Events.

2. A Stipulated Penalty of $2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day HOTC fails to engage and use an IRO, as required in Section III.D, Appendix A, and Appendix B.

3. A Stipulated Penalty of $2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day HOTC fails to submit the Implementation Report or any Annual Reports to OIG in accordance with the requirements of Section V by the deadlines for submission.

4. A Stipulated Penalty of $2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day HOTC fails to submit any Eligibility Review Report or Unallowable Cost Review Report in accordance with the requirements of Section III.D and Appendix B.

5. A Stipulated Penalty of $1,500 for each day HOTC fails to grant access as required in Section VII. (This Stipulated Penalty shall begin to accrue on the date HOTC fails to grant access.)
6. A Stipulated Penalty of $5,000 for each false certification submitted by or on behalf of HOTC as part of its Implementation Report, Annual Report, additional documentation to a report (as requested by the OIG), or otherwise required by this CIA.

7. A Stipulated Penalty of $1,000 for each day HOTC fails to comply fully and adequately with any obligation of this CIA. OIG shall provide notice to HOTC stating the specific grounds for its determination that HOTC has failed to comply fully and adequately with the CIA obligation(s) at issue and steps HOTC shall take to comply with the CIA. (This Stipulated Penalty shall begin to accrue 10 days after HOTC receives this notice from OIG of the failure to comply.) A Stipulated Penalty as described in this Subsection shall not be demanded for any violation for which OIG has sought a Stipulated Penalty under Subsections 1-6 of this Section.

B. Timely Written Requests for Extensions

HOTC may, in advance of the due date, submit a timely written request for an extension of time to perform any act or file any notification or report required by this CIA. Notwithstanding any other provision in this Section, if OIG grants the timely written request with respect to an act, notification, or report, Stipulated Penalties for failure to perform the act or file the notification or report shall not begin to accrue until one day after HOTC fails to meet the revised deadline set by OIG. Notwithstanding any other provision in this Section, if OIG denies such a timely written request, Stipulated Penalties for failure to perform the act or file the notification or report shall not begin to accrue until three business days after HOTC receives OIG’s written denial of such request or the original due date, whichever is later. A “timely written request” is defined as a request in writing received by OIG at least five business days prior to the date by which any act is due to be performed or any notification or report is due to be filed.

C. Payment of Stipulated Penalties

1. Demand Letter. Upon a finding that HOTC has failed to comply with any of the obligations described in Section X.A and after determining that Stipulated Penalties are appropriate, OIG shall notify HOTC of: (a) HOTC’s failure to comply; and (b) OIG’s exercise of its contractual right to demand payment of the Stipulated Penalties. (This notification shall be referred to as the “Demand Letter.”)
2. **Response to Demand Letter.** Within 10 days after the receipt of the Demand Letter, HOTC shall either: (a) cure the breach to OIG’s satisfaction and pay the applicable Stipulated Penalties or (b) request a hearing before an HHS administrative law judge (ALJ) to dispute OIG’s determination of noncompliance, pursuant to the agreed upon provisions set forth below in Section X.E. In the event HOTC elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until HOTC cures, to OIG’s satisfaction, the alleged breach in dispute. Failure to respond to the Demand Letter in one of these two manners within the allowed time period shall be considered a material breach of this CIA and shall be grounds for exclusion under Section X.D.

3. **Form of Payment.** Payment of the Stipulated Penalties shall be made by electronic funds transfer to an account specified by OIG in the Demand Letter.

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

**D. Exclusion for Material Breach of this CIA**

1. **Definition of Material Breach.** A material breach of this CIA means:
   
   a. a repeated or flagrant violation of the obligations under this CIA, including, but not limited to, the obligations addressed in Section X.A;
   
   b. a failure by HOTC to report a Reportable Event, take corrective action, and make the appropriate refunds, as required in Section III.I;
   
   c. a failure to respond to a Demand Letter concerning the payment of Stipulated Penalties in accordance with Section X.C; or
d. a failure to engage and use an IRO in accordance with Section III.D, Appendix A, and Appendix B.

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

3. **Opportunity to Cure.** HOTC shall have 30 days from the date of receipt of the Notice of Material Breach and Intent to Exclude to demonstrate to OIG’s satisfaction that:

   a. HOTC is in compliance with the obligations of the CIA cited by OIG as being the basis for the material breach;

   b. the alleged material breach has been cured; or

   c. the alleged material breach cannot be cured within the 30 day period, but that: (i) HOTC has begun to take action to cure the material breach; (ii) HOTC is pursuing such action with due diligence; and (iii) HOTC has provided to OIG a reasonable timetable for curing the material breach.

4. **Exclusion Letter.** If, at the conclusion of the 30 day period, HOTC fails to satisfy the requirements of Section X.D.3, OIG may exclude HOTC from participation in the Federal health care programs. OIG shall notify HOTC in writing of its determination to exclude HOTC. (This letter shall be referred to as the “Exclusion Letter.”) Subject to the Dispute Resolution provisions in Section X.E, below, the exclusion shall go into effect 30 days after the date of HOTC’s receipt of the Exclusion Letter. The exclusion shall have national effect. Reinstatement to program participation is not automatic. After the end of the period of exclusion, HOTC may apply for reinstatement by submitting a written request for reinstatement in accordance with the provisions at 42 C.F.R. §§ 1001.3001-.3004.
E. Dispute Resolution

1. Review Rights. Upon OIG’s delivery to HOTC of its Demand Letter or of its Exclusion Letter, and as an agreed-upon contractual remedy for the resolution of disputes arising under this CIA, HOTC shall be afforded certain review rights comparable to the ones that are provided in 42 U.S.C. § 1320a-7(f) and 42 C.F.R. Part 1005 as if they applied to the Stipulated Penalties or exclusion sought pursuant to this CIA. Specifically, OIG’s determination to demand payment of Stipulated Penalties or to seek exclusion shall be subject to review by an HHS ALJ and, in the event of an appeal, the HHS Departmental Appeals Board (DAB), in a manner consistent with the provisions in 42 C.F.R. § 1005.2-1005.21. Notwithstanding the language in 42 C.F.R. § 1005.2(c), the request for a hearing involving Stipulated Penalties shall be made within 10 days after receipt of the Demand Letter and the request for a hearing involving exclusion shall be made within 25 days after receipt of the Exclusion Letter.

2. Stipulated Penalties Review. Notwithstanding any provision of Title 42 of the United States Code or Title 42 of the Code of Federal Regulations, the only issues in a proceeding for Stipulated Penalties under this CIA shall be: (a) whether HOTC was in full and timely compliance with the obligations of this CIA for which OIG demands payment; and (b) the period of noncompliance. HOTC shall have the burden of proving its full and timely compliance and the steps taken to cure the noncompliance, if any. OIG shall not have the right to appeal to the DAB an adverse ALJ decision related to Stipulated Penalties. If the ALJ agrees with OIG with regard to a finding of a breach of this CIA and orders HOTC to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable 20 days after the ALJ issues such a decision unless HOTC requests review of the ALJ decision by the DAB. If the ALJ decision is properly appealed to the DAB and the DAB upholds the determination of OIG, the Stipulated Penalties shall become due and payable 20 days after the DAB issues its decision.

3. Exclusion Review. Notwithstanding any provision of Title 42 of the United States Code or Title 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 HOTC 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) HOTC had begun to take action to cure the material breach within that period; (ii) HOTC has pursued and is pursuing such action with due diligence; and (iii) HOTC provided to OIG within that period a reasonable timetable for curing the material breach and HOTC has followed the timetable.

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

4. Finality of Decision. The review by an ALJ or DAB provided for above shall not be considered to be an appeal right arising under any statutes or regulations. Consequently, the parties to this CIA agree that the DAB’s decision (or the ALJ’s decision if not appealed) shall be considered final for all purposes under this CIA.

XI. EFFECTIVE AND BINDING AGREEMENT

HOTC and OIG agree as follows:

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

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Hospice of the Comforter, Inc.
B. This CIA constitutes the complete agreement between the parties and may not be amended except by written consent of the parties to this CIA.

C. OIG may agree to a suspension of HOTC’s obligations under this CIA based on a certification by HOTC that it is no longer providing health care items or services that will be billed to any Federal health care program and that it does not have any ownership or control interest, as defined in 42 U.S.C. §1320a-3, in any entity that bills any Federal health care program. If HOTC is relieved of its CIA obligations, HOTC will be required to notify OIG in writing at least 30 days in advance if HOTC plans to resume providing health care items or services that are billed to any Federal health care program or to obtain an ownership or control interest in any entity that bills any Federal health care program. At such time, OIG shall evaluate whether the CIA will be reactivated or modified.

D. The undersigned HOTC 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.

E. This CIA may be executed in counterparts, each of which constitutes an original and all of which constitute one and the same CIA. Facsimiles of signatures shall constitute acceptable, binding signatures for purposes of this CIA.
Corporate Integrity Agreement
Hospice of the Comforter, Inc.
ON BEHALF OF THE OFFICE OF INSPECTOR GENERAL
OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES

/Robert K. DeConti/ 10/24/13
__________________________
ROBERT K. DECONTI
Assistant I.G. for Legal Affairs
Office of Inspector General
U. S. Department of Health and Human Services

/Tonya Keusseyan/ 9/10/13
__________________________
TONYA KEUSSEYAN
Senior Counsel
Office of Inspector General
U.S. Department of Health and Human Services

Corporate Integrity Agreement
Hospice of the Comforter, Inc.
APPENDIX A

INDEPENDENT REVIEW ORGANIZATION

This Appendix contains the requirements relating to the Independent Review Organization (IRO) required by Section III.D of the CIA.

A. IRO Engagement

1. HOTC shall engage an IRO that possesses the qualifications set forth in Paragraph B, below, to perform the responsibilities in Paragraph C, below. The IRO shall conduct the review in a professionally independent and objective fashion, as set forth in Paragraph D. Within 30 days after OIG receives the information identified in Section V.A.8 of the CIA or any additional information submitted by HOTC in response to a request by OIG, whichever is later, OIG will notify HOTC if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, HOTC may continue to engage the IRO.

2. If HOTC engages a new IRO during the term of the CIA, this IRO shall also meet the requirements of this Appendix. If a new IRO is engaged, HOTC shall submit the information identified in Section V.A.8 of the CIA to OIG within 30 days of engagement of the IRO. Within 30 days after OIG receives this information or any additional information submitted by HOTC at the request of OIG, whichever is later, OIG will notify HOTC if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, HOTC may continue to engage the IRO.

B. IRO Qualifications

The IRO shall:

1. assign individuals to conduct the Eligibility Review and Unallowable Cost Review who have expertise in the Medicare hospice benefit, including the standards and requirements for hospice eligibility, certification, and recertification;

2. assign individuals to design and select the Eligibility Review sample who are knowledgeable about the appropriate statistical sampling techniques;
3. assign individuals to conduct the Eligibility Review who are licensed nurses or physicians with demonstrated hospice experience or expertise; and

4. have sufficient staff and resources to conduct the reviews required by the CIA on a timely basis.

C. **IRO Responsibilities**

The IRO shall:

1. perform each Eligibility Review and the Unallowable Cost review in accordance with the specific requirements of the CIA;

2. follow all applicable Medicare and applicable hospice eligibility guidance in making assessments in the Eligibility Reviews;

3. if in doubt of the application of a particular Medicare policy or regulation, request clarification from the appropriate authority (e.g., fiscal intermediary or carrier);

4. respond to all OIG inquires in a prompt, objective, and factual manner; and

5. prepare timely, clear, well-written reports that include all the information required by Appendix B to the CIA.

D. **IRO Independence and Objectivity**

The IRO must perform the Eligibility Review in a professionally independent and objective fashion, as defined in the most recent Government Auditing Standards issued by the United States Government Accountability Office.
E. IRO Removal/Termination

1. Provider and IRO. If HOTC terminates its IRO or if the IRO withdraws from the engagement during the term of the CIA, HOTC must submit a notice explaining its reasons for termination or the reason for withdrawal to OIG no later than 30 days after termination or withdrawal. HOTC must engage a new IRO in accordance with Paragraph A of this Appendix and within 60 days of termination or withdrawal of the IRO.

2. OIG Removal of IRO. In the event OIG has reason to believe the IRO does not possess the qualifications described in Paragraph B, is not independent and objective as set forth in Paragraph D, or has failed to carry out its responsibilities as described in Paragraph C, OIG may, at its sole discretion, require HOTC to engage a new IRO in accordance with Paragraph A of this Appendix. HOTC must engage a new IRO within 60 days of termination of the IRO.

Prior to requiring HOTC to engage a new IRO, OIG shall notify HOTC of its intent to do so and provide a written explanation of why OIG believes such a step is necessary. To resolve any concerns raised by OIG, HOTC may present additional information regarding the IRO’s qualifications, independence or performance of its responsibilities. OIG will attempt in good faith to resolve any differences regarding the IRO with HOTC prior to requiring HOTC to terminate the IRO. However, the final determination as to whether or not to require HOTC to engage a new IRO shall be made at the sole discretion of OIG.
APPENDIX B

ELIGIBILITY REVIEW

A. Eligibility Review. The IRO shall perform the Eligibility Review annually to cover each of the five Reporting Periods. The IRO shall perform all components of each Eligibility Review.

1. Definitions. For the purposes of the Eligibility Reviews, the following definitions shall be used:

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

   b. Population: The Population for the Admissions Review shall be defined as all Medicare beneficiaries who were admitted to HOTC in the prior calendar year. The Population for the Long Length of Stay Review shall be defined as all Medicare beneficiaries who were admitted to HOTC during the prior calendar year and who received uninterrupted services from HOTC for 270 days or more during the prior calendar year.

   c. Error Rate: The Error Rate for the Admissions Review shall be the percentage of Medicare beneficiaries in the Admissions Review determined to be ineligible for the hospice benefit. The Error Rate for the Long Length of Stay Review shall be the percentage of Medicare beneficiaries in the Long Length of Stay determined to be ineligible for the hospice benefit.

2. Eligibility Review Procedures.

   The Eligibility Review shall consist of a review of (1) the initial admission (Admission Review) and 2) the most recent recertification period for Long Length of Stay patients (Long Length of Stay Review).
a. **Admissions Review:** HOTC shall create a list of all Medicare beneficiaries who were admitted to HOTC in the prior calendar year. The IRO shall then randomly select 50 Medicare beneficiaries from this list compiled by HOTC.

b. **Long Length of Stay Review:** HOTC shall also create a list of all Medicare beneficiaries who were admitted to HOTC during the prior calendar year and received uninterrupted services from HOTC for 270 days or more during the prior calendar year. The IRO shall then randomly select 50 Medicare beneficiaries from the list compiled by HOTC.

The medical records of the Medicare beneficiaries selected for review as part of the Admissions Review and the Long Length of Stay Review shall be reviewed based on the supporting documentation available at HOTC’s office or under HOTC’s control and applicable hospice statutes, regulations and guidance to determine whether the Medicare beneficiary was eligible for the hospice benefit and whether the claim to Medicare was properly documented, submitted, and paid.

3. **Referral of Information.** OIG, in its sole discretion, may refer the findings of the Eligibility Review (and any related workpapers) received from HOTC to the appropriate Federal health care program payor, including the Medicare contractor (e.g., carrier, fiscal intermediary), for appropriate follow-up by that payor.

4. **Systems Review.** If the Error Rate for either the Admissions Review or Long Length of Stay Review is 5% or greater, the IRO shall also conduct a Systems Review. The Systems Review shall consist of (1) a review of HOTC’s systems and processes for determining and documenting a Medicare beneficiary’s eligibility for the hospice benefit, including the processes for certification and recertification of beneficiaries and (2) for each Medicare beneficiary determined to be ineligible for the hospice benefit, the IRO shall perform a detailed review of the system(s) and process(es) that resulted in HOTC’s erroneous determination that the beneficiary was eligible for the hospice benefit, to identify any problems or weaknesses that may have resulted in the identified error(s). The IRO shall provide its observations and recommendations on suggested improvements to the system(s) and the process(es) for determining eligibility for the hospice benefit.
5. Other Requirements.

a. **Supplemental Materials.** The IRO shall request all documentation and materials required for its review of the patients selected as part of the Eligibility Review and HOTC shall furnish such documentation and materials to the IRO prior to the IRO initiating its review. If the IRO accepts any supplemental documentation or materials from HOTC after the IRO has completed its initial review (Supplemental Materials), the IRO shall identify in the Eligibility Review Report the Supplemental Materials, the date the Supplemental Materials were accepted, and the relative weight the IRO gave to the Supplemental Materials in its review. In addition, the IRO shall include a narrative in the Eligibility Review Report describing the process by which the Supplemental Materials were accepted and the IRO’s reasons for accepting the Supplemental Materials.

b. **Patients Without Supporting Documentation.** For the purpose of appraising patients included in the Eligibility Review, any patient for which HOTC cannot produce documentation sufficient to support the hospice services provided to that patient shall be considered an error and the total reimbursement received by HOTC for such services shall be deemed an Overpayment. Replacement sampling for patients with missing documentation is not permitted.

c. **Use of First Samples Drawn.** For the purposes of the Admissions Review and Long Length of Stay Review discussed in this Appendix, the patients selected in each first sample shall be used (i.e., it is not permissible to generate more than one list of random samples and then select one for use with the applicable review).
6. **Repayment of Identified Overpayments.** In accordance with Section III.H.1, HOTC shall repay within 60 days any Overpayment(s) identified in the Eligibility Review, regardless of the Error Rate, to the appropriate payor and in accordance with payor refund policies. HOTC shall make available to OIG all documentation that reflects the refund of the Overpayment(s) to the payor.

B. **Eligibility Review Report.** The IRO shall prepare an Eligibility Review Report for each Eligibility Review performed. The following information shall be included in the Eligibility Review Report.

1. **Eligibility Review Methodology.**

   a. **Eligibility Review Population.** A description of the Population subject to the Eligibility Review.

   b. **Eligibility Review Objective.** A clear statement of the objective intended to be achieved by the Eligibility Review.

   c. **Source of Data.** A description of the specific documentation relied upon by the IRO when performing the Eligibility Review (e.g., medical records, physician orders, certificates of medical necessity, requisition forms, local medical review policies (including title and policy number), CMS program memoranda (including title and issuance number), Medicare carrier or intermediary manual or bulletins (including issue and date), other policies, regulations, or directives).

   d. **Review Protocol.** A narrative description of how the Eligibility Review was conducted and what was evaluated.

   e. **Supplemental Materials.** A description of any Supplemental Materials as required by A.5.a above.

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2. **Statistical Sampling Documentation.**

   a. A copy of the printout of the random numbers generated by the “Random Numbers” function of the statistical sampling software used by the IRO.

   b. A description or identification of the statistical sampling software package used to select the Sample.

3. **Eligibility Review Findings.**

   a. **Narrative Results**

      i. A description of HOTC’s hospice eligibility certification and recertification processes, including the identification, by position description, of the personnel involved.

      ii. A narrative explanation of the IRO’s findings and supporting rationale (including reasons for errors, patterns noted, concerns relating to the eligibility for hospice or appropriateness of hospice, etc.) regarding the Eligibility Review.

   b. **Quantitative Results**

      i. Total number and percentage of instances in which the IRO determined that the documentation for a Medicare beneficiary did not support that the beneficiary was eligible for the Medicare hospice benefit, regardless of the effect on the payment.

      ii. Total number and percentage of instances in which the documentation for a Medicare beneficiary did not support that the beneficiary was eligible for the Medicare hospice benefit
and in which such difference resulted in an Overpayment to HOTC.

iii. Total dollar amount of all Overpayments in the Eligibility Review.

iv. Error Rate for the Eligibility Review.

v. A spreadsheet of the Eligibility Review results that includes the following information for each Medicare beneficiary: Federal health care program billed, beneficiary health insurance claim number, date(s) of service, allowed amount reimbursed by payor, correct allowed amount (as determined by the IRO), correct allowed amount (as determined by the IRO), dollar difference between allowed amount reimbursed by payor and the correct allowed amount.

4. *Systems Review Findings*. The IRO shall prepare a Systems Review Report based on the Systems Review performed (if applicable) that shall include the IRO’s observations, findings, and recommendations regarding:

a. the strengths and weaknesses in HOTC’s systems and processes for the certification and recertification of eligibility for the Medicare hospice benefit; and

b. possible improvements to HOTC’s systems and processes for the certification and recertification of eligibility for the Medicare hospice benefit to address the specific identified problems or weaknesses.

5. *Credentials*. The names and credentials of the individuals who: (1) designed the statistical sampling procedures and the review methodology utilized for the Eligibility Review and (2) performed the Eligibility Review.
CORPORATE INTEGRITY AGREEMENT
BETWEEN THE
OFFICE OF INSPECTOR GENERAL
OF THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND
KAI HEART, INC. D/B/A KAI HEART HOME HEALTH CARE

I. PREAMBLE

Kai Heart, Inc. d/b/a Kai Heart Home Health Care (Kai Heart) 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 with the statutes, regulations, and written directives of Medicare, Medicaid, and all other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)) (Federal health care program requirements). Contemporaneously with this CIA, Kai Heart is entering into a Settlement Agreement with the United States.

II. TERM AND SCOPE OF THE CIA

A. The period of the compliance obligations assumed by Kai Heart under this CIA shall be five years from the effective date of this CIA. The “Effective Date” shall be the date on which the final signatory of this CIA executes this CIA. Each one-year period, beginning with the one-year period following the Effective Date, shall be referred to as a “Reporting Period.”

B. Sections VII, X, and XI shall expire no later than 120 days after OIG’s receipt of: (1) Kai Heart’s final annual report; or (2) any additional materials submitted by Kai Heart pursuant to OIG’s request, whichever is later.

C. The scope of this CIA shall be governed by the following definitions:

1. “Covered Persons” includes:

   a. all owners, officers, directors, and employees of Kai Heart; and
b. all contractors, subcontractors, agents, and other persons who provide patient care items or services or who perform billing or coding functions on behalf of Kai Heart, excluding vendors whose sole connection with Kai Heart is selling or otherwise providing medical supplies or equipment to Kai Heart and who do not bill the Federal health care programs for such medical supplies or equipment.

Notwithstanding the above, this term does not include part-time or per diem employees, contractors, subcontractors, agents, and other persons 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. “Relevant Covered Persons” includes Covered Persons involved in the delivery of patient care items or services and/or in the preparation or submission of claims for reimbursement from any Federal health care program.

III. CORPORATE INTEGRITY OBLIGATIONS

Kai Heart shall establish and maintain a Compliance Program that includes the following elements:

A. Compliance Officer and Committee

1. **Compliance Officer.** Within 90 days after the Effective Date, Kai Heart shall appoint a Covered Person to serve as its Compliance Officer and shall maintain a Compliance Officer for the term of the CIA. The Compliance Officer shall be responsible for developing and implementing policies, procedures, and practices designed to ensure compliance with the requirements set forth in this CIA and with Federal health care program requirements. The Compliance Officer shall be a member of senior management of Kai Heart, shall report directly to the Chief Executive Officer of Kai Heart, shall make periodic (at least quarterly) reports regarding compliance matters directly to the Board of Directors of Kai Heart, and shall be authorized to report on such matters to the Board of Directors at any time. The Compliance Officer shall not be or be subordinate to the General Counsel or Chief Financial Officer. The Compliance Officer shall be responsible for monitoring the day-to-day compliance activities engaged in by Kai Heart as well as for any reporting obligations created under this CIA. Any noncompliance job responsibilities of the Compliance Officer shall be limited and must
not interfere with the Compliance Officer’s ability to perform the duties outlined in this CIA.

Kai Heart shall report to OIG, in writing, any change in the identity of the Compliance Officer, or any actions or changes that would affect the Compliance Officer’s ability to perform the duties necessary to meet the obligations in this CIA, within five days after such a change.

2. **Compliance Committee.** Within 90 days after the Effective Date, Kai Heart shall appoint a Compliance Committee. The Compliance Committee shall, at a minimum, include the Compliance Officer and other members of senior management necessary to meet the requirements of this CIA (e.g., senior executives of relevant departments, such as billing, clinical, human resources, audit, and operations). The Compliance Officer shall chair the Compliance Committee and the Committee shall support the Compliance Officer in fulfilling his/her responsibilities (e.g., shall assist in the analysis of the Kai Heart’s risk areas and shall oversee monitoring of internal and external audits and investigations). The Compliance Committee shall meet at least quarterly.

Kai Heart shall report to OIG, in writing, any changes in the composition of the Compliance Committee, or any actions or changes that would affect the Compliance Committee’s ability to perform the duties necessary to meet the obligations in this CIA, within 15 days after such a change.

3. **Board of Directors Compliance Obligations.** The Board of Directors (Board) shall be responsible for the review and oversight of matters related to compliance with Federal health care program requirements and the obligations of this CIA.

The Board shall, at a minimum, be responsible for the following:

a. meeting at least quarterly to review and oversee Kai Heart's Compliance Program, including but not limited to the performance of the Compliance Officer and Compliance Committee; and

b. for each Reporting Period of the CIA, adopting a resolution, signed by each member of the Board summarizing its review and oversight of Kai Heart’s compliance with Federal health care program requirements and the obligations of this CIA.

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care program requirements and the obligations of this CIA.

At minimum, the resolution shall include the following language:

“The Board of Directors has made a reasonable inquiry into the operations of Kai Heart’s Compliance Program including the performance of the Compliance Officer and the Compliance Committee. Based on its inquiry and review, the Board has concluded that, to the best of its knowledge, Kai Heart has implemented an effective Compliance Program to meet Federal health care program requirements and the obligations of the CIA.”

If the Board is unable to provide such a conclusion in the resolution, the Board shall include in the resolution a written explanation of the reasons why it is unable to provide the conclusion and the steps it is taking to implement an effective Compliance Program at Kai Heart.

Kai Heart shall report to OIG, in writing, any changes in the composition of the Board, or any actions or changes that would affect the Board’s ability to perform the duties necessary to meet the obligations in this CIA, within 15 days after such a change.

B. Written Standards

1. Code of Conduct. Within 90 days after the Effective Date, Kai Heart shall develop, implement, and distribute a written Code of Conduct to all Covered Persons. Kai Heart shall make the promotion of, and adherence to, the Code of Conduct an element in evaluating the performance of all employees. The Code of Conduct shall, at a minimum, set forth:

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

   b. Kai Heart’s requirement that all of its Covered Persons shall be expected to comply with all Federal health care program requirements and with Kai Heart’s own Policies and Procedures;
c. the requirement that all of Kai Heart’s Covered Persons shall be expected to report to the Compliance Officer, or other appropriate individual designated by Kai Heart, suspected violations of any Federal health care program requirements or of Kai Heart’s own Policies and Procedures; and

d. the right of all individuals to use the Disclosure Program described in Section III.E, and Kai Heart’s commitment to nonretaliation and to maintain, as appropriate, confidentiality and anonymity with respect to such disclosures.

Within 90 days after the Effective Date, each Covered Person shall certify, in writing or in electronic form, that he or she has received, read, understood, and shall abide by Kai Heart’s Code of Conduct. New Covered Persons shall receive the Code of Conduct and shall complete the required certification within 30 days after becoming a Covered Person or within 90 days after the Effective Date, whichever is later.

Kai Heart shall periodically review the Code of Conduct to determine if revisions are appropriate and shall make any necessary revisions based on such review. Any revised Code of Conduct shall be distributed within 30 days after any revisions are finalized. Each Covered Person shall certify, in writing, that he or she has received, read, understood, and shall abide by the revised Code of Conduct within 30 days after the distribution of the revised Code of Conduct.

2. **Policies and Procedures.** Within 90 days after the Effective Date, Kai Heart shall implement written Policies and Procedures regarding the operation of its compliance program, including the compliance program requirements outlined in this CIA and Kai Heart’s compliance with Federal health care program requirements, including but not limited to:

   a. the Federal health care program requirements regarding home health services;

   b. the Federal health care program requirements regarding the accurate coding and submission of claims; and

   c. the Federal health care program requirements regarding accurate and timely patient assessments and OASIS data
collection and submission, including but not limited to 42 C.F.R. § 484.20.

Within 90 days after the Effective Date, the Policies and Procedures shall be made available to all Covered Persons. Appropriate and knowledgeable staff shall be available to explain the Policies and Procedures.

At least annually (and more frequently, if appropriate), Kai Heart shall assess and update, as necessary, the Policies and Procedures. Within 30 days after the effective date of any revisions, any such revised Policies and Procedures shall be made available to all Covered Persons.

C. Training and Education

1. General Training. Within 90 days after the Effective Date, Kai Heart shall provide at least two hours of General Training to each Covered Person. This training, at a minimum, shall explain Kai Heart’s:

   a. CIA requirements; and

   b. Compliance Program, including the Code of Conduct.

   New Covered Persons shall receive the General Training described above within 30 days after becoming a Covered Person or within 90 days after the Effective Date, whichever is later. After receiving the initial General Training described above, each Covered Person shall receive at least one hour of General Training in each subsequent Reporting Period.

2. Specific Training. Within 90 days after the Effective Date, each Relevant Covered Person shall receive at least 2 hours of Specific Training in addition to the General Training required above. This Specific Training shall include a discussion of:

   a. the Federal health care program requirements regarding home health services, including but not limited to 42 C.F.R. § 484;

   b. the Federal health care program requirements regarding medical necessity and home bound status;
c. the Federal health care program requirements regarding the accurate coding and submission of claims;

d. the Federal health care program requirements regarding accurate and timely patient assessments and OASIS data collection and submission, including but not limited to 42 C.F.R. § 484.20;

e. policies, procedures, and other requirements applicable to the documentation of medical records;

f. the personal obligation of each individual involved in the claims submission process to ensure that such claims are accurate;

g. the personal obligation of each individual involved in patient assessments and the OASIS data collection and submission process to ensure that such information is accurate;

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

i. the legal sanctions for violations of the Federal health care program requirements; and

j. examples of proper and improper claims submission practices.

New Relevant Covered Persons shall receive this training within 30 days after the beginning of their employment or becoming Relevant Covered Persons, or within 90 days after the Effective Date, whichever is later.

After receiving the initial Specific Training described in this section, each Relevant Covered Person shall receive at least two of Specific Training, in addition to the General Training, in each subsequent Reporting Period.

3. **Board Member Training.** Within 90 days after the Effective Date, Kai Heart shall provide at least two hours of training to each member of the Board of Directors, in addition to the General Training. This training shall address the
responsibilities of board members and corporate governance.

New members of the Board of Directors shall receive the Board Member Training described above within 30 days after becoming a member or within 90 days after the Effective Date, whichever is later.

4. **Certification.** Each individual who is required to attend training shall certify, in writing or in electronic form, that he or she has received the required training. The certification shall specify the type of training received and the date received. The Compliance Officer (or designee) shall retain the certifications, along with all course materials.

5. **Qualifications of Trainer.** Persons providing the training shall be knowledgeable about the subject area.

6. **Update of Training.** Kai Heart shall review the training annually, and, where appropriate, update the training to reflect changes in Federal health care program requirements, any issues discovered during internal audits or the Claims Review, and any other relevant information.

7. **Computer-based Training.** Kai Heart may provide the training required under this CIA through appropriate computer-based training approaches. If Kai Heart chooses to provide computer-based training, it shall make available appropriately qualified and knowledgeable staff or trainers to answer questions or provide additional information to the individuals receiving such training.

D. **Review Procedures**

1. **General Description**

   a. **Engagement of Independent Review Organization.** Within 90 days after the Effective Date, Kai Heart shall engage an entity (or entities), such as an accounting, auditing, or consulting firm (hereinafter “Independent Review Organization” or “IRO”), to perform the reviews listed in this Section III.D. The applicable requirements relating to the IRO are outlined in Appendix A to this CIA, which is incorporated by reference.

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

2. **Claims Review.** The IRO shall review Kai Heart’s coding, billing, and claims submission to the Federal health care programs and the reimbursement received (Claims Review) and shall prepare a Claims Review Report, as outlined in Appendix B to this CIA, which is incorporated by reference.

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

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

5. **Validation Review.** In the event OIG has reason to believe that: (a) Kai Heart’s Claims Review or Unallowable Cost Review fails to conform to the requirements of this CIA; or (b) the IRO’s findings or Claims Review or Unallowable Cost Review Report is incorrect.

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Cost Review results are inaccurate, OIG may, at its sole discretion, conduct its own review to determine whether the Claims Review or Unallowable Cost Review complied with the requirements of the CIA and/or the findings or Claims Review or Unallowable Cost Review results are inaccurate (Validation Review). Kai Heart shall pay for the reasonable cost of any such review performed by OIG or any of its designated agents. Any Validation Review of Reports submitted as part of Kai Heart’s final Annual Report shall be initiated no later than one year after Kai Heart’s final submission (as described in Section II) is received by OIG.

Prior to initiating a Validation Review, OIG shall notify Kai Heart of its intent to do so and provide a written explanation of why OIG believes such a review is necessary. To resolve any concerns raised by OIG, Kai Heart may request a meeting with OIG to: (a) discuss the results of any Claims Review or Unallowable Cost Review submissions or findings; (b) present any additional information to clarify the results of the Claims Review or Unallowable Cost Review or to correct the inaccuracy of the Claims Review or Unallowable Cost Review; and/or (c) propose alternatives to the proposed Validation Review. Kai Heart agrees to provide any additional information as may be requested by OIG under this Section III.D.5 in an expedited manner. OIG will attempt in good faith to resolve any Claims Review or Unallowable Cost Review issues with Kai Heart prior to conducting a Validation Review. However, the final determination as to whether or not to proceed with a Validation Review shall be made at the sole discretion of OIG.

6. Independence and Objectivity Certification. The IRO shall include in its report(s) to Kai Heart a certification that the IRO has (a) evaluated its professional independence and objectivity with respect to the reviews conducted under this Section III.D and (b) concluded that it is, in fact, independent and objective, in accordance with the requirements specified in Appendix A to this CIA.

E. Disclosure Program

Within 90 days after the Effective Date, Kai Heart shall establish a Disclosure Program that includes a mechanism (e.g., a toll-free compliance telephone line) to enable individuals to disclose, to the Compliance Officer or some other person who is not in the disclosing individual’s chain of command, any identified issues or questions associated with Kai Heart’s policies, conduct, practices, or procedures with respect to a Federal health care program believed by the individual to be a potential violation of criminal, civil, or administrative law. Kai Heart shall appropriately publicize the existence of the disclosure mechanism (e.g., via periodic e-mails to employees or by posting the information in prominent common areas).
The Disclosure Program shall emphasize a nonretribution, nonretaliation policy, and shall include a reporting mechanism for anonymous communications for which appropriate confidentiality shall be maintained. Upon receipt of a disclosure, the Compliance Officer (or designee) shall gather all relevant information from the disclosing individual. The Compliance Officer (or designee) shall make a preliminary, good faith inquiry into the allegations set forth in every disclosure to ensure that he or she has obtained all of the information necessary to determine whether a further review should be conducted. For any disclosure that is sufficiently specific so that it reasonably: (1) permits a determination of the appropriateness of the alleged improper practice; and (2) provides an opportunity for taking corrective action, Kai Heart shall conduct an internal review of the allegations set forth in the disclosure and ensure that proper follow-up is conducted.

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

F. Ineligible Persons

1. **Definitions.** For purposes of this CIA:

   a. an “Ineligible Person” shall include an individual or entity who:

   i. is currently excluded, debarred, suspended, or otherwise ineligible to participate in the Federal health care programs or in Federal procurement or nonprocurement programs; or

   ii. has been convicted of a criminal offense that falls within the scope of 42 U.S.C. § 1320a-7(a), but has not yet been excluded, debarred, suspended, or otherwise declared ineligible.

   b. “Exclusion Lists” include:
i. the HHS/OIG List of Excluded Individuals/Entities (available through the Internet at http://www.oig.hhs.gov); and

ii. the General Services Administration’s List of Parties Excluded from Federal Programs (available through the Internet at http://www.epls.gov).

2. Screening Requirements. Kai Heart shall ensure that all prospective and current Covered Persons are not Ineligible Persons, by implementing the following screening requirements.

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

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

   c. Kai Heart shall implement a policy requiring all Covered Persons to disclose immediately any debarment, exclusion, suspension, or other event that makes that person an Ineligible Person.

   Nothing in Section III.F affects Kai Heart’s responsibility to refrain from (and liability for) billing Federal health care programs for items or services furnished, ordered, or prescribed by excluded persons. Kai Heart understands that items or services furnished by excluded persons are not payable by Federal health care programs and that Kai Heart may be liable for overpayments and/or criminal, civil, and administrative sanctions for employing or contracting with an excluded person regardless of whether Kai Heart meets the requirements of Section III.F.

3. Removal Requirement. If Kai Heart has actual notice that a Covered Person has become an Ineligible Person, Kai Heart shall remove such Covered Person from responsibility for, or involvement with, Kai Heart’s business operations related to the Federal health care programs and shall remove such Covered Person from any...
position for which the Covered Person’s compensation or the items or services furnished, ordered, or prescribed by the Covered Person are paid in whole or part, directly or indirectly, by Federal health care programs or otherwise with Federal funds at least until such time as the Covered Person is reinstated into participation in the Federal health care programs.

4. **Pending Charges and Proposed Exclusions.** If Kai Heart has actual notice that a Covered Person is charged with a criminal offense that falls within the scope of 42 U.S.C. §§ 1320a-7(a), 1320a-7(b)(1)-(3), or is proposed for exclusion during the Covered Person’s employment or contract term, Kai Heart shall take all appropriate actions to ensure that the responsibilities of that Covered Person have not and shall not adversely affect the quality of care rendered to any beneficiary, patient, or resident, or any claims submitted to any Federal health care program.

G. **Notification of Government Investigation or Legal Proceedings**

Within 30 days after discovery, Kai Heart shall notify OIG, in writing, of any ongoing investigation or legal proceeding known to Kai Heart conducted or brought by a governmental entity or its agents involving an allegation that Kai Heart, an owner of Kai Heart, or any entity in which an owner of Kai Heart has an ownership or control interest in at any time during the term of the CIA 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. Kai Heart shall also provide written notice to OIG within 30 days after the resolution of the matter, and shall provide OIG with a description of the findings and/or results of the investigation or proceedings, if any.

H. **Repayment of Overpayments**

1. **Definition of Overpayments.** For purposes of this CIA, an “Overpayment” shall mean the amount of money Kai Heart has received in excess of the amount due and payable under any Federal health care program requirements.

2. **Repayment of Overpayments**

   a. If, at any time, Kai Heart identifies or learns of any Overpayment, Kai Heart shall repay the Overpayment to the appropriate payor (e.g., Medicare fiscal intermediary or carrier) within 60 days after identification of the
Overpayment and take remedial steps within 90 days after identification (or such additional time as may be agreed to by the payor) to correct the problem, including preventing the underlying problem and the Overpayment from recurring. If not yet quantified, within 60 days after identification, Kai Heart 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 payor shall be done in accordance with the payor’s policies.

b. Notwithstanding the above, notification and repayment of any Overpayment amount that routinely is reconciled or adjusted pursuant to policies and procedures established by the payor should be handled in accordance with such policies and procedures.

I. Reportable Events

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

   a. a substantial Overpayment;

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

   c. the employment of or contracting with a Covered Person who is an Ineligible Person as defined by Section III.F.1.a; or

   d. the filing of a bankruptcy petition by Kai Heart.

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

2. Reporting of Reportable Events. If Kai Heart determines (after a reasonable opportunity to conduct an appropriate review or investigation of the allegations) through any means that there is a Reportable Event, Kai Heart shall notify
OIG, in writing, within 30 days after making the determination that the Reportable Event exists.

3. **Reportable Events under Section III.I.1.a.** For Reportable Events under Section III.I.1.a, the report to OIG shall be made within 30 days of the identification of the Overpayment, and shall include:

   a. a description of the steps taken by Kai Heart to identify and quantify the Overpayment;

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

   c. a description of Kai Heart’s actions taken to correct the Reportable Event; and

   d. any further steps Kai Heart plans to take to address the Reportable Event and prevent it from recurring.

Within 60 days of identification of the Overpayment, Kai Heart shall provide OIG with a copy of the notification and repayment to the payor required in Section III.H.2.

4. **Reportable Events under Section III.I.1.b and c.** For Reportable Events under Section III.I.1.b and III.I.1.c, the report to OIG shall include:

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

   b. a description of Kai Heart’s actions taken to correct the Reportable Event;

   c. any further steps Kai Heart plans to take to address the Reportable Event and prevent it from recurring; and

   d. if the Reportable Event has resulted in an Overpayment, a description of the steps taken by Kai Heart to identify and quantify the Overpayment.
5.  **Reportable Events under Section III.I.1.d.** For Reportable Events under Section III.I.1.d, the report to the OIG shall include documentation of the bankruptcy filing and a description of any Federal health care program authorities implicated.

6.  **Reportable Events Involving the Stark Law.** Notwithstanding the reporting requirements outlined above, any Reportable Event that involves only a probable violation of section 1877 of the Social Security Act, 42 U.S.C. §1395nn (the Stark Law) should be submitted by Kai Heart to the Centers for Medicare & Medicaid Services (CMS) through the self-referral disclosure protocol (SRDP), with a copy to the OIG. The requirements of Section III.H.2 that require repayment to the payor of any identified Overpayment within 60 days shall not apply to any Overpayment that may result from a probable violation of only the Stark Law that is disclosed to CMS pursuant to the SRDP.

IV.  **CHANGES TO BUSINESS UNITS OR LOCATIONS**

A.  **Change or Closure of Unit or Location**

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

B.  **Purchase or Establishment of New Unit or Location**

In the event that, after the Effective Date, Kai Heart, purchases or establishes a new business unit or location related to the furnishing of items or services that may be reimbursed by Federal health care programs, Kai Heart shall notify OIG at least 30 days prior to such purchase or the operation of the new business unit or location. This notification shall include the address of the new business unit or location, phone number, fax number, the location’s Medicare and state Medicaid program provider number and/or supplier number(s); and the name and address of each Medicare and state Medicaid program contractor to which Kai Heart currently submits claims. Each new business unit or location and all Covered Persons at each new business unit or location shall be subject to the applicable requirements of this CIA.
C. **Sale of Unit or Location**

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

V. **IMPLEMENTATION AND ANNUAL REPORTS**

A. **Implementation Report**

Within 120 days after the Effective Date, Kai Heart shall submit a written report to OIG summarizing the status of its implementation of the requirements of this CIA (Implementation Report). The Implementation Report shall, at a minimum, include:

1. the name, address, phone number, and position description of the Compliance Officer required by Section III.A, and a summary of other noncompliance job responsibilities the Compliance Officer may have;

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

3. a copy of Kai Heart’s Code of Conduct required by Section III.B.1;

4. the number of individuals required to complete the Code of Conduct certification required by Section III.B.1, the percentage of individuals who have completed such certification, and an explanation of any exceptions (the documentation supporting this information shall be available to OIG upon request);

5. a summary of all Policies and Procedures required by Section III.B (copies of the Policies and Procedures shall be made available to OIG upon request);

6. the following information regarding each type of training required by Section III.C:
a. a description of such training, including a summary of the topics covered, the length of sessions, and a schedule of training sessions;

b. the number of individuals required to be trained, percentage of individuals actually trained, and an explanation of any exceptions.

A copy of all training materials and the documentation supporting this information shall be made available to OIG upon request.

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

8. the following information regarding the IRO(s): (a) identity, address, and phone number; (b) a copy of the engagement letter; (c) information to demonstrate that the IRO has the qualifications outlined in Appendix A to this CIA; (d) a summary and description of any and all current and prior engagements and agreements between Kai Heart and the IRO; and (e) a certification from the IRO regarding its professional independence and objectivity with respect to Kai Heart;

9. a description of the process by which Kai Heart fulfills the requirements of Section III.F regarding Ineligible Persons;

10. a list of all of Kai Heart’s locations (including locations and mailing addresses); the corresponding name under which each location is doing business; the corresponding phone numbers and fax numbers; each location’s Medicare and state Medicaid program provider number and/or supplier number(s); and the name and address of each Medicare and state Medicaid program contractor to which Kai Heart currently submits claims;

11. a description of Kai Heart’s corporate structure, including identification of any and all individual owners, any parent and sister companies, subsidiaries, and their respective lines of business; and

12. the certifications required by Section V.C.
B. **Annual Reports**

Kai Heart shall submit to OIG annually a report with respect to the status of, and findings regarding, Kai Heart’s compliance activities for each of the five Reporting Periods (Annual Report). Each Annual Report shall include, at a minimum:

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

2. the Board resolution required by Section III.A.3;

3. a summary of any changes or amendments to Kai Heart’s Code of Conduct required by Section III.B.1 and the reason for such changes, along with a copy of the revised Code of Conduct;

4. the number of individuals required to complete the Code of Conduct certification required by Section III.B.1, the percentage of individuals who have completed such certification, and an explanation of any exceptions (the documentation supporting this information shall be made available to OIG upon request);

5. a summary of any significant changes or amendments to the Policies and Procedures required by Section III.B and the reasons for such changes (e.g., change in contractor policy);

6. the following information regarding each type of training required by Section III.C:

   a. a description of the initial and annual training, including a summary of the topics covered, the length of sessions, and a schedule of training sessions;

   b. the number of individuals required to complete the initial and annual training, the percentage of individuals who actually completed the initial and annual training, and an explanation of any exceptions.

A copy of all training materials and the documentation to support this information shall be made available to OIG upon request.

**Corporate Integrity Agreement**  
**Kai Heart, Inc. d/b/a Kai Heart Home Health Care**
7. a complete copy of all reports prepared pursuant to Section III.D, along with a copy of the IRO’s engagement letter;

8. Kai Heart’s response to the reports prepared pursuant to Section III.D, along with corrective action plan(s) related to any issues raised by the reports;

9. a summary and description of any and all current and prior engagements and agreements between Kai Heart and the IRO (if different from what was submitted as part of the Implementation Report);

10. a certification from the IRO regarding its professional independence and objectivity with respect to Kai Heart;

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

12. a report of the aggregate Overpayments that have been returned to the Federal health care programs. Overpayment amounts shall be broken down into the following categories: inpatient Medicare, outpatient Medicare, Medicaid (report each applicable state separately, if applicable), and other Federal health care programs. Overpayment amounts that are routinely reconciled or adjusted pursuant to policies and procedures established by the payor do not need to be included in this aggregate Overpayment report;

13. a summary of the disclosures in the disclosure log required by Section III.E that relate to Federal health care programs (the complete disclosure log shall be made available to OIG upon request);

14. any changes to the process by which Kai Heart fulfills the requirements of Section III.F regarding Ineligible Persons;

15. a summary describing any ongoing investigation or legal proceeding required to have been reported pursuant to Section III.G. The summary shall include a description of the allegation, the identity of the investigating or prosecuting agency, and the status of such investigation or legal proceeding;
16. a description of all changes to the most recently provided list of Kai Heart’s locations (including addresses) as required by Section V.A.10; the corresponding name under which each location is doing business; the corresponding phone numbers and fax numbers; each location’s Medicare and state Medicaid program provider number(s) and/or supplier number(s); and the name and address of each Medicare and state Medicaid program contractor to which Kai Heart currently submits claims; and

17. the certifications required by Section V.C.

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

C. Certifications

The Implementation Report and each Annual Report shall include a certification by the Compliance Officer that:

1. to the best of his or her knowledge, except as otherwise described in the report, Kai Heart is in compliance with all of the requirements of this CIA;

2. he or she has reviewed the report and has made reasonable inquiry regarding its content and believes that the information in the report is accurate and truthful; and

3. to the best of his or her knowledge, Kai Heart has complied with its obligations under the Settlement Agreement: (a) not to resubmit to any Federal health care program payors any previously denied claims related to the Covered Conduct addressed in the Settlement Agreement, and not to appeal any such denials of claims; (b) not to charge to or otherwise seek payment from federal or state payors for unallowable costs (as defined in the Settlement Agreement); and (c) to identify and adjust any past charges or claims for unallowable costs.

D. Designation of Information

Kai Heart shall clearly identify any portions of its submissions that it believes are trade secrets, or information that is commercial or financial and privileged or confidential, and therefore potentially exempt from disclosure under the Freedom of Information Act (FOIA), 5 U.S.C. § 552. Kai Heart shall refrain from identifying any
information as exempt from disclosure if that information does not meet the criteria for exemption from disclosure under FOIA.

VI. NOTIFICATIONS AND SUBMISSION OF REPORTS

Unless otherwise stated in writing after the Effective Date, all notifications and reports required under this CIA shall be submitted to the following entities:

OIG:
Administrative and Civil Remedies Branch
Office of Counsel to the Inspector General
Office of Inspector General
U.S. Department of Health and Human Services
Cohen Building, Room 5527
330 Independence Avenue, S.W.
Washington, DC 20201
Telephone: 202.619.2078
Facsimile: 202.205.0604

Kai Heart:
Gloria Thompson
1720 Regal Row, Suite 235
Dallas, TX 75235
Telephone: 214.689.982
Facsimile: 214.689.8695

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. Upon request by OIG, Kai Heart may be required to provide OIG with an electronic copy of each notification or report required by this CIA in searchable portable document format (pdf), in addition to a paper copy.

VII. OIG INSPECTION, AUDIT, AND REVIEW RIGHTS

In addition to any other rights OIG may have by statute, regulation, or contract, OIG or its duly authorized representative(s) may examine or request copies of Kai Heart’s books, records, and other documents and supporting materials and/or conduct on-
site reviews of any of Kai Heart’s locations for the purpose of verifying and evaluating: (a) Kai Heart’s compliance with the terms of this CIA; and (b) Kai Heart’s compliance with the requirements of the Federal health care programs. The documentation described above shall be made available by Kai Heart 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 Kai Heart’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. Kai Heart shall assist OIG or its duly authorized representative(s) in contacting and arranging interviews with such individuals upon OIG’s request. Kai Heart’s employees may elect to be interviewed with or without a representative of Kai Heart present.

VIII. DOCUMENT AND RECORD RETENTION

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

IX. DISCLOSURES

Consistent with HHS’s FOIA procedures, set forth in 45 C.F.R. Part 5, OIG shall make a reasonable effort to notify Kai Heart prior to any release by OIG of information submitted by Kai Heart pursuant to its obligations under this CIA and identified upon submission by Kai Heart as trade secrets, or information that is commercial or financial and privileged or confidential, under the FOIA rules. With respect to such releases, Kai Heart shall have the rights set forth at 45 C.F.R. § 5.65(d).

X. BREACH AND DEFAULT PROVISIONS

Kai Heart 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, Kai Heart and OIG hereby agree that failure to comply with certain obligations as set forth in this CIA may lead to the imposition of the following monetary penalties (hereinafter referred to as “Stipulated Penalties”) in accordance with the following provisions.
1. A Stipulated Penalty of $2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day Kai Heart fails to establish and implement any of the following obligations as described in Section III:

   a. a Compliance Officer;
   
   b. a Compliance Committee;
   
   c. the Board of Directors compliance obligations;
   
   d. a written Code of Conduct;
   
   e. written Policies and Procedures;
   
   f. the training of Covered Persons, Relevant Covered Persons, and Board Members;
   
   g. a Disclosure Program;
   
   h. Ineligible Persons screening and removal requirements;
   
   i. notification of Government investigations or legal proceedings; and
   
   j. reporting of Reportable Events.

2. A Stipulated Penalty of $2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day Kai Heart fails to engage and use an IRO, as required in Section III.D, Appendix A, and Appendix B.

3. A Stipulated Penalty of $2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day Kai Heart fails to submit the Implementation Report or any Annual Reports to OIG in accordance with the requirements of Section V by the deadlines for submission.

4. A Stipulated Penalty of $2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day Kai Heart fails to submit any Claims Review Report or Unallowable Cost Review Report in accordance with the requirements of Section III.D and Appendix B.
5. A Stipulated Penalty of $1,500 for each day Kai Heart fails to grant access as required in Section VII. (This Stipulated Penalty shall begin to accrue on the date Kai Heart fails to grant access.)

6. A Stipulated Penalty of $5,000 for each false certification submitted by or on behalf of Kai Heart as part of its Implementation Report, Annual Report, additional documentation to a report (as requested by the OIG), or otherwise required by this CIA.

7. A Stipulated Penalty of $1,000 for each day Kai Heart fails to comply fully and adequately with any obligation of this CIA. OIG shall provide notice to Kai Heart stating the specific grounds for its determination that Kai Heart has failed to comply fully and adequately with the CIA obligation(s) at issue and steps Kai Heart shall take to comply with the CIA. (This Stipulated Penalty shall begin to accrue 10 days after Kai Heart receives this notice from OIG of the failure to comply.) A Stipulated Penalty as described in this Subsection shall not be demanded for any violation for which OIG has sought a Stipulated Penalty under Subsections 1-6 of this Section.

B. Timely Written Requests for Extensions

Kai Heart may, in advance of the due date, submit a timely written request for an extension of time to perform any act or file any notification or report required by this CIA. Notwithstanding any other provision in this Section, if OIG grants the timely written request with respect to an act, notification, or report, Stipulated Penalties for failure to perform the act or file the notification or report shall not begin to accrue until one day after Kai Heart fails to meet the revised deadline set by OIG. Notwithstanding any other provision in this Section, if OIG denies such a timely written request, Stipulated Penalties for failure to perform the act or file the notification or report shall not begin to accrue until three business days after Kai Heart receives OIG’s written denial of such request or the original due date, whichever is later. A “timely written request” is defined as a request in writing received by OIG at least five business days prior to the date by which any act is due to be performed or any notification or report is due to be filed.

C. Payment of Stipulated Penalties

1. Demand Letter. Upon a finding that Kai Heart has failed to comply with any of the obligations described in Section X.A and after determining that Stipulated
Penalties are appropriate, OIG shall notify Kai Heart of: (a) Kai Heart’s failure to comply; and (b) OIG’s exercise of its contractual right to demand payment of the Stipulated Penalties. (This notification shall be referred to as the “Demand Letter.”)

2. **Response to Demand Letter.** Within 10 days after the receipt of the Demand Letter, Kai Heart shall either: (a) cure the breach to OIG’s satisfaction and pay the applicable Stipulated Penalties or (b) request a hearing before an HHS administrative law judge (ALJ) to dispute OIG’s determination of noncompliance, pursuant to the agreed upon provisions set forth below in Section X.E. In the event Kai Heart elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until Kai Heart cures, to OIG’s satisfaction, the alleged breach in dispute. Failure to respond to the Demand Letter in one of these two manners within the allowed time period shall be considered a material breach of this CIA and shall be grounds for exclusion under Section X.D.

3. **Form of Payment.** Payment of the Stipulated Penalties shall be made by electronic funds transfer to an account specified by OIG in the Demand Letter.

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

D. **Exclusion for Material Breach of this CIA**

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

   a. a repeated or flagrant violation of the obligations under this CIA, including, but not limited to, the obligations addressed in Section X.A;

   b. a failure by Kai Heart to report a Reportable Event, take corrective action, and make the appropriate refunds, as required in Section III.I;
c. a failure to respond to a Demand Letter concerning the payment of Stipulated Penalties in accordance with Section X.C; or

d. a failure to engage and use an IRO in accordance with Section III.D, Appendix A, and Appendix B.

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

3. **Opportunity to Cure.** Kai Heart shall have 30 days from the date of receipt of the Notice of Material Breach and Intent to Exclude to demonstrate to OIG’s satisfaction that:

a. Kai Heart is in compliance with the obligations of the CIA cited by OIG as being the basis for the material breach;

b. the alleged material breach has been cured; or

c. the alleged material breach cannot be cured within the 30 day period, but that: (i) Kai Heart has begun to take action to cure the material breach; (ii) Kai Heart is pursuing such action with due diligence; and (iii) Kai Heart has provided to OIG a reasonable timetable for curing the material breach.

4. **Exclusion Letter.** If, at the conclusion of the 30 day period, Kai Heart fails to satisfy the requirements of Section X.D.3, OIG may exclude Kai Heart from participation in the Federal health care programs. OIG shall notify Kai Heart in writing of its determination to exclude Kai Heart. (This letter shall be referred to as the “Exclusion Letter.”) Subject to the Dispute Resolution provisions in Section X.E, below, the exclusion shall go into effect 30 days after the date of Kai Heart’s receipt of the Exclusion Letter. The exclusion shall have national effect. Reinstatement to program participation is not automatic. After the end of the period of exclusion, Kai Heart may
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apply for reinstatement by submitting a written request for reinstatement in accordance with the provisions at 42 C.F.R. §§ 1001.3001-.3004.

E. Dispute Resolution

1. Review Rights. Upon OIG’s delivery to Kai Heart of its Demand Letter or of its Exclusion Letter, and as an agreed-upon contractual remedy for the resolution of disputes arising under this CIA, Kai Heart shall be afforded certain review rights comparable to the ones that are provided in 42 U.S.C. § 1320a-7(f) and 42 C.F.R. Part 1005 as if they applied to the Stipulated Penalties or exclusion sought pursuant to this CIA. Specifically, OIG’s determination to demand payment of Stipulated Penalties or to seek exclusion shall be subject to review by an HHS ALJ and, in the event of an appeal, the HHS Departmental Appeals Board (DAB), in a manner consistent with the provisions in 42 C.F.R. § 1005.2-1005.21. Notwithstanding the language in 42 C.F.R. § 1005.2(c), the request for a hearing involving Stipulated Penalties shall be made within 10 days after receipt of the Demand Letter and the request for a hearing involving exclusion shall be made within 25 days after receipt of the Exclusion Letter.

2. Stipulated Penalties Review. Notwithstanding any provision of Title 42 of the United States Code or Title 42 of the Code of Federal Regulations, the only issues in a proceeding for Stipulated Penalties under this CIA shall be: (a) whether Kai Heart was in full and timely compliance with the obligations of this CIA for which OIG demands payment; and (b) the period of noncompliance. Kai Heart shall have the burden of proving its full and timely compliance and the steps taken to cure the noncompliance, if any. OIG shall not have the right to appeal to the DAB an adverse ALJ decision related to Stipulated Penalties. If the ALJ agrees with OIG with regard to a finding of a breach of this CIA and orders Kai Heart to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable 20 days after the ALJ issues such a decision unless Kai Heart requests review of the ALJ decision by the DAB. If the ALJ decision is properly appealed to the DAB and the DAB upholds the determination of OIG, the Stipulated Penalties shall become due and payable 20 days after the DAB issues its decision.

3. Exclusion Review. Notwithstanding any provision of Title 42 of the United States Code or Title 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 Kai Heart 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) Kai Heart had begun to take action to cure the material breach within that period; (ii) Kai Heart has pursued and is pursuing such action with due diligence; and (iii) Kai Heart provided to OIG within that period a reasonable timetable for curing the material breach and Kai Heart has followed the timetable.

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

4. Finality of Decision. The review by an ALJ or DAB provided for above shall not be considered to be an appeal right arising under any statutes or regulations. Consequently, the parties to this CIA agree that the DAB’s decision (or the ALJ’s decision if not appealed) shall be considered final for all purposes under this CIA.

XI. EFFECTIVE AND BINDING AGREEMENT

Kai Heart and OIG agree as follows:

A. This CIA shall be binding on the successors, assigns, and transferees of Kai Heart.

B. This CIA shall become final and binding on the date the final signature is obtained on the CIA.
C. This CIA constitutes the complete agreement between the parties and may not be amended except by written consent of the parties to this CIA.

D. OIG may agree to a suspension of Kai Heart’s obligations under this CIA based on a certification by Kai Heart that it is no longer providing health care items or services that will be billed to any Federal health care program and that neither it nor any owner of Kai Heart has any ownership or control interest, as defined in 42 U.S.C. §1320a-3, in any entity that bills any Federal health care program. If Kai Heart is relieved of its CIA obligations, Kai Heart will be required to notify OIG in writing at least 30 days in advance if Kai Heart or any owner of Kai Heart plans to resume providing health care items or services that are billed to any Federal health care program or to obtain an ownership or control interest in any entity that bills any Federal health care program. At such time, OIG shall evaluate whether the CIA will be reactivated or modified.

E. The undersigned Kai Heart 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.

F. This CIA may be executed in counterparts, each of which constitutes an original and all of which constitute one and the same CIA. Facsimiles of signatures shall constitute acceptable, binding signatures for purposes of this CIA.
ON BEHALF OF KAI HEART

/Gloria Thompson/

___________________________________________
Gloria Thompson, Owner, Director, President
Chief Executive Officer

/McDonald Dan Awuku/

___________________________________________
McDonald Dan Awuku, Owner, Director, Secretary

/Hsi-Ling Yu/

___________________________________________
Hsi-Ling Yu, Owner, Director, Vice President
Chief Operating Officer

DATE

11/02/2012

DATE

11-2-12

DATE

11-2-2012
ON BEHALF OF THE OFFICE OF INSPECTOR GENERAL
OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES

/Robert K. DeConti/ 11/5/12
__________________________  
ROBERT K. DECONTI  
Assistant Inspector General for Legal Affairs  
Office of Inspector General  
U. S. Department of Health and Human Services

/Ellen E. Slavin/ 11/2/12
__________________________  
ELLEN E. SLAVIN  
Senior Counsel  
Office of Inspector General  
U. S. Department of Health and Human Services

Corporate Integrity Agreement  
Kai Heart, Inc. d/b/a Kai Heart Home Health Care
APPENDIX A

INDEPENDENT REVIEW ORGANIZATION

This Appendix contains the requirements relating to the Independent Review Organization (IRO) required by Section III.D of the CIA.

A. IRO Engagement

1. Kai Heart shall engage an IRO that possesses the qualifications set forth in Paragraph B, below, to perform the responsibilities in Paragraph C, below. The IRO shall conduct the review in a professionally independent and objective fashion, as set forth in Paragraph D. Within 30 days after OIG receives the information identified in Section V.A.8 of the CIA or any additional information submitted by Kai Heart in response to a request by OIG, whichever is later, OIG will notify Kai Heart if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, Kai Heart may continue to engage the IRO.

2. If Kai Heart engages a new IRO during the term of the CIA, this IRO shall also meet the requirements of this Appendix. If a new IRO is engaged, Kai Heart shall submit the information identified in Section V.A.8 of the CIA to OIG within 30 days of engagement of the IRO. Within 30 days after OIG receives this information or any additional information submitted by Kai Heart at the request of OIG, whichever is later, OIG will notify Kai Heart if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, Kai Heart may continue to engage the IRO.

B. IRO Qualifications

The IRO shall:

1. assign individuals to conduct the Claims Review, and Unallowable Cost Review, if applicable, who have expertise in the documentation requirements for home bound status and medical necessity, billing, coding, reporting, and other requirements of home health care and in the general requirements of the Federal health care program(s) from which Kai Heart seeks reimbursement;

2. assign individuals to design and select the Claims Review sample who are knowledgeable about the appropriate statistical sampling techniques;

3. assign individuals to conduct the Claims Review portion of the IRO Review who have relevant clinical credentials and expertise in the documentation requirements for verification of OASIS accuracy, homebound status, and medical
necessity and who have maintained these clinical credentials (e.g., completed applicable continuing education requirements); and

4. have sufficient staff and resources to conduct the reviews required by the CIA on a timely basis.

C. IRO Responsibilities

The IRO shall:

1. perform each Claims Review and Unallowable Cost review, if applicable in accordance with the specific requirements of the CIA;

2. follow all applicable Medicare and Medicaid rules and reimbursement guidelines in making assessments in the Claims Review;

3. if in doubt of the application of a particular Medicare or Medicaid policy or regulation, request clarification from the appropriate authority (e.g., fiscal intermediary or carrier);

4. respond to all OIG inquires in a prompt, objective, and factual manner; and

5. prepare timely, clear, well-written reports that include all the information required by Appendix B to the CIA.

D. IRO Independence and Objectivity

The IRO must perform the Claims Review in a professionally independent and objective fashion, as defined in the most recent Government Auditing Standards issued by the United States Government Accountability Office.

E. IRO Removal/Termination

1. Provider and IRO. If Kai Heart terminates its IRO or if the IRO withdraws from the engagement during the term of the CIA, Kai Heart must submit a notice explaining its reasons for termination or the reason for withdrawal to OIG no later than 30 days after termination or withdrawal. Kai Heart must engage a new IRO in accordance with Paragraph A of this Appendix and within 60 days of termination or withdrawal of the IRO.

2. OIG Removal of IRO. In the event OIG has reason to believe the IRO does not possess the qualifications described in Paragraph B, is not independent and
objective as set forth in Paragraph D, or has failed to carry out its responsibilities as described in Paragraph C, OIG may, at its sole discretion, require Kai Heart to engage a new IRO in accordance with Paragraph A of this Appendix. Kai Heart must engage a new IRO within 60 days of termination of the IRO.

Prior to requiring Kai Heart to engage a new IRO, OIG shall notify Kai Heart of its intent to do so and provide a written explanation of why OIG believes such a step is necessary. To resolve any concerns raised by OIG, Kai Heart may present additional information regarding the IRO’s qualifications, independence or performance of its responsibilities. OIG will attempt in good faith to resolve any differences regarding the IRO with Kai Heart prior to requiring Kai Heart to terminate the IRO. However, the final determination as to whether or not to require Kai Heart to engage a new IRO shall be made at the sole discretion of OIG.
APPENDIX B

CLAIMS REVIEW

A. Claims Review. The IRO shall perform the Claims Review annually to cover each of the five Reporting Periods. The IRO shall perform all components of each Claims Review.

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

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

b. **Paid Claim**: A claim submitted by Kai Heart and for which Kai Heart has received reimbursement from the Medicare program.

c. **Population**: The Population shall be defined as all Paid Claims during the 12-month period covered by the Claims Review.

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

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

2. **Discovery Sample**. The IRO shall randomly select and review a sample of 50 Paid Claims (Discovery Sample). The Paid Claims shall be reviewed based on the supporting documentation available at Kai Heart’s office or under Kai Heart’s control and applicable billing and coding regulations and guidance to determine whether the claim was correctly coded, submitted, and reimbursed.
If the Error Rate (as defined above) for the Discovery Sample is less than 5%, no additional sampling is required, nor is the Systems Review required. (Note: The guidelines listed above do not imply that this is an acceptable error rate. Accordingly, Kai Heart should, as appropriate, further analyze any errors identified in the Discovery Sample. Kai Heart recognizes that OIG or other HHS component, in its discretion and as authorized by statute, regulation, or other appropriate authority may also analyze or review Paid Claims included, or errors identified, in the Discovery Sample or any other segment of the universe.)

3. **Full Sample.** If the Discovery Sample indicates that the Error Rate is 5% or greater, the IRO shall select an additional sample of Paid Claims (Full Sample) using commonly accepted sampling methods. The Full Sample shall be designed to: (1) estimate the actual Overpayment in the population with a 90% confidence level and with a maximum relative precision of 25% of the point estimate; and (2) conform with the Centers for Medicare and Medicaid Services’ statistical sampling for overpayment estimation guidelines. The Paid Claims selected for the Full Sample shall be reviewed based on supporting documentation available at Kai Heart or under Kai Heart’s control and applicable billing and coding regulations and guidance to determine whether the claim was correctly coded, submitted, and reimbursed. For purposes of calculating the size of the Full Sample, the Discovery Sample may serve as the probe sample, if statistically appropriate. Additionally, the IRO may use the Paid Claims sampled as part of the Discovery Sample, and the corresponding findings for those Paid Claims, as part of its Full Sample, if: (1) statistically appropriate and (2) the IRO selects the Full Sample Paid Claims using the seed number generated by the Discovery Sample. OIG, in its sole discretion, may refer the findings of the Full Sample (and any related workpapers) received from Kai Heart to the appropriate Federal health care program payor, including the Medicare contractor (e.g., carrier, fiscal intermediary, or DMERC), for appropriate follow-up by that payor.

4. **Systems Review.** If Kai Heart’s Discovery Sample identifies an Error Rate of 5% or greater, Kai Heart’s IRO shall also conduct a Systems Review. The Systems Review shall consist of the following:

   a. a review of Kai Heart’s billing and coding systems and processes relating to claims submitted to Federal health care programs (including, but not limited to, the operation of the billing system, the process by which claims are coded, safeguards to ensure OASIS accuracy, proper coding, claims submission and billing; and procedures to identify and correct inaccurate coding and billing);

   b. for each claim in the Discovery Sample and Full Sample that resulted in an Overpayment, the IRO shall review the
system(s) and process(es) that generated the claim and identify any problems or weaknesses that may have resulted in the identified Overpayments. The IRO shall provide its observations and recommendations on suggested improvements to the system(s) and the process(es) that generated the claim.

5. **Other Requirements**

a. **Supplemental Materials.** The IRO shall request all documentation and materials required for its review of the Paid Claims selected as part of the Discovery Sample or Full Sample (if applicable), and Kai Heart shall furnish such documentation and materials to the IRO prior to the IRO initiating its review of the Discovery Sample or Full Sample (if applicable). If the IRO accepts any supplemental documentation or materials from Kai Heart after the IRO has completed its initial review of the Discovery Sample or Full Sample (if applicable) (Supplemental Materials), the IRO shall identify in the Claims Review Report the Supplemental Materials, the date the Supplemental Materials were accepted, and the relative weight the IRO gave to the Supplemental Materials in its review. In addition, the IRO shall include a narrative in the Claims Review Report describing the process by which the Supplemental Materials were accepted and the IRO’s reasons for accepting the Supplemental Materials.

b. **Paid Claims without Supporting Documentation.** Any Paid Claim for which Kai Heart cannot produce documentation sufficient to support the Paid Claim shall be considered an error and the total reimbursement received by Kai Heart for such Paid Claim shall be deemed an Overpayment. Replacement sampling for Paid Claims with missing documentation is not permitted.

c. **Use of First Samples Drawn.** For the purposes of all samples (Discovery Sample(s) and Full Sample(s)) discussed in this Appendix, the Paid Claims selected in each first sample shall be used (i.e., it is not permissible to generate more than one list of random samples and then select one for use with the Discovery Sample or Full Sample).
6. **Repayment of Identified Overpayments.** Kai Heart shall repay within 30 days any Overpayment(s) identified in the Discovery Sample or the Full Sample (if applicable), regardless of the Error Rate, to the appropriate payor and in accordance with payor refund policies. Kai Heart shall make available to OIG all documentation that reflects the refund of the Overpayment(s) to the payor.

B. **Claims Review Report.** The IRO shall prepare a Claims Review Report as described in this Appendix for each Claims Review performed. The following information shall be included in the Claims Review Report for each Discovery Sample and Full Sample (if applicable).

1. **Claims Review Methodology**
   
   a. **Claims Review Population.** A description of the Population subject to the Claims Review.
   
   b. **Claims Review Objective.** A clear statement of the objective intended to be achieved by the Claims Review.
   
   c. **Source of Data.** A description of the specific documentation relied upon by the IRO when performing the Claims Review (e.g., medical records, physician orders, certificates of medical necessity, OASIS data, requisition forms, local medical review policies (including title and policy number), CMS program memoranda (including title and issuance number), Medicare carrier or intermediary manual or bulletins (including issue and date), other policies, regulations, or directives).
   
   d. **Review Protocol.** A narrative description of how the Claims Review was conducted and what was evaluated.
   
   e. **Supplemental Materials.** A description of any Supplemental Materials as required by A.5.a., above.

2. **Statistical Sampling Documentation**
   
   a. A copy of the printout of the random numbers generated by the “Random Numbers” function of the statistical sampling software used by the IRO.
b. A copy of the statistical software printout(s) estimating how many Paid Claims are to be included in the Full Sample, if applicable.

c. A description or identification of the statistical sampling software package used to select the sample and determine the Full Sample size, if applicable.

3. Claims Review Findings

a. Narrative Results

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

ii. A narrative explanation of the IRO’s findings and supporting rationale (including reasons for errors, patterns noted, etc.) regarding the Claims Review, including the results of the Discovery Sample, and the results of the Full Sample (if any).

b. Quantitative Results

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

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

iii. Total dollar amount of all Overpayments in the sample.

iv. Total dollar amount of Paid Claims included in the sample and the net Overpayment associated with the sample.

v. Error Rate in the sample.
vi. A spreadsheet of the Claims Review results that includes the following information for each Paid Claim: Federal health care program billed, beneficiary health insurance claim number, date of service, code submitted (e.g., DRG, CPT code, etc.), code reimbursed, allowed amount reimbursed by payor, correct code (as determined by the IRO), correct allowed amount (as determined by the IRO), dollar difference between allowed amount reimbursed by payor and the correct allowed amount.

c. Recommendations. The IRO’s report shall include any recommendations for improvements to Kai Heart’s billing and coding system based on the findings of the Claims Review.

4. **Systems Review Findings.** The IRO shall prepare a Systems Review Report based on the Systems Review performed (if applicable) that shall include the IRO’s observations, findings, and recommendations regarding:

   a. the strengths and weaknesses in Kai Heart’s billing systems and processes;

   b. the strengths and weaknesses in Kai Heart’s coding systems and processes;

   c. the strengths and weaknesses in Kai Heart’s OASIS data collection systems and processes; and

   d. possible improvements to Kai Heart’s billing and coding systems and processes to address the specific problems or weaknesses that resulted in the identified Overpayments.

5. **Credentials.** The names and credentials of the individuals who: (1) designed the statistical sampling procedures and the review methodology utilized for the Claims Review and (2) performed the Claims Review.
Jimmo v. Sebelius Settlement Agreement
Fact Sheet

Overview:
On January 24, 2013, the U. S. District Court for the District of Vermont approved a settlement agreement in the case of Jimmo v. Sebelius, in which the plaintiffs alleged that Medicare contractors were inappropriately applying an “Improvement Standard” in making claims determinations for Medicare coverage involving skilled care (e.g., the skilled nursing facility (SNF), home health (HH), and outpatient therapy (OPT) benefits). The settlement agreement sets forth a series of specific steps for the Centers for Medicare & Medicaid Services (CMS) to undertake, including issuing clarifications to existing program guidance and new educational material on this subject. The goal of this settlement agreement is to ensure that claims are correctly adjudicated in accordance with existing Medicare policy, so that Medicare beneficiaries receive the full coverage to which they are entitled.

Background:
In the case of Jimmo v. Sebelius, the Center for Medicare Advocacy (CMA) alleged that Medicare claims involving skilled care were being inappropriately denied by contractors based on a rule-of-thumb “Improvement Standard”—under which a claim would be summarily denied due to a beneficiary’s lack of restoration potential, even though the beneficiary did in fact require a covered level of skilled care in order to prevent or slow further deterioration in his or her clinical condition. In the Jimmo lawsuit, CMS denied establishing an improper rule-of-thumb “Improvement Standard.” The Court never ruled on the validity of the Jimmo plaintiffs’ allegations.

While an expectation of improvement would be a reasonable criterion to consider when evaluating, for example, a claim in which the goal of treatment is restoring a prior capability, Medicare policy has long recognized that there may also be specific instances where no improvement is expected but skilled care is, nevertheless, required in order to prevent or slow deterioration and maintain a beneficiary at the maximum practicable level of function. For example, in the regulations at 42 CFR 409.32(c), the level of care criteria for SNF coverage specify that the “...restoration potential of a patient is not the deciding factor in determining whether skilled services are needed. Even if full recovery or medical improvement is not possible, a patient may need skilled services to prevent further deterioration or preserve current capabilities.”

The Medicare statute and regulations have never supported the imposition of an “Improvement Standard” rule-of-thumb in determining whether skilled care is required to prevent or slow deterioration in a patient’s condition. A beneficiary’s lack of restoration potential cannot, in itself, serve as the basis for denying coverage, without regard to an individualized assessment of the beneficiary’s medical condition and the reasonableness and necessity of the treatment, care, or services in question. Conversely, coverage in this context would not be available in a situation where the beneficiary’s care needs can be addressed safely and effectively through the use of nonskilled personnel.

Thus, such coverage depends not on the beneficiary’s restoration potential, but on whether skilled care is required, along with the underlying reasonableness and necessity of the services themselves. Any Medicare coverage or appeals decisions concerning skilled care coverage must reflect this basic principle. In this context, it is also essential and has always been required that claims for skilled care coverage include sufficient documentation to substantiate clearly that skilled care is required, that it is in fact provided, and that the services themselves are reasonable and necessary, thereby facilitating accurate and appropriate claims adjudication.
The Settlement Agreement - No Expansion of Medicare Coverage:
The Jimmo v. Sebelius settlement agreement itself includes language specifying that “Nothing in this Settlement Agreement modifies, contracts, or expands the existing eligibility requirements for receiving Medicare coverage.”

The settlement agreement is intended to clarify that when skilled services are required in order to provide care that is reasonable and necessary to prevent or slow further deterioration, coverage cannot be denied based on the absence of potential for improvement or restoration. As such, any actions undertaken in connection with this settlement do not represent an expansion of coverage, but rather, serve to clarify existing policy so that Medicare claims will be adjudicated consistently and appropriately.

Forthcoming Activities:
CMS plans to conduct the following activities under the terms of the settlement agreement:

Clarifying Policy – Updating Program Manuals
The first action CMS will undertake as specified in the settlement agreement will be revising the relevant program manuals used by Medicare contractors. The Medicare program manuals will be reworded for clarity, so as to reinforce the intent of the policy. Specifically, in accordance with the settlement agreement, manual revisions will clarify that coverage of therapy “…does not turn on the presence or absence of a beneficiary’s potential for improvement from the therapy, but rather on the beneficiary’s need for skilled care.”

Educational Campaign – Informing Stakeholders
The next step CMS will take will be an educational campaign for contractors, adjudicators, and providers and suppliers. CMS will disseminate to these recipients a variety of written materials, including:

- Program Transmittal;
- Medicare Learning Network (MLN) Matters article;
- Updated 1-800 MEDICARE scripts.

CMS will also conduct national conference calls with providers and suppliers as well as Medicare contractors, Administrative Law Judges, medical reviewers, and agency staff, to communicate the policy clarifications described herein and answer questions.

Claims Review
In addition, to ensure beneficiaries receive the care to which they are entitled, CMS will engage in accountability measures, including review of a random sample of SNF, HH, and OPT coverage decisions to determine overall trends and identify any problems, as well as a review of individual claims determinations that may not have been made in accordance with the principles set forth in the settlement agreement.

According to the terms of the settlement agreement, CMS will complete the manual revisions and educational campaign by January 23, 2014, which is within one year of the approval date of the settlement agreement.