

**CORPORATE INTEGRITY AGREEMENT  
BETWEEN THE  
OFFICE OF INSPECTOR GENERAL  
OF THE  
DEPARTMENT OF HEALTH AND HUMAN SERVICES  
AND  
SAVASENIORCARE, LLC AND  
SAVASENIORCARE ADMINISTRATIVE AND CONSULTING, LLC**

**I. PREAMBLE**

SavaSeniorCare, LLC (Sava LLC), SavaSeniorCare Administrative and Consulting, LLC (collectively “Sava”) hereby enter 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, Sava 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 Sava 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. This CIA applies to any long term care facility in which Sava has an ownership or control interest, as defined in 42 U.S.C. § 1320a-3(a)(3), and any long term care facility directly or indirectly managed or operated by Sava (hereafter referred to as “Sava Facilities”).

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

D. For purposes of this CIA, the term “Covered Persons” includes:

1. all owners who are natural persons, officers, directors, and employees of Sava;
2. all owners who are natural persons, officers, directors, and employees of any long term care facility in which Sava has a direct or indirect ownership or control interest, as defined in 42 U.S.C. § 1320a-3(a)(3), and of any long term care facility managed or operated directly or indirectly by Sava at any time during the term of the CIA; and
3. all contractors, subcontractors, agents, and other persons who: (1) are involved directly or indirectly in the delivery of resident care; (2) make assessments of residents that affect treatment decisions or reimbursement; (3) perform billing, coding, audit, or review functions; (4) make decisions or provide oversight about staffing, resident care, reimbursement, policies and procedures, or this CIA; or (5) perform any function that relates to or is covered by this CIA, including individuals who are responsible for quality assurance, setting policies or procedures, or making staffing decision.;
4. Notwithstanding the above, this term presumptively 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.
5. Any nonemployee private caregivers and/or attending physicians hired by any resident or the family or guardians of any resident of a Sava Facility are not Covered Persons, regardless of the hours worked per year at Sava.

### **III. CORPORATE INTEGRITY OBLIGATIONS**

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

#### **A. Compliance Officer and Committee, Board of Directors, and Management Compliance Obligations**

1. *Compliance Officer.* Within 90 days after the Effective Date, Sava shall appoint a Compliance Officer and shall maintain a Compliance Officer for the term of the CIA. The Compliance Officer must have sufficient compliance and quality

assurance experience to effectively oversee the implementation of the requirements of this CIA. The Compliance Officer shall be an employee and a member of senior management of SavaSeniorCare Administrative and Consulting, LLC, shall report directly to the Chief Executive Officer of Sava LLC and SavaSeniorCare Administrative and Consulting, LLC, and shall not be or be subordinate to the General Counsel, Chief Financial Officer, or Chief Operating Officer, or have any responsibilities that involve acting in any capacity as legal counsel or supervising legal counsel functions for Sava. The Compliance Officer shall be responsible for, without limitation:

- a. developing and implementing policies, procedures, and practices designed to ensure compliance with the requirements set forth in this CIA, and Federal health care program requirements;
- b. making periodic (at least quarterly) reports regarding compliance matters directly to the Board of Directors of Sava, and shall be authorized to report on such matters to the Board of Directors at any time. Written documentation of the Compliance Officer's reports to the Board of Directors shall be made available to OIG upon request; and
- c. monitoring the day-to-day compliance activities engaged in by Sava, any reporting obligations created under this CIA, and whether Sava is appropriately identifying and correcting quality of care problems.

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.

SavaSeniorCare Administrative and Consulting, LLC shall report to OIG, in writing, any changes 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, Sava shall appoint a Compliance Committee.

- a. *General Responsibilities.* This committee shall support the Compliance Officer in fulfilling his/her responsibilities as set forth above in section III.A.1 The Compliance Committee shall, at a minimum, include the Compliance Officer and

other members of senior management of Sava necessary to meet the requirements of this CIA (e.g., representatives from among senior personnel responsible for clinical operations and quality of care, human resources, operations, and the Medical Director). The Compliance Officer shall chair the Compliance Committee.

The Compliance Committee shall meet, at a minimum, every month. For each scheduled Compliance Committee meeting, senior management of Sava shall report to the Compliance Committee on the adequacy of care being provided by Sava Facilities. The minutes of the Compliance Committee meetings shall be made available to the OIG upon request.

SavaSeniorCare Administrative and Consulting, LLC, on behalf of Sava, shall report to OIG, in writing, 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.

- b. *Staffing Responsibilities.* The Compliance Committee shall assess Sava's nursing staffing and make recommendations regarding how to improve such staffing. The Compliance Committee shall consult with nurse managers, registered nurses (RNs), licensed practical nurses (LPNs), and certified nursing aides (CNAs) and the Independent Monitor required under Section III.D of this CIA regarding staffing. The Compliance Committee shall:
  - i. review the development and implementation of the staffing-related policies and procedures required by Section III.B of this CIA.
  - ii. assess, on an on-going basis, whether Sava Facilities provided nursing staff necessary to meet residents' needs;
  - iii. make recommendations as to how Sava Facilities can improve the quantity, quality, and composition of nursing staff necessary to meet residents' needs;

- iv. identify obstacles related to the recruitment, retention, and training of nursing staff at Sava Facilities; and
  - v. make recommendations as to how Sava Facilities can improve the recruitment, retention, and training of nursing staff.
- c. *Quality of Care Review Program.* The Compliance Committee shall ensure that, within 120 days after the Effective Date, SavaSeniorCare Administrative and Consulting, LLC establishes and implements a program for performing internal quality audits and reviews (hereinafter “Quality of Care Review Program”). The Quality of Care Review Program shall:
- i. assess whether the residents at Sava Facilities are receiving the quality of care and quality of life consistent with professionally recognized standards of care, 42 C.F.R. Part 483, and any other applicable federal and state statutes, regulations, and directives;
  - ii. review quality of care related incidents and complete root cause analyses; and
  - iii. develop corrective action plans in response to identified quality of care problems and track the implementation and effectiveness of those plans.
- d. *Quality of Care Dashboard.* The Compliance Committee, in consultation with the Monitor required under Section III.D of this CIA, shall create and implement a “Quality of Care Dashboard” (Dashboard). Quality indicator data shall be collected and reported on the Dashboard. Within 150 days after the Effective Date, the Compliance Committee shall: (1) identify and establish the overall quality improvement goals for Sava based on its assessment of Sava Facilities’ quality of care risk areas; (2) identify and establish the quality indicators related to those goals that Sava will monitor through the data analysis; and (3) establish performance

metrics for each quality indicator. The Compliance Committee shall measure, analyze, and track the performance metrics for the quality indicators on a monthly basis, monitoring progress towards the quality improvement goals. At least annually, the Compliance Committee shall review the quality indicators to determine if revisions are appropriate and shall make any necessary revisions based on such review.

3. *Board of Directors Compliance Obligations.* The Board of Directors (or a committee of the Board) of Sava LLC (Board) shall be responsible for the review and oversight of matters related to compliance with the requirements and obligations of this CIA, Federal health care program requirements, and professionally recognized standards of care. The Board must include independent (i.e., non-executive) members. The Board shall be readily available to the Compliance Officer and the Monitor required under Section III.D of this CIA to respond to any issues or questions that might arise.

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

- a. meeting at least quarterly to review and oversee Sava's compliance program, including, but not limited to, the performance of the Compliance Officer and the Compliance Committee;
- b. reviewing the adequacy of Sava's system of internal controls, quality assurance monitoring, and resident care;
- c. reviewing the adequacy of Sava's response to state, federal, internal, and external reports of quality of care problems;
- d. determining whether Sava adopts and implements policies, procedures, and practices designed to ensure compliance with the requirements set forth in this CIA, Federal health care program requirements, and professionally recognized standards of care;
- e. reviewing and responding to the data analysis presented on the Dashboard and determining whether Sava implements effective responses when the data

indicates potential quality problems or that Sava is not meeting its established goals; and

- f. for each Reporting Period of the CIA, adopting a resolution, signed by each member of the Board summarizing its review and oversight of Sava's compliance with the obligations of this CIA, Federal health care program requirements, and professionally recognized standards of care.

The above described Board responsibilities are not intended to suggest that the Board is responsible for the day-to-day operations of Sava or the Sava Facilities. At a minimum, the resolution shall include the following language:

“The Board of Directors has made a reasonable inquiry into the operations of Sava's Compliance Program, including the performance of the Compliance Officer and the Compliance Committee. The Board has also provided oversight on quality of care issues. Based on its inquiry and review, the Board has concluded that, to the best of its knowledge, Sava has implemented an effective Compliance Program to meet the obligations of the CIA, Federal health care program requirements, and professionally recognized standards of care.”

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 Sava.

Sava 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.

4. *Management Certifications.* In addition to the responsibilities set forth in this CIA for all Covered Persons, certain Sava employees (Certifying Employees) are expected to monitor and oversee activities within their areas of authority and shall annually certify that the applicable Sava department is in compliance with applicable Federal health care program requirements and with the obligations of this CIA. These Certifying Employees shall include, at a minimum, the following: Chief Executive

Officer, Chief Operating Officer, Chief Financial Officer, Chief Integrity Officer, Chief Information Officer, Senior Vice Presidents of Care Management, Senior Vice Presidents of Clinical Operations and Division Presidents. For each Reporting Period, each Certifying Employee shall sign a certification that states:

“I have been trained on and understand the compliance requirements and responsibilities as they relate to [insert name of department], an area under my supervision. My job responsibilities include ensuring compliance with regard to the [insert name of department] with all applicable Federal health care program requirements, obligations of the Corporate Integrity Agreement, and Sava policies, and I have taken steps to promote such compliance. To the best of my knowledge, the [insert name of department] of Sava is in compliance with all applicable Federal health care program requirements and the obligations of the Corporate Integrity Agreement. I understand that this certification is being provided to and relied upon by the United States.”

If any Certifying Employee is unable to provide such a certification, the Certifying Employee shall provide a written explanation of the reasons why he or she is unable to provide the certification outlined above.

Within 90 days after the Effective Date, SavaSeniorCare Administrative and Consulting, LLC, shall develop and implement a written process for Certifying Employees to follow for the purpose of completing the certification required by this section (e.g., reports that must be reviewed, assessments that must be completed, sub-certifications that must be obtained, etc., prior to the Certifying Employee making the required certification).

B. Written Standards

Within 90 days after the Effective Date, Sava shall develop and implement written Policies and Procedures regarding the operation of Sava’s compliance program, including the compliance program requirements outlined in this CIA and Sava’s compliance with Federal health care program requirements and professionally recognized standards of care (Policies and Procedures). Throughout the term of this CIA, Provider shall enforce its Policies and Procedures and shall make compliance with its Policies and Procedures an element of evaluating the performance of all employees of Sava and Sava Facilities.



At a minimum, the Policies and Procedures shall address:

1. the requirements applicable to Medicare's Prospective Payment System (PPS) for skilled nursing facilities, including, but not limited to: ensuring the accuracy of the clinical data required under the Minimum Data Set (MDS) as specified by the Resident Assessment Instrument User's Manual; ensuring that Sava is appropriately and accurately using the current Resource Utilization Groups or patient case mix classification system; and ensuring the accuracy of billing and cost report preparation policies and procedures;
2. the coordinated interdisciplinary approach to providing care, including but not limited to all areas addressed in 42 C.F.R. § 483;
3. staffing, including but not limited to nursing staff levels that are sufficient to meet residents' needs, as required by Federal and state laws, such as 42 C.F.R. § 483.30 (nursing services); using an acuity-based staffing protocol that includes direct care nurse staffing per patient day requirements for each class of nursing staff (e.g., RNs, LPNs, CNAs) and minimizing the number of individuals working on a temporary assignment or not employed by Sava (not including those persons who are included in the definition of Covered Persons) and creating and maintaining a standardized system to track the number of individuals who fall within this category so that the number/proportion of or changing trends in such staff can be adequately identified by Sava or the Monitor;
4. capital improvements, including but not limited to a process to ensure that Sava and its nursing facilities address facility maintenance and repairs, equipment adequacy, supplies, and make necessary capital expenditures to provide a habitable environment and to protect the health and safety of residents; and
5. the accuracy of medical records.

The Policies and Procedures shall be made available to all Covered Persons.

At least annually (and more frequently, if appropriate), Sava shall assess and update, as necessary, the Policies and Procedures. Any new or revised Policies and Procedures shall be made available to all Covered Persons.

All Policies and Procedures shall be made available to OIG upon request.

### C. Training and Education

1. *Covered Persons Training.* Within 120 days after the Effective Date, SavaSeniorCare Administrative and Consulting, LLC, shall develop a written plan (Training Plan) that outlines the steps Sava and the Sava Facilities will take to ensure that all Covered Persons receive (a) at least annual training regarding Sava's CIA requirements and Compliance Program, and (b) as appropriate to each Covered Person's job category, adequate on-going training regarding: (i) policies, procedures, and other requirements applicable to the documentation of medical records; (ii) the policies implemented pursuant to Section III.B of this CIA, as appropriate for the job category of each Covered Person; (iii) the coordinated interdisciplinary approach to providing care and related communication between disciplines; (iv) the personal obligation of each individual involved in resident care to ensure that care is appropriate and meets professionally recognized standards of care; (v) examples of proper and improper care; and (vi) reporting requirements and legal sanctions for violations of the Federal health care program requirements. The Training Plan shall also include training to address quality of care problems identified by the Compliance Committee. In determining what training should be performed, the Compliance Committee shall review the complaints received, satisfaction surveys, staff turnover data, any state or federal surveys, including those performed by the Centers for Medicare & Medicaid Services (CMS) survey and its agents the Joint Commission or other such private agencies, any internal surveys, the CMS quality indicators, and the findings, reports, and recommendations of the Monitor required under Section III.D of this CIA.

Training required in this section shall be competency-based. Specifically, the training must be developed and provided in such a way as to focus on Covered Persons achieving learning outcomes to a specified competency and to place emphasis on what a Covered Person has learned as a result of the training.

2. *Board Member Training.* Within 90 days after the Effective Date, each member of the Board of Directors shall receive at least two hours of training. This training shall address the corporate governance responsibilities of board members, and the responsibilities of board members with respect to review and oversight of the Compliance Program. Specifically, the training shall address the unique responsibilities of health care Board members, including the risks, oversight areas, and strategic approaches to conducting oversight of a health care entity. This training may be conducted by an outside compliance expert hired by the Board and should include a discussion of the OIG's guidance on Board member responsibilities.

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.

3. *Training Records.* Sava shall make available to OIG, upon request, training materials and records verifying that Covered Persons and Board members have timely received the training required under this section.

Sava may provide the training required under this CIA through appropriate computer-based training approaches. If Sava 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. Independent Monitor

Within 60 days after the Effective Date, Sava shall retain an appropriately qualified monitoring team (the “Monitor”), selected by OIG after consultation with Sava. The Monitor may retain additional personnel, including but not limited to independent consultants, if needed to help meet the Monitor’s obligations under this CIA. The Monitor may confer and correspond with Sava or OIG individually or together. The Monitor and Sava shall not negotiate or enter into a financial relationship, other than the monitoring engagement required by this section, and the Monitor shall refrain from recruiting or hiring any employee of Sava until after the date of OIG’s CIA closure letter to Sava or six months after the expiration of this CIA, whichever is later.

The Monitor is not an agent of OIG. However, the Monitor may be removed by OIG at its sole discretion. If the Monitor resigns or is removed for any other reasons prior to the termination of the CIA, Sava shall retain, within 60 days of the resignation or removal, another Monitor selected by OIG, with the same functions and authorities.

1. *Scope of Review.* The Monitor shall be responsible for assessing the effectiveness, reliability, and thoroughness of the following:

- a. Sava’s internal quality control systems, including but not limited to:
  - i. whether the systems in place to promote quality of care and to respond to quality of care problems are operating in a timely and effective manner;

- ii. whether the communication system is effective, allowing for accurate information, decisions, and results of decisions to be transmitted to the proper individuals in a timely fashion; and
  - iii. whether the training programs are effective, thorough, and competency-based.
- b. Sava's response to quality of care issues, which shall include an assessment of:
  - i. Sava's ability to identify the problem;
  - ii. Sava's ability to determine the scope of the problem, including but not limited to whether the problem is isolated or systemic;
  - iii. Sava's ability to conduct a root cause analysis;
  - iv. Sava's ability to create an action plan to respond to the problem;
  - v. Sava's ability to execute the action plan; and
  - vi. Sava's ability to monitor and evaluate whether the assessment, action plan, and execution of that plan was effective, reliable, and thorough.
- c. Sava's proactive steps to ensure that each resident receives care in accordance with:
  - i. professionally recognized standards of health care;
  - ii. the rules and regulations set forth in 42 C.F.R. Part 483;
  - iii. State and local statutes, regulations, and other directives or guidelines; and

- iv. the Policies and Procedures adopted by Sava, including those implemented under Section III.B of this CIA;
- d. Sava's systems for review of Sava Facilities' compliance with staffing requirements;
- e. Sava's ability to analyze outcome measures, such as the CMS Quality Indicators, and other data;
- f. Sava's Quality of Care Review Program required under Section III.A of this CIA;
- g. Sava's Quality of Care Dashboard required under Section III.A of this CIA; and
- h. Sava's ability to identify and correct physical plant problems, including the implementation and effectiveness of the capital improvements process required under Section III.B of this CIA.

2. *Access.* The Monitor shall have:

- a. immediate access to Sava and Sava Facilities, at any time and without prior notice, to assess compliance with this CIA, to assess the effectiveness of the internal quality assurance mechanisms, and to ensure that the data being generated is accurate and complete;
- b. immediate access:
  - i. the CMS quality indicators;
  - ii. internal or external surveys or reports;
  - iii. Disclosure Program complaints;
  - iv. resident satisfaction surveys;
  - v. staffing data in the format requested by the Monitor;

- vi. reports of abuse, neglect, or an incident that required hospitalization or emergency room treatment;
  - vii. reports of any falls;
  - viii. reports of any incident involving a resident that prompts a full internal investigation;
  - ix. resident records;
  - x. documents in the possession or control of any quality assurance committee, peer review committee, medical review committee, or other such committee; and
  - xi. any other data in the format the Monitor determines relevant to fulfilling the duties required under this CIA;
- c. immediate access to residents, and Covered Persons for interviews outside the presence of Sava or the Sava Facilities' supervisory staff or counsel, provided such interviews are conducted in accordance with all applicable laws and the rights of such individuals. The Monitor shall give full consideration to an individual's clinical condition before interviewing a resident.

3. *Baseline Systems Assessment.* Within six months after the Effective Date of the CIA, the Monitor shall:

- a. complete an assessment of the effectiveness, reliability, scope, and thoroughness of the systems described in Section III.D.1;
- b. in conducting this assessment, visit at least four of Sava's facilities (selected by the Monitor) and, at a minimum, observe quality assurance meetings, observe corporate compliance meetings, observe care planning meetings, observe Board meetings, interview key employees, review relevant documents, and observe resident care; and

- c. submit a written report to Sava and OIG that sets forth, at a minimum:
  - i. a summary of the Monitor's activities in conducting the assessment;
  - ii. the Monitor's findings regarding the effectiveness, reliability, scope, and thoroughness of each of the systems described in Section III.D.1; and
  - iii. the Monitor's recommendations to Sava as to how to improve the effectiveness, reliability, scope, and thoroughness of the systems described in Section III.D.1.

4. *Systems Improvements Assessments.* On a semi-annual basis, the Monitor shall:

- a. re-assess the effectiveness, reliability, and thoroughness of the systems described in Section III.D.1;
- b. assess Sava's and Sava Facilities' response to recommendations made in prior written assessment reports;
- c. in conducting these assessments, visit at least four of Sava's Facilities (selected by the Monitor) and, at a minimum, observe quality assurance meetings, observe corporate compliance meetings, observe care planning meetings, observe Board meetings, interview key employees, review relevant documents, and observe resident care (the Monitor may also want to have regular telephone calls with Sava and any of its poorer performing facilities; and
- b. submit a written report to Sava and OIG that sets forth, at a minimum:
  - i. a summary of the Monitor's activities in conducting the assessment;

- ii. the Monitor’s findings regarding the effectiveness, reliability, scope, and thoroughness of each of the systems described in Section III.D.1;
- iii. the Monitor’s recommendations to Sava as to how to improve the effectiveness, reliability, scope, and thoroughness of the systems described in Section III.D.1; and
- iv. the Monitor’s assessment of Sava’s response to the Monitor’s prior recommendations.

For the first Reporting Period, the assessment shall be based on the portion of the Reporting Period that was not covered in the Baseline Systems Assessment. For each subsequent Reporting Period, one assessment shall be based on the first six months of the Reporting Period and the other assessment shall be based on the second six months of the Reporting Period. The Monitor shall submit written reports no later than 30 days after the end of the relevant six-month period to Provider and OIG.

5. *Financial Obligations of Sava and the Monitor.*

- a. Sava shall be responsible for all reasonable costs incurred by the Monitor in connection with this engagement, including but not limited to labor costs (direct and indirect); consultant and subcontract costs; materials cost (direct and indirect); and other direct costs (travel, other miscellaneous).
- b. Sava shall pay the Monitor’s bills within 30 days of receipt. Failure to pay the Monitor within 30 calendar days of submission of the Monitor’s invoice for services previously rendered shall constitute a basis to impose stipulated penalties or exclude Sava, as provided under Section X of this CIA. While Sava must pay all of the Monitor’s bills within 30 days, Sava may bring any disputed Monitor’s costs or bills to OIG’s attention.
- c. The Monitor shall charge a reasonable amount for its fees and expenses, and shall submit monthly invoices to SavaSeniorCare Administrative and Consulting, LLC, with a



reasonable level of detail reflecting all key category costs billed.

- d. The Monitor shall submit a written report for each Reporting Period representing an accounting of its costs throughout the year to Sava and to OIG by the submission deadline of Sava's Annual Report. This report shall reflect, on a cumulative basis, all key category costs included on monthly invoices.

6. *Additional Sava Obligations.* Sava shall:

- a. As a condition of retaining the Monitor, Sava shall require the Monitor to enter into a subcontract with an individual or entity, approved by OIG, that can create objective and independent Quality Indicator data analysis reports of the type described in the attached Appendix A;
- b. within 30 days after receipt of each written report of the Baseline Systems Assessment or Systems Improvement Assessments, submit a written response to OIG and the Monitor to each recommendation contained in those reports stating what action Sava took in response to each recommendation or why Sava has elected not to take action based on the recommendation;
- c. notify the Monitor monthly, or sooner, regarding each of the following occurrences to the extent known by Sava:
  - i. Deaths or injuries related to use of restraints;
  - ii. Deaths or injuries related to use of psychotropic medications;
  - iii. Suicides;
  - iv. Deaths or injuries related to abuse or neglect (as defined in the applicable federal guidelines);

- v. Fires, storm damage that poses a threat to residents or otherwise may disrupt the care provided, flooding, or major equipment failures at Sava Facilities;
- vi. Strikes or other work actions that could affect resident care;
- vii. Man-made disasters that pose a threat to residents (e.g., toxic waste spills);
- viii. The appointment of a receiver to manage a Sava Facility or the potential closure of a Sava Facility; and
- ix. Any other incident that involves or causes actual harm to a resident when such incident is required to be reported to any local, state, or federal government agency or presents an imminent danger to the health, safety, or well-being of residents or places residents unnecessarily in high-risk situations.

Each such report shall contain, if applicable, the full name and date of birth of the residents(s) involved, the persons involved, the date of death or incident, and a brief description of the events surrounding the death or incident, actions taken to address the situation, and a summary of any related reports made to Federal or state regulatory or enforcement agencies or to professional licensing bodies.

- d. provide to its Compliance Committee and Board of Directors Committee copies of all documents and reports provided to the Monitor;
- e. ensure the Monitor's immediate access to the facility, residents, Covered Persons, and documents, and assist in obtaining full cooperation by its current employees, contractors, and agents;
- f. provide access to current residents and provide contact information for their families and guardians consistent with

the rights of such individuals under state or federal law, and not impede their cooperation with the Monitor;

- g. assist in locating and, if requested, attempt to obtain cooperation from past employees, contractors, agents, and residents and their families;
- h. provide the last known contact information for former residents, their families, or guardians consistent with the rights of such individuals under state or federal law, and not impede their cooperation; and
- i. not sue or otherwise bring any action against the Monitor related to any findings made by the Monitor or related to any exclusion or other sanction of Sava under this CIA; provided, however, that this clause shall not apply to any suit or other action based solely on the dishonest or illegal acts of the Monitor, whether acting alone or in collusion with others.

7. *Additional Monitor Obligations.* The Monitor shall:

- a. abide by all state and federal laws and regulations concerning the privacy, dignity, and employee rights of all Covered Persons, and residents;
- b. abide by the legal requirements of Sava to maintain the confidentiality of each resident's personal and clinical records. Nothing in this subsection, however, shall limit or affect the Monitor's obligation to provide information, including information from resident clinical records, to OIG, and, when legally or professionally required, to other agencies;
- c. at all times act reasonably in connection with its duties under the CIA including when requesting information from Sava;
- d. if the Monitor has concerns about action plans that are not being enforced or systemic problems that could affect the Sava Facilities' ability to render quality care to its residents, then the Monitor shall:

- i. report such concerns in writing to OIG; and
  - ii. simultaneously provide notice and a copy of the report to the Compliance Committee and Board;
- e. where independently required to do so by applicable law or professional licensing standards, report any finding to an appropriate regulatory or law enforcement authority, and simultaneously submit copies of such reports to OIG and to Sava;
- f. not be bound by any other private or governmental agency's findings or conclusions, including, but not limited to, Joint Commission, CMS, or the state survey agency. Likewise, such private and governmental agencies shall not be bound by the Monitor's findings or conclusions. The Monitor's reports shall not be the sole basis for determining deficiencies by the state survey agencies. The parties agree that CMS and its contractors shall not introduce any material generated by the Monitor, or any opinions, testimony, or conclusions from the Monitor as evidence into any proceeding involving a Medicare or Medicaid survey, certification, or other enforcement action against Sava, and Sava shall similarly be restricted from using material generated by the Monitor, or any opinions, testimony, or conclusions from the Monitor as evidence in any of these proceedings. Nothing in the previous sentence, however, shall preclude OIG or Sava from using any material generated by the Monitor, or any opinions, testimony, or conclusions from the Monitor in any action under the CIA or pursuant to any other OIG authorities or in any other situations not explicitly excluded in this subsection;
- g. abide by the provisions of the Health Insurance Portability and Accountability Act (HIPAA) of 1996 to the extent required by law including, without limitation, entering into a business associate agreement with Sava; and
- h. except to the extent required by law, maintain the confidentiality of any proprietary financial and operational

information, processes, procedures, and forms obtained in connection with its duties under this CIA and not comment publicly concerning its findings except to the extent authorized by OIG.

E. Review Procedures

1. *General Description*

- a. *Engagement of Independent Review Organization.* Within 90 days after the Effective Date, Sava 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.E. The applicable requirements relating to the IRO are outlined in Appendix B to this CIA, which is incorporated by reference.
- b. *Retention of Records.* The IRO and Sava shall retain and make available to OIG, upon request, all work papers, supporting documentation, correspondence, and draft reports (those exchanged between the IRO and Sava) related to the reviews.
- c. *Access to Records and Personnel.* Sava shall ensure that the IRO has access to all records and personnel necessary to complete the reviews listed in this Section III.E and that all records furnished to the IRO are accurate and complete.

2. *Claims Review.* The IRO shall review claims submitted by Sava and reimbursed by the Medicare program, to determine whether the items and services furnished were medically necessary and reasonable and appropriately documented and whether the claims were correctly coded, submitted and reimbursed (Claims Review) and shall prepare a Claims Review Report, as outlined in Appendix C to this CIA, which is incorporated by reference.

3. *Independence and Objectivity Certification.* The IRO shall include in its report(s) to Sava a certification that the IRO has (a) evaluated its professional independence and objectivity with respect to the reviews required under this Section III.E and (b) concluded that it is, in fact, independent and objective, in accordance with the

requirements specified in Appendix B to this CIA. The IRO's certification shall include a summary of all current and prior engagements between Sava and the IRO.

F. Risk Assessment and Internal Review Process

Within 150 days after the Effective Date, Sava shall develop and implement a centralized annual risk assessment and internal review process to identify and address risks associated with Sava's participation in the Federal health care programs, including but not limited to the risks associated with standards of care, staffing levels, and the submission of claims for items and services furnished to Medicare and Medicaid program beneficiaries. The risk assessment and internal review process shall require the Chief Compliance Officer, the Chief Clinical Officer, the Medical Director, and legal and other department leaders, at least annually, to: (1) identify and prioritize risks, (2) develop internal audit work plans related to the identified risk areas, (3) implement the internal audit work plans, (4) develop corrective action plans in response to the results of any internal audits performed, and (5) track the implementation of the corrective action plans in order to assess the effectiveness of such plans. Sava shall maintain the risk assessment and internal review process for the term of the CIA.

G. Disclosure Program

Within 90 days after the Effective Date, Sava 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 Sava's policies, conduct, practices, or procedures with respect to quality of care or a Federal health care program believed by the individual to be a potential violation of criminal, civil, or administrative law. Sava 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. The Disclosure Program also shall include a requirement that all of Sava's Covered Persons shall be expected to report suspected violations of any Federal health care program requirements to the Compliance Officer or other appropriate individual designated by Sava. 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, Sava shall conduct an internal review of the allegations set forth in the disclosure and ensure that proper follow-up is conducted. If the inappropriate or improper practices places residents at risk of harm, then Sava will ensure that that practice ceases immediately and that appropriate action is taken.

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

The disclosure log shall be sent to the Monitor required under Section III.D of this CIA not less than monthly.

#### H. Ineligible Persons

1. *Definitions.* For purposes of this CIA:
  - a. an “Ineligible Person” shall include an individual or entity who:
    - i. is currently excluded from participation in any Federal health care program; 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.
  - b. “Exclusion List” means the HHS/OIG List of Excluded Individuals/Entities (LEIE) (available through the Internet at <http://www.oig.hhs.gov>).

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

- a. Sava shall screen all prospective Covered Persons against the Exclusion List 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. Sava shall screen all current Covered Persons against the Exclusion List within 90 days after the Effective Date and on a monthly basis thereafter.
- c. Sava shall implement a policy requiring all Covered Persons to disclose immediately if they become an Ineligible Person.

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

3. *Removal Requirement.* If Sava has actual notice that a Covered Person has become an Ineligible Person, Sava shall remove such Covered Person from responsibility for, or involvement with, Sava's business operations related to the Federal health care program(s) from which such Covered Person has been excluded 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 any Federal health care program(s) from which the Covered Person has been excluded at least until such time as the Covered Person is reinstated into participation in such Federal health care program(s).

4. *Pending Charges and Proposed Exclusions.* If Sava 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, Sava 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 or the accuracy of any claims submitted to any Federal health care program.

I. Notification of Government Investigation or Legal Proceeding

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

In addition, within 15 days after notification, Sava shall notify OIG, in writing, of any adverse final determination made by a federal, state, or local government agency or accrediting or certifying agency (e.g., Joint Commission) relating to quality of care issues.

J. Overpayments

1. *Definition of Overpayment.* An “Overpayment” means any funds that Sava receives or retains under any Federal health care program to which Sava, after applicable reconciliation, is not entitled under such Federal health care program.

2. *Overpayment Policies and Procedures.* Within 90 days after the Effective Date, Sava shall develop and implement written policies and procedures regarding the identification, quantification, and repayment of Overpayments received from any Federal health care program.

K. 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.H.1.a; or
- d. the filing of a bankruptcy petition by Sava, and/or the appointment of a receiver by a bankruptcy court or a governing body.

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

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

3. *Reportable Events under Section III.K.1.a and III.K.1.b.* For Reportable Events under Section III.K.1.a and b, the report to OIG shall include:

- a. a complete description of all details relevant to the Reportable Event, including, at a minimum, the types of claims, transactions or other conduct giving rise to the Reportable Event; the period during which the conduct occurred; and the names of individuals and entities believed to be implicated, including an explanation of their roles in the Reportable Event;
- b. a statement of the Federal criminal, civil or administrative laws that are probably violated by the Reportable Event, if any;
- c. the Federal health care programs affected by the Reportable Event;
- d. a description of the steps taken by Sava to identify and quantify any Overpayments; and
- e. a description of Sava's actions taken to correct the Reportable Event and prevent it from recurring.

If the Reportable Event involves an Overpayment, within 60 days of identification of the Overpayment, Sava shall repay the Overpayment, in accordance with the

requirements of 42 U.S.C. § 1320a-7k(d) and any applicable CMS guidance and provide OIG with a copy of the notification and repayment.

5. *Reportable Events under Section III.K.1.c.* For Reportable Events under Section III.K.1.c, the report to OIG shall include:

- a. the identity of the Ineligible Person and the job duties performed by that individual;
- b. the dates of the Ineligible Person's employment or contractual relationship;
- c. a description of the Exclusion List screening that Sava completed before and/or during the Ineligible Person's employment or contract and any flaw or breakdown in the screening process that led to the hiring or contracting with the Ineligible Person;
- d. a description of how the Ineligible Person was identified; and
- e. a description of any corrective action implemented to prevent future employment or contracting with an Ineligible Person.

6. *Reportable Events under Section III.K.1.d.* For Reportable Events under Section III.K.1.d, the report to OIG shall include:

- a. a complete description of the Reportable Event;
- b. a description of Sava and/or the Sava Facility's action taken to ensure that the Reportable Event does not adversely impact resident care;
- c. any further steps Sava and/or the Sava Facility plans to take to address the Reportable Event;
- d. if the Reportable Event involves the filing of a bankruptcy petition, documentation of the bankruptcy filing and a description of any Federal health care program requirements implicated; and

- e. if the Reportable Event involves the appointment of a receiver, documentation regarding the receivership, including, but not limited to, the identification and contact information of the receiver.

7. *Reportable Events Involving the Stark Law.* Notwithstanding the reporting requirements outlined above, any Reportable Event that involves solely a probable violation of section 1877 of the Social Security Act, 42 U.S.C. §1395nn (the Stark Law) should be submitted by Sava to CMS through the self-referral disclosure protocol (SRDP), with a copy to the OIG. If Sava identifies a probable violation of the Stark Law and repays the applicable Overpayment directly to the CMS contractor, then Sava is not required by this Section III.K to submit the Reportable Event to CMS through the SRDP.

#### **IV. SUCCESSOR LIABILITY**

In the event that, after the Effective Date, Sava proposes to (a) sell any or all of its long term care facility business (in which Sava has an ownership or control interest), business units, or locations (whether through a sale of assets, sale of stock, or other type of transaction) relating to the furnishing of items or services that may be reimbursed by a Federal health care program, or (b) purchase or establish a new business, business unit, or location relating to the furnishing of items or services that may be reimbursed by a Federal health care program, the CIA shall be binding on the purchaser of any long term care facility (in which Sava has an ownership or control interest) business, business unit, or location and any 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 determined and agreed to in writing by OIG. Sava shall give notice of such sale or purchase to OIG at least 30 days prior to the closing of the transaction.

If, in advance of a proposed sale or a proposed purchase, Sava wishes to obtain a determination by OIG that the proposed purchaser or the proposed acquisition will not be subject to the requirements of the CIA, Sava must notify OIG in writing of the proposed sale or purchase and include the following information at least 30 days in advance: a description of the business, business unit, or location to be sold or purchased, a brief description of the terms of the transaction and, in the case of a proposed sale, the name and contact information of the prospective purchaser.

## V. IMPLEMENTATION AND ANNUAL REPORTS

### A. Implementation Report.

Within 160 days after the Effective Date, Sava 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. the names of the Board members who are responsible for satisfying the Board Committee compliance obligations described in Section III.A;
4. a description of the Quality of Care Review Program required by Section III.A.2;
5. a description of the Dashboard required by Section III.A.2;
6. the names and positions of the Certifying Employees and the written process for Certifying Employees to follow for the purpose of completing the certification required by Section III.A.4;
7. a list of all Policies and Procedures required by Section III.B;
8. the Training Plan required by Section III.C.1 and a description of the Board of Directors training required by Section III.C.2 (including a summary of the topics covered, the length of the training, and when the training was provided);
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 B to this CIA; and (d) a certification from the IRO regarding its professional independence and objectivity with respect to Sava;

10. a description of the risk assessment and internal review process required by Section III.F;
11. a description of the Disclosure Program required by Section III.G;
12. a description of the Ineligible Persons screening and removal process required by Section III.H;
13. a copy of Sava's policies and procedures regarding the identification, quantification, and repayment of Overpayments required by Section III.J;
14. a description of Sava's corporate structure, including identification of any individual owners and investors, parent and sister companies, subsidiaries, affiliates, and their respective lines of business and landlords;
15. a list of all of Sava's locations (including locations and mailing addresses), the corresponding name under which each location is doing business, and the location's Medicare and state Medicaid program provider number and/or supplier number(s); and
16. the certifications required by Section V.C.

B. Annual Reports. Sava shall submit to OIG a report on its compliance with the CIA requirements for each of the five Reporting Periods (Annual Report). Each Annual Report shall include, at a minimum, the following information:

1. any change in the identity, position description, or other noncompliance job responsibilities of the Compliance Officer, a current list of the Compliance Committee members, a current list of the Board members who are responsible for satisfying the Board of Directors compliance obligations, and a current list of the Certifying Employees, along with the identification of any changes made during the Reporting Period to the Compliance Committee, Board of Directors, Certifying Employees and a description of any changes to the written process for Certifying Employees;
2. the dates of each report made by the Compliance Officer to the Board (written documentation of such reports shall be made available to OIG upon request);
3. a summary of activities and findings under Sava's Quality of Care Review Program and a summary of any corrective action taken in response to any

problems identified through its Quality of Care Review Program as required by Section III.A.2;

4. a summary of the Compliance Committee's measurement, analysis, and tracking of the performance metrics included in Sava's Dashboard, Sava's progress towards its quality improvement goals, and any changes to the Dashboard and the reasons for such changes, and activities, assessments, recommendations, and findings related to staffing and Sava's response to those findings;

5. the Board resolution required by Section III.A.3 and a description of the documents and other materials reviewed by the Board, as well as any additional steps taken, in its oversight of the compliance program and in support of making the resolution;

6. a list of any new or revised Policies and Procedures developed during the Reporting Period;

7. a description of any changes to Sava's Training Plan developed pursuant to Section III.C and summary of any Board of Directors training provided during the Reporting Period;

8. Sava's response and action plan(s) related to any written recommendations of the Monitor pursuant to Section III.D;

9. a complete copy of all reports prepared pursuant to Section III.E and Sava's response to the reports, along with corrective action plan(s) related to any issues raised by the reports;

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

11. a description of any changes to the risk assessment and internal review process required by Section III.F, including the reasons for such changes;

12. a summary of the following components of the risk assessment and internal review process during the Reporting Period: (a) work plans developed, (b) internal audits performed, (c) corrective action plans developed in response to internal audits, and (d) steps taken to track the implementation of the corrective action plans. Copies of any work plans, internal audit reports, and corrective action plans shall be made available to OIG upon request;

13. a summary of the disclosures in the disclosure log required by Section III.G that relate to Federal health care programs and delivery of resident care, including at least the following information: (a) a description of the disclosure, (b) the date the disclosure was received, (c) the resolution of the disclosure, and (d) the date the disclosure was resolved (if applicable). The complete disclosure log shall be made available to OIG upon request;

14. a description of any changes to the Ineligible Persons screening and removal process required by Section III.H, including the reasons for such changes;

15. a summary describing any ongoing investigation or legal proceeding required to have been reported pursuant to Section III.I. 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 any changes to the Overpayment policies and procedures required by Section III.J, including the reasons for such changes;

17. a description of all changes to the most recently provided list of Sava's locations as required by Section V.A.15;

18. a description of any changes to Sava's corporate structure, including any individual owners and investors, parent and sister companies, subsidiaries, affiliates, and their respective lines of business, and the landlord; and

19. 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

1. *Certifying Employees.* In each Annual Report, Sava shall include the certifications of Certifying Employees as required by Section III.A.4;



2. *Compliance Officer and Chief Executive Officer.* The Implementation Report and each Annual Report shall include a certification by the Compliance Officer and Chief Executive Officer that:

- a. to the best of his or her knowledge, except as otherwise described in the report, Sava has implemented and is in compliance with all of the requirements of this CIA;
- b. 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
- c. he or she understands that the certification is being provided to and relied upon by the United States.

D. Designation of Information. Sava 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. Sava 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

Sava:  
Annaliese Impink  
Executive Vice President -  
Compliance, Ethics and Customer Experience  
SavaSeniorCare Administrative and Consulting, LLC  
8601 Dunwoody Place, Suite 775  
Sandy Springs, GA 30350  
Cell: 678-488-2545  
[ANImpink@SavaSC.com](mailto:ANImpink@SavaSC.com)

Unless otherwise specified, all notifications and reports required by this CIA may be made by electronic mail, overnight mail, hand delivery, or other means, provided that there is proof that such notification was received. Upon request by OIG, Sava may be required to provide OIG with an additional copy of each notification or report required by this CIA in OIG's requested format (electronic or paper).

## **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 conduct interviews, examine and/or request copies of or to copy Sava's books, records, and other documents and supporting materials and conduct on-site reviews of any of Sava's locations for the purpose of verifying and evaluating: (a) Sava's compliance with the terms of this CIA; and (b) Sava's compliance with the requirements of the Federal health care programs. The documentation described above shall be made available by Sava to OIG or its duly authorized representative(s) at all reasonable times for inspection, audit, and/or reproduction. Furthermore, for purposes of this provision, OIG or its duly authorized representative(s) may interview any of Sava's owners, employees, contractors, and directors 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. Sava shall assist OIG or its duly authorized representative(s) in contacting and arranging interviews with such individuals upon OIG's request. Sava's owners, employees, contractors, and directors may elect to be interviewed with or without a representative of Sava present.

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

Sava 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 Sava prior to any release by OIG of information submitted by Sava pursuant to its obligations under this CIA and identified upon submission by Sava as trade secrets, or information that is commercial or financial and privileged or confidential, under the FOIA rules. With respect to such releases, Sava shall have the rights set forth at 45 C.F.R. § 5.42(a).

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

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

A. Specific Performance of CIA Provisions. The parties agree that, if OIG determines that Sava is failing to comply with a provision of this CIA, OIG may seek specific performance of that provision. OIG shall provide Sava with prompt written notification of such determination. (This notification shall be referred to as the "Noncompliance Notice.") Sava shall have 30 days from receipt of the Noncompliance Notice within which to either: (1) cure the alleged failure to comply; or (2) reply in writing that Sava disagrees with the determination of noncompliance and request a hearing before an HHS administrative law judge (ALJ), pursuant to the provisions set forth in Section X.F of this CIA.

B. Stipulated Penalties for Failure to Comply with Certain Obligations. As a contractual remedy, Sava 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 Sava fails to establish, implement, or comply with 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 Quality of Care Review Program;
- e. a Dashboard;
- f. the management certification obligations and the development and implementation of a written process for Certifying Employees;
- g. written Policies and Procedures;
- h. the development of a written training plan and the training and education of Covered Persons and Board Members;
- i. retention of a Monitor;
- j. a risk assessment and internal review process;
- k. a Disclosure Program;
- l. Ineligible Persons screening and removal requirements;
- m. notification of Government investigations or legal proceedings;
- n. policies and procedures regarding the repayment of Overpayments; and
- o. 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 Sava fails to engage and use an IRO, as required by Section III.E, Appendix B, or Appendix C.

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 Sava fails to submit any

Claims Review Report in accordance with the requirements of Section III.E and Appendix C or fails to repay any Overpayment identified by the IRO, as required by Appendix C;

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 Sava fails to submit a complete Implementation Report, Annual Reports, or any certification to OIG in accordance with the requirements of Section V by the deadlines for submission.

5. A Stipulated Penalty of \$1,500 for each day Sava fails to grant access as required in Section VII (This Stipulated Penalty shall begin to accrue on the date Sava fails to grant access.).

6. A Stipulated Penalty of \$50,000 for each false certification submitted by or on behalf of Sava as part of its Implementation Report, any Annual Report, additional documentation to a report (as requested by the OIG), or otherwise required by this CIA.

7. A Stipulated Penalty of \$2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day Sava fails to pay a Monitor, as required in Section III.D.5.

8. A Stipulated Penalty of \$2,500 for each day Sava fails to comply fully and adequately with any of its obligations with respect to the Monitor, including but not limited to the obligation to grant the Monitor access, as set forth in Section III.D.2, and the obligation to adequately and timely respond to any written recommendation of the Monitor, as set forth in Section III.D.6. OIG shall provide notice to Sava stating the specific grounds for its determination that Sava has failed to comply fully and adequately with the CIA obligation(s) at issue and steps Sava shall take to comply with the CIA. (This Stipulated Penalty shall begin to accrue 10 days after Sava receives this notice from OIG of the failure to comply.)

9. A Stipulated Penalty of \$2,500 for each day Sava fails to grant the IRO access to all records and personnel necessary to complete the reviews listed in Section III.E, and for each day Sava fails to furnish accurate and complete records to the IRO, as required by Section III.E and Appendix B.

10. A Stipulated Penalty of \$1,000 for each day Sava fails to comply fully and adequately with any obligation of this CIA. OIG shall provide notice to Sava stating the specific grounds for its determination that Sava has failed to comply fully and

adequately with the CIA obligation(s) at issue and steps Sava shall take to comply with the CIA. (This Stipulated Penalty shall begin to accrue 10 days after the date Sava 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 1-9 of this Section.

C. Timely Written Requests for Extensions. Sava 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 Sava 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 days after Sava 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 days prior to the date by which any act is due to be performed or any notification or report is due to be filed.

D. Payment of Stipulated Penalties

1. *Demand Letter.* Upon a finding that Sava has failed to comply with any of the obligations described in Section X.B and after determining that Stipulated Penalties are appropriate, OIG shall notify Sava of: (a) Sava'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, Sava shall either: (a) cure the breach to OIG's satisfaction and pay the applicable Stipulated Penalties; or (b) request a hearing before an ALJ to dispute OIG's determination of noncompliance, pursuant to the agreed upon provisions set forth below in Section X.F. In the event Sava elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until Sava 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.E.

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.E.1.d, these provisions for payment of Stipulated Penalties shall not affect or otherwise set a standard for OIG's decision that Sava has materially breached this CIA, which decision shall be made at OIG's discretion and shall be governed by the provisions in Section X.E, below.

E. Exclusion for Material Breach of this CIA

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

- a. repeated violations or a flagrant violation of any of the obligations under this CIA, including, but not limited to, the obligations addressed in Section X.B;
- b. a failure by Sava to report a Reportable Event, take corrective action, or make the appropriate refunds, as required in Section III.K;
- c. a violation of any obligation under this CIA that has a material impact on the quality of resident care;
- d. a failure to respond to a Noncompliance Notice concerning specific performance in accordance with Section X.A;
- e. a failure to respond to a Demand Letter concerning the payment of Stipulated Penalties in accordance with Section X.D;
- f. a failure to retain, pay, or use the Monitor, or failure to respond to the recommendations of the Monitor, in accordance with Section III.D: or
- g. a failure to engage and use an IRO in accordance with Section III.E, Appendix B, or Appendix C.

2. *Notice of Material Breach and Intent to Exclude.* The parties agree that a material breach of this CIA by Sava constitutes an independent basis for Sava's exclusion from participation in the Federal health care programs. The length of the

exclusion shall be in the OIG's discretion, but not more than five years per material breach. Upon a determination by OIG that Sava has materially breached this CIA and that exclusion is the appropriate remedy, OIG shall notify Sava of: (a) Sava'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.") The exclusion may be directed at one or more of Sava's facilities or corporate entities, depending upon the facts of the breach.

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

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

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

#### F. Dispute Resolution

1. *Review Rights.* Upon OIG's delivery to Sava of its Noncompliance Notice, Demand Letter, or Exclusion Letter, and as an agreed-upon contractual remedy for the resolution of disputes arising under this CIA, Sava 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 specific performance, Stipulated Penalties, or exclusion sought pursuant to this CIA. Specifically, OIG's determination to demand specific performance, payment of Stipulated Penalties, or 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 specific performance or 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. The procedures relating to the filing of a request for a hearing can be found at <http://www.hhs.gov/dab/division/civil/procedures/divisionprocedures.html>.

2. *Specific Performance 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 specific performance of CIA provisions shall be:

- a. whether, at the time specified in the Noncompliance Notice, Sava was in full and timely compliance with the obligations of this CIA for which OIG seeks specific performance; and
- b. whether Sava failed to cure.

Sava 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 specific performance. If the ALJ agrees with OIG, Sava shall take the actions OIG deems necessary to cure within 20 days after the ALJ issues such a decision unless Sava 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, Sava shall take the actions OIG deems necessary to cure within 20 days after the DAB issues its decision.

3. *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 Sava was in full and timely compliance with the obligations of this CIA for which OIG demands payment; and (b) the period of noncompliance. Sava 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 Sava to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable 20 days after the ALJ issues such a decision unless Sava 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.

4. *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 whether Sava was in material breach of this CIA and, if so, whether:

- a. Sava cured such breach within 30 days of its receipt of the Notice of Material Breach; or
- b. the alleged material breach could not have been cured within the 30-day period, but that, during the 30-day period following Sava's receipt of the Notice of Material Breach: (i) Sava had begun to take action to cure the material breach; (ii) Sava pursued such action with due diligence; and (iii) Sava provided to OIG a reasonable timetable for curing the material breach.

For purposes of the exclusion herein, exclusion shall take effect only after an ALJ decision favorable to OIG, or, if the ALJ rules for Sava, only after a DAB decision in favor of OIG. Sava's election of its contractual right to appeal to the DAB shall not abrogate OIG's authority to exclude Sava 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 Sava 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. Sava 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 Sava, Sava shall be reinstated effective on the date of the original exclusion.

5. *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**

Sava and OIG agree as follows:

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

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 Sava's obligations under this CIA based on a certification by Sava that it is no longer providing health care items or services that will be billed to any Federal health care program and 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 Sava is relieved of its CIA obligations, Sava shall be required to notify OIG in writing at least 30 days in advance if Sava 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. All requirements and remedies set forth in this CIA are in addition to and do not affect (1) Sava's responsibility to follow all applicable Federal health care program requirements or (2) the government's right to impose appropriate remedies for failure to follow applicable Federal health care program requirements.

E. The undersigned Sava signatories represent and warrant that they are authorized to execute this CIA. The undersigned OIG signatories represent that they are signing this CIA in their official capacities and that they are 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. Electronically-transmitted copies of signatures shall constitute acceptable, binding signatures for purposes of this CIA.

**ON BEHALF OF SAVA**

/Jerry S. Roles/

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Jerry S. Roles  
Chief Executive Officer

May 12, 2021

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DATE

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

/Lisa M. Re/

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5/13/21

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LISA M. RE  
Assistant Inspector General for Legal Affairs  
Office of Inspector General  
U. S. Department of Health and Human Services

DATE

/Sandra Sands/

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5/13/21

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SANDRA JEAN SANDS  
Senior Counsel  
Office of Inspector General  
U.S. Department of Health and Human Services

DATE

/Lisa Veigel/

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5/21/21

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LISA G. VEIGEL  
Senior Counsel  
Office of Inspector General  
U.S. Department of Health and Human Services

DATE

## APPENDIX A

### DATA ANALYSIS SUBCONTRACT DESCRIPTION

1. Under the Monitor's subcontract with a data analysis expert, as required by Section III.D of the CIA, the data analysis expert shall provide, at a minimum, the following reports to the Monitor and Sava on a quarterly basis:

- a. Facility Reports: a summary report for Sava, showing facility-level quality indicator (QI) values and information on the MDS assessments underlying these values.
- b. Facility Comparison Reports: a summary table that includes QI values for each facility covered by the CIA and allows Sava to compare the QI values among the facilities.
- c. Peer Comparison Reports: a summary report comparing Sava's QI values to the QI values of an appropriate peer comparison group.
- d. Resident Reports: if the data is available to the data analysis expert, a resident-level report showing which QI values were triggered by each resident in the Facility Report.

2. The data analysis expert will provide the Monitor with a QI User Guide, which will describe the format and contents of the reports listed above and provide QI definitions in terms of the underlying MDS assessment items.

## APPENDIX B

### 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. Sava 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 E. Within 30 days after OIG receives the information identified in Section V.A.9 of the CIA or any additional information submitted by Sava in response to a request by OIG, whichever is later, OIG will notify Sava if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, Sava may continue to engage the IRO.

2. If Sava engages a new IRO during the term of the CIA, that IRO must also meet the requirements of this Appendix. If a new IRO is engaged, Sava shall submit the information identified in Section V.A.9 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 Sava at the request of OIG, whichever is later, OIG will notify Sava if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, Sava may continue to engage the IRO.

#### B. IRO Qualifications

The IRO shall:

1. assign individuals to conduct the Claims Review who have expertise in the Medicare program requirements applicable to the claims being reviewed;
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 coding review portions of the Claims Review who have a nationally recognized coding certification and who have maintained this certification (e.g., completed applicable continuing education requirements);

4. assign licensed nurses or physicians with relevant education, training and specialized expertise (or other licensed health care professionals acting within their scope of practice and specialized expertise) to make the medical necessity determinations required by the Claims Review; and

5. 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 in accordance with the specific requirements of the CIA;

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

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

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 C to the CIA.

D. Sava Responsibilities

Sava shall ensure that the IRO has access to all records and personnel necessary to complete the reviews listed in III.D of this CIA and that all records furnished to the IRO are accurate and complete.

E. 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 U.S. Government Accountability Office.



F. IRO Removal/Termination

1. *Sava and IRO.* If Sava terminates its IRO or if the IRO withdraws from the engagement during the term of the CIA, Sava must submit a notice explaining (a) its reasons for termination of the IRO or (b) the IRO's reasons for its withdrawal to OIG, no later than 30 days after termination or withdrawal. Sava 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 E, or has failed to carry out its responsibilities as described in Paragraph C, OIG shall notify Sava in writing regarding OIG's basis for determining that the IRO has not met the requirements of this Appendix. Sava shall have 30 days from the date of OIG's written notice to provide information regarding the IRO's qualifications, independence or performance of its responsibilities in order to resolve the concerns identified by OIG. If, following OIG's review of any information provided by Sava regarding the IRO, OIG determines that the IRO has not met the requirements of this Appendix, OIG shall notify Sava in writing that Sava shall be required to engage a new IRO in accordance with Paragraph A of this Appendix. Sava must engage a new IRO within 60 days of its receipt of OIG's written notice. The final determination as to whether or not to require Sava to engage a new IRO shall be made at the sole discretion of OIG.

## APPENDIX C

### SKILLED NURSING FACILITY CLAIMS REVIEW

A. Claims Review. The IRO shall perform the Skilled Nursing Facility Claims Review (Claims Review) annually to cover each of the five Reporting Periods. The Claims Review shall be conducted at 5% of Sava's facilities or at least 10 facilities, whichever is greater ("Subject Facilities"), for each Reporting Period. 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 Sava has received in excess of the amount due and payable under Medicare program requirements, as determined by the IRO in connection with the Claims Review performed under this Appendix C.
- b. Patient Stay: A covered Medicare Part A stay in a Subject Facility during the Reporting Period under review.
- c. Paid Claim: A claim submitted by Sava and for which Sava has received reimbursement from the Medicare Part A program.
- d. Population: The Population shall be defined as all Patient Stays for which at least one Paid Claim was submitted during the 12-month period covered by the Claims Review.

2. *Selection of Subject Facilities*. OIG shall select the Subject Facilities and provide the identities of those facilities to the IRO at least 30 days before the end of each Reporting Period. In order to facilitate the OIG's selection of the Subject Facilities, at least 90 days prior to the end of the Reporting Period, Sava shall furnish to OIG the most recent Program for Evaluating Payment Patterns Electronic Report ("PEPPER") and the following data for each Sava facility for the prior calendar year: (1) geographic location, (2) Federal health care program patient census, (3) Medicare revenues, (4) average patient lengths of stay, and (5) other data determined by the OIG in its discretion.

3. *Claims Review Sample*. The IRO shall randomly select and review a sample of 30 Patient Stays in the Population at each Subject Facility (each selection of

Patient Stays at a Subject Facility shall be referred to as a “Claims Review Sample”). The IRO shall review the Patient Stay and all Paid Claims associated with each selected Patient Stay. The Patient Stay and associated Paid Claims shall be reviewed based on the supporting documentation available at Sava’s office or under Sava’s control, and applicable Medicare program requirements and practice guidelines endorsed by the American Physical Therapy Association, the American Occupational Therapy Association, and the American Speech-Language-Hearing Association to determine whether the items and services furnished were (a) medically necessary and reasonable, (b) appropriate and sufficient to meet the needs of a patient in the assigned Case Mix Groups, (c) appropriately documented, and (d) whether the associated Paid Claims were correctly coded, submitted, and reimbursed. The IRO’s review shall include a review of the following:

- a. eligibility for skilled nursing, rehabilitation therapy, and non-therapy ancillary services;
- b. required physician orders;
- c. comprehensive assessments to determine the individual needs of the patient;
- d. comprehensive care planning;
- e. provision of nursing, therapy, and non-therapy ancillary services according to the individualized care plans;
- f. provision of rehabilitation therapy services that are medically necessary and reasonable given the patient’s condition to improve, maintain, or slow deterioration of the patient’s condition, or restore his or her prior levels of function;
- g. discharge planning; and
- h. whether the information in the Minimum Data Set (MDS) associated with a Patient Stay that affects reimbursement is supported by the medical record.

For each Paid Claim associated with a Patient Stay in the Claims Review Sample that results in an Overpayment, the IRO shall review the system(s) and process(es) that generated the Paid 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 process(es) that generated the Paid Claim.

4. *Other Requirements.*

- a. Supplemental Materials. The IRO shall request all documentation and materials required for its review of each Paid Claims associated with each Patient Stay selected as part of the Claims Review Sample and Sava shall furnish such documentation and materials for each Paid Claim associated with each Patient Stay selected as part of the Claims Review Sample to the IRO prior to the IRO initiating its review of a specific Patient Stay in the Claims Review Sample. If the IRO accepts any supplemental documentation or materials from Sava after the IRO has completed its initial review of a particular Patient Stay selected as part of the Claims Review Samples (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 Sava cannot produce documentation shall be considered an error and the total reimbursement received by Sava 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 the Claims Review Sample discussed in this Appendix, the first set of Patient Stays selected for the Subject Facility 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 a Claims Review Sample).

5. *Repayment of Identified Overpayments.* Sava shall repay within 60 days any Overpayment(s) identified by the IRO in the Claims Review Sample, in accordance with the requirements of 42 U.S.C. § 1320a-7k(d) and 42 C.F.R. § 401.301-305 (and any

applicable CMS guidance) (the “CMS overpayment rule”). If Sava determines that the CMS overpayment rule requires that an extrapolated Overpayment be repaid for any of the Subject Facilities, Sava shall repay that amount at the mean point estimate as calculated by the IRO. Sava shall make available to OIG all documentation that reflects the refund of the Overpayment(s) to the payor. OIG, in its sole discretion, may refer the findings of the Claims Review (and any related work papers) received from Sava to the appropriate Medicare contractor for appropriate follow up by 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 Claims Review Sample.

1. *Claims Review Methodology*.
  - a. Review Population. A description of the Population subject to the Claims Review.
  - b. Review Objective. A clear statement of the objective intended to be achieved by the Claims Review.
  - c. Source of Data. A description of (1) the process used to identify the Patient Stays in the Population and (2) the specific documentation and other information sources relied upon by the IRO when performing the Claims Review (e.g., patient medical records, Sava policies and procedures; Medicare carrier or intermediary manual or bulletins (including issue and date); practice guidelines endorsed by the American Physical Therapy Association, the American Occupational Therapy Association, and the American Speech-Language-Hearing Association; and 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 description or identification of the statistical sampling software package used by the IRO.
3. *Claims Review Findings.*
- a. Narrative Results.
    - i. A description of Sava’s billing and coding system(s), including the identification, by position description, of the personnel involved in the coding and billing.
    - ii. A description of the controls in place at Sava to ensure that all items and services billed to Medicare Part A are medically necessary and reasonable, appropriate and sufficient to meet the needs of a patient in the assigned Case Mix Groups, and appropriately documented.
    - iii. 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 Claims Review Sample and the IRO’s findings regarding items A.3.a-h above.
  - b. Quantitative Results.
    - i. Total number and percentage of instances in which the IRO determined that the coding of the Paid Claims submitted by Sava differed from what should have been the correct coding and in which such difference resulted in an Overpayment to Sava.
    - ii. Total number and percentage of instances in which the IRO determined that a Paid Claim was not appropriately

documented and in which such documentation errors resulted in an Overpayment to Sava.

- iii. Total number and percentage of instances in which the IRO determined that a Paid Claim was for items or services that were not medically necessary and resulted in an Overpayment to Sava.
- iv. Total number and percentage of instances in which the IRO determined that a Paid Claim was for items and services that were not appropriate and sufficient to meet the needs of a patient in the assigned Case Mix Groups and resulted in an Overpayment to Sava.
- v. Total dollar amount of all Overpayments in the Claim Review Sample.
- vi. Total dollar amount of Paid Claims in the Claims Review Sample.
- vii. Error Rate in the Claims Review Sample. The Error Rate shall be calculated by dividing the Overpayment in Claims Review Sample by the total dollar amount associated with the Paid Claims in the Claims Review Sample.
- viii. An estimate of the Overpayment in the Population at the mean point estimate.
- ix. A spreadsheet of the Claims Review results for each Subject Facility that includes the following information for each selected Patient Stay and the associated Paid Claims: the Federal health care program billed; beneficiary health insurance claim number, dates of service, code submitted (e.g., PDPM or RUG code), code reimbursed, allowed amount 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 Sava's billing and coding system or to Sava's controls for ensuring that all items and services billed to Medicare Part A are medically necessary and reasonable, appropriate and sufficient to meet the needs of a patient in the assigned Case Mix Groups, and appropriately documented, based on the findings of the Claims Review.

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