

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

**I. PREAMBLE**

Arizant Inc. and any subsidiary thereof doing business in the United States (Arizant) hereby enters into this Corporate Integrity Agreement (CIA) with the Office of Inspector General (OIG) of the United States Department of Health and Human Services (HHS) in order 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, Arizant is entering into a Settlement Agreement with the United States, and this CIA is incorporated by reference into the Settlement Agreement.

Arizant conducts business with various government programs, primarily through its customers who supply items manufactured by Arizant to beneficiaries covered by Medicare, Medicaid, and other Federal health care programs. Since 2003, Arizant has operated a voluntary compliance program, which, as represented by Arizant, includes a Compliance Help-Line and regular training to all employees and other appropriate individuals concerning Arizant's Code of Conduct and related compliance program. This training also includes review of disciplinary procedures aimed, in part, at ensuring that Arizant's activities are in compliance with all Federal health care program requirements and meeting Arizant's goals of promoting high ethical standards in the conduct of Arizant's business practices. Arizant agrees to continue the operation of its compliance measures in accordance with the terms set forth below for the term of this CIA. Arizant may modify its voluntary compliance measures as appropriate, but, at a minimum, Arizant shall ensure that during the term of the CIA, it shall comply with the obligations set forth in this CIA.

## **II. TERM AND SCOPE OF THE CIA**

A. The period of the compliance obligations assumed by Arizant under this CIA shall be 5 years from the effective date of this CIA, unless otherwise specified. The effective date shall be the date on which the final signatory of this CIA executes this CIA (Effective Date). Each one-year period, beginning with the one-year period following the Effective Date, shall be referred to as a “Reporting Period.”

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

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

1. “Covered Persons” includes:
  - a. all officers, directors, and employees of Arizant; and
  - b. all individuals that sell or market on behalf of Arizant items or services for which reimbursement may be made by the Federal health care programs, with the exception of unrelated third parties that purchase products in arms-length transactions and then distribute such items or services i.e., wholesalers or distributors whose only relationship with Arizant is the purchase of such items or services, and unrelated group purchasing organizations that market Arizant products to their members.

Notwithstanding the above, this term does not include part-time or per diem employees, contractors, subcontractors, agents, and other persons who are not reasonably expected to work more than 160 hours per year, except that any such individuals shall become “Covered Persons” at the point when they work more than 160 hours during the calendar year.

2. “Relevant Covered Persons” includes all Covered Persons that engage in the marketing or sale on behalf of Arizant of items or

services for which reimbursement may be made by the Federal health care programs.

3. “Compliance Officer” means an individual possessing suitable knowledge, training, education, and credentials in the medical device manufacturing process.
4. “Compliance Committee” means a group of individuals from senior management, in accordance with Section III.C.2, who will function exclusive of and in addition to the management review pursuant to 21 C.F.R. § 820.20(c); provided that Compliance Committee members may also be participants in such management review.

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

Arizant shall maintain its Compliance Program, which shall include the following elements:

#### **A. Compliance Officer and Committee.**

1. *Compliance Officer.* Arizant shall maintain a Compliance Officer for the term of the CIA. The Compliance Officer shall be responsible for developing and implementing policies, procedures, and practices designed to ensure compliance with the requirements set forth in this CIA and with Federal health care program requirements. The Compliance Officer shall be a member of senior management of Arizant, shall make periodic (at least quarterly) reports regarding compliance matters directly to the Board of Directors of Arizant, and shall be authorized to report on such matters to the Board of Directors at any time. The Compliance Officer shall not be or be subordinate to the General Counsel or Chief Financial Officer. The Compliance Officer shall be responsible for monitoring the day-to-day compliance activities engaged in by Arizant as well as for any reporting obligations created under this CIA.

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

2. *Compliance Committee.* Arizant shall maintain a Compliance Committee for the term of the CIA. The Compliance Committee shall, at a minimum, include the Compliance Officer and other members of senior management necessary to meet the requirements of this CIA (e.g., senior executives of relevant departments, such as billing, clinical, human resources, audit, and operations). The Compliance Officer shall chair the Compliance Committee and the Committee shall support the Compliance Officer in fulfilling his/her responsibilities (e.g., shall assist in the analysis of the organization's risk areas and shall oversee monitoring of internal and external audits and investigations).

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

B. Written Standards.

1. *Code of Conduct.* Arizant shall maintain its written Code of Conduct. Arizant shall make the promotion of, and adherence to, the Code of Conduct an element in evaluating the performance of all employees. The Code of Conduct shall, at a minimum, set forth:

- a. Arizant's commitment to full compliance with all Federal health care program requirements;
- b. Arizant's requirement that all of its Covered Persons shall be expected to comply with all Federal health care program requirements and with Arizant's own Policies and Procedures as implemented pursuant to this Section III.B (including the requirements of this CIA);
- c. the requirement that all of Arizant's Covered Persons shall be expected to report to the Compliance Officer or other appropriate individual designated by Arizant suspected violations of any Federal health care program requirements or of Arizant's own Policies and Procedures;

- d. the possible consequences to both Arizant and Covered Persons of failure to comply with Federal health care program requirements and with Arizant's own Policies and Procedures and the failure to report such noncompliance; and
- e. the right of all individuals to use the Disclosure Program described in Section III.E, and Arizant's commitment to nonretaliation and to maintain, as appropriate, confidentiality and anonymity with respect to such disclosures.

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

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

2. Policies and Procedures. To the extent not already accomplished, within 90 days after the Effective Date, Arizant shall implement written Policies and Procedures regarding the operation of Arizant's compliance program and its compliance with Federal health care program requirements. At a minimum, the Policies and Procedures shall address:

- a. the subjects relating to the Code of Conduct identified in Section III.B.1;
- b. the Federal health care programs' use of codes from the Healthcare Common Procedure Coding System (HCPCS) in identifying the services and items for which health care providers seek reimbursement;

- c. how to handle questions from Arizant's customers regarding Medicare or Medicaid reimbursement for Arizant's products;
- d. how to disseminate information regarding reimbursement for Arizant's products;
- e. current sources of official guidance from fiscal intermediaries and/or the Centers for Medicare and Medicaid Services (CMS) regarding reimbursement questions;
- f. proper methods of promoting, marketing, and selling items and services for which Federal health care program reimbursement may be made, in accordance with all applicable statutes, regulations, and requirements, including, but not limited to, the federal anti-kickback statute;
- g. the personal obligation of each individual involved in the marketing and sales of items and services for which Federal health care program reimbursement may be made to ensure that those products are marketed and sold in accordance with all applicable Federal health care program requirements.

Within 90 days after the Effective Date, the relevant portions of the Policies and Procedures shall be distributed to all individuals whose job functions relate to those Policies and Procedures. Appropriate and knowledgeable staff shall be available to explain the Policies and Procedures.

At least annually, Arizant shall assess and update as necessary the Policies and Procedures. Within 30 days after the effective date of any revisions, the relevant portions of any such revised Policies and Procedures shall be distributed to all individuals whose job functions relate to those Policies and Procedures.

### C. Training and Education.

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

- a. CIA requirements; and
- b. Arizant's Compliance Program (including the Code of Conduct and the Policies and Procedures as they pertain to general compliance issues).

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

2. *Specific Training.* Within 90 days after the Effective Date, each Relevant Covered Person shall receive at least 5 hours of Specific Training in addition to the General Training required above. This Specific Training shall include a discussion of:

- a. proper methods of promoting, marketing, and selling items and services for which Federal health care program reimbursement may be made, in accordance with all applicable statutes, regulations, and requirements, including, but not limited to, the federal anti-kickback statute and the Policies and Procedures required by this CIA;
- b. the personal obligation of each individual involved in the marketing and sales of items and services for which Federal health care program reimbursement may be made to ensure that those products are marketed and sold in accordance with all applicable Federal health care program requirements;
- c. the personal obligation of each individual involved in Arizant's customer relations, sales, and marketing functions to ensure that customers are given accurate information regarding Arizant's products, or redirected to payer resources;
- d. Arizant's requirement that all of its Covered Persons shall be expected to comply with all Federal health care program requirements and with Arizant's own Policies and Procedures

as implemented pursuant to Section III.B (including the requirements of this CIA);

- e. applicable reimbursement statutes, regulations, and program requirements and directives;
- f. the legal sanctions for violations of the Federal health care program requirements;
- g. publicly available government documents regarding Federal health care program coverage of Arizant products; and
- h. payer contact information.

Relevant Covered Persons shall receive this training within 30 days after the beginning of their employment or becoming Relevant Covered Persons, or within 90 days after the Effective Date, whichever is later. An Arizant employee who has completed the Specific Training shall review a new Relevant Covered Person's work, to the extent that the work relates to the marketing or sale of items or services reimbursable by Federal health care programs, until such time as the new Relevant Covered Person completes his or her Specific Training.

After receiving the initial Specific Training described in this Section, each Relevant Covered Person shall receive at least 3 hours of Specific Training annually.

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

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

5. *Update of Training.* Arizant shall annually review the training, and, where appropriate, update the training to reflect changes in Federal health care program requirements, any issues discovered during internal audits or the IRO Sales and Marketing Engagement, and any other relevant information.



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

D. Review Procedures.

1. *General Description.*

a. Retention of Independent Review Organization. Within 90 days after the Effective Date, Arizant shall retain an entity (or entities), such as an accounting, auditing, law, or consulting firm (hereinafter “Independent Review Organization” or “IRO”), to perform reviews to assist Arizant in assessing and evaluating its sales and marketing systems, processes, policies, and procedures. Each IRO retained by Arizant shall have appropriate expertise in the engagements to be performed. Each IRO shall assess, along with Arizant, whether it can perform the IRO review in a professionally independent and/or objective fashion, as appropriate to the nature of the engagement, taking into account any other business relationships or engagements that may exist. Prior to conducting the engagements set forth below, the IRO shall submit its workplan(s) to the OIG for approval. However, any comments or recommendations made by the OIG in connection with a review of the submitted workplan(s) will not preclude the OIG from making further comments or recommendations for future workplan(s) after reviewing the applicable IRO report(s).

b. IRO Engagements. The IRO shall perform engagements to assist Arizant in assessing and evaluating its systems, processes, policies and procedures related to the sales and marketing of items and services for which Federal health care program reimbursement may be made (Sales and Marketing Engagement). Each Sales and Marketing Engagement shall be performed annually and shall cover each of the Reporting Periods as defined below. The objectives of the Sales and Marketing engagement shall be (i) to examine the

accuracy of information provided by Arizant to its customers relating to Federal health care program reimbursement, if any, for its products; and (ii) to test whether Arizant's sales and marketing activities, including Arizant's customer-related business expenditures, comply with the federal anti-kickback statute.

c. Retention of Records. The IRO and Arizant shall retain and make available to OIG, upon request, all work papers, supporting documentation, correspondence, and draft reports (those exchanged between the IRO and Arizant) related to the reviews, in accordance with the document retention requirements of Section VIII below.

2. *Sales and Marketing Engagement Report*. The IRO shall prepare a report based upon each Sales and Marketing Engagement performed (Sales and Marketing Engagement Report). At a minimum, the Sales and Marketing Engagement Report shall include: (a) a clear statement of the objective intended to be achieved by the Sales and Marketing Engagement; (b) a description of the specific documentation relied upon and individuals interviewed by the IRO when performing its review; (c) a narrative description of how the Sales and Marketing Engagement was conducted; (d) the results, conclusions, and recommendations developed by the IRO based upon the review performed; and (e) the names and credentials of the individuals who performed the Sales and Marketing Engagement.

3. *Validation Review*. In the event OIG has reason to believe that: (a) Arizant's Sales and Marketing Engagement fails to conform to the requirements of this CIA; or (b) the IRO's findings or engagement results are inaccurate, OIG may, at its sole discretion, conduct its own review to determine whether the particular engagement complied with the requirements of the CIA and/or the findings or engagement results are inaccurate ("Validation Review"). Arizant shall pay for the reasonable cost of any such review performed by OIG or any of its designated agents so long as it is initiated within one year after Arizant's final submission (as described in Section II) is received by OIG.

Prior to initiating a Validation Review, OIG shall notify Arizant of its intent to do so and provide a written explanation of why OIG believes such a review is necessary. To resolve any concerns raised by OIG, Arizant may request a meeting with OIG to discuss the results of any Sales and Marketing Engagement submissions or findings; present any additional or relevant information to clarify the results of the particular engagement or to correct the inaccuracy of the engagement findings; or propose alternatives to the proposed

Validation Review. Arizant shall provide any additional information as may be requested by OIG under this Section in an expedited manner. OIG will attempt in good faith to resolve any questions regarding an engagement with Arizant prior to conducting a Validation Review. However, the final determination as to whether or not to proceed with a Validation Review shall be made at the sole discretion of OIG.

4. *Independence/Objectivity Certification.* The IRO shall include in its report(s) to Arizant a certification or sworn affidavit that it has evaluated its professional independence and/or objectivity, as appropriate to the nature of the engagement, with regard to the Sales and Marketing Engagement and that it has concluded that it is, in fact, independent and/or objective.

E. Disclosure Program.

Arizant shall maintain its Disclosure Program that includes the Compliance Help-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 Arizant's policies, conduct, practices, or procedures with respect to a Federal health care program believed by the individual to be a potential violation of criminal, civil, or administrative law. Arizant shall appropriately publicize the existence of the disclosure mechanism (e.g., via periodic e-mails to employees or by posting the information in prominent common areas).

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

The Compliance Officer shall maintain a disclosure log, which shall include a record and summary of each disclosure received (whether anonymous or not), the status

of the respective internal reviews, and any corrective action taken in response to the internal reviews. The disclosure log shall be made available to OIG, upon request.

F. Ineligible Persons.

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

- a. an “Ineligible Person” shall include an individual or entity who:
  - i. is currently excluded, debarred, suspended, or otherwise ineligible to participate in the Federal health care programs or in Federal procurement or nonprocurement programs; or
  - ii. has been convicted of a criminal offense that falls within the ambit of 42 U.S.C. § 1320a-7(a), but has not yet been excluded, debarred, suspended, or otherwise declared ineligible.
- b. “Exclusion Lists” include:
  - i. the HHS/OIG List of Excluded Individuals/Entities (available through the Internet at <http://oig.hhs.gov>); and
  - ii. the General Services Administration’s List of Parties Excluded from Federal Programs (available through the Internet at <http://epls.arnet.gov>).
- c. “Screened Persons” include prospective and current owners (other than owners who are solely shareholders and who have an ownership interest of less than 5%), officers, directors, employees, contractors, and agents of Arizant.

2. *Screening Requirements.* Arizant shall ensure that all Screened Persons are not Ineligible Persons, by implementing the following screening requirements.

- a. Arizant shall screen all Screened Persons against the Exclusion Lists prior to engaging their services and, as part of the hiring or

contracting process, shall require such persons to disclose whether they are an Ineligible Person.

- b. Arizant shall screen all Screened Persons against the Exclusion Lists within 90 days after the Effective Date and on an annual basis thereafter.
- c. Arizant shall implement a policy requiring all Screened Persons to disclose immediately any debarment, exclusion, suspension, or other event that makes that person an Ineligible Person.

Nothing in this Section affects the responsibility of (or liability for) Arizant to refrain from billing Federal health care programs for items or services furnished, ordered, or prescribed by an Ineligible Person.

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

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

G. Notification of Government Investigation or Legal Proceedings.

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

#### H. Reporting.

##### 1. *Reportable Events.*

a. Definition of Reportable Event. For purposes of this CIA, a “Reportable Event” means anything that involves 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. A Reportable Event may be the result of an isolated event or a series of occurrences.

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

- i. a complete description of the Reportable Event, including the relevant facts, persons involved, and legal and Federal health care program authorities implicated;
- ii. a description of Arizant’s actions taken to correct the Reportable Event; and
- iii. any further steps Arizant plans to take to address the Reportable Event and prevent it from recurring.

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

In the event that, after the Effective Date, Arizant changes locations or sells, closes, purchases, or establishes a new business unit or location related to the furnishing of items or services that may be reimbursed by Federal health care programs, Arizant shall notify OIG of this fact as soon as possible, but no later than within 30 days after the date of change of location, sale, closure, purchase, or establishment. This notification shall include the address of the new business unit or location, phone number, fax number, Medicare provider number, provider identification number and/or supplier number, and the corresponding contractor's name and address that has issued each Medicare number. Each new business unit or location shall be subject to all the requirements of this CIA.

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

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

1. the name, address, phone number, and position description of the Compliance Officer required by Section III.A, and a summary of other noncompliance job responsibilities the Compliance Officer may have;
2. the names and positions of the members of the Compliance Committee required by Section III.A;
3. a copy of Arizant's Code of Conduct required by Section III.B.1;
4. a copy of all Policies and Procedures required by Section III.B.2;
5. the number of individuals required to complete the Code of Conduct certification required by Section III.B.1, the percentage of individuals who have completed such certification, and an explanation of any exceptions (the documentation supporting this information shall be available to OIG, upon request);

6. the following information regarding each type of training required by Section III.C:
  - a. a description of such training, including a summary of the topics covered, the length of sessions and a schedule of training sessions;
  - b. number of individuals required to be trained, percentage of individuals actually trained, and an explanation of any exceptions.

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

7. a description of the Disclosure Program required by Section III.E;
8. the following information regarding the IRO(s): (a) identity, address, and phone number; (b) a copy of the engagement letter; (c) a summary and description of any and all current and prior engagements and agreements between Arizant and the IRO; and (d) the proposed start and completion dates of the Sales and Marketing Engagement;
9. a certification from the IRO regarding its professional independence and/or objectivity with respect to Arizant;
10. a description of the process by which Arizant fulfills the requirements of Section III.F regarding Ineligible Persons;
11. the name, title, and responsibilities of any person who is determined to be an Ineligible Person under Section III.F; the actions taken in response to the screening and removal obligations set forth in Section III.F; and the actions taken to identify, quantify, and repay any overpayments to Federal health care programs relating to items or services furnished, ordered or prescribed by an Ineligible Person;
12. a list of all of Arizant's locations (including locations and mailing addresses); the corresponding name under which each location is



doing business; the corresponding phone numbers and fax numbers; each location's Medicare provider number(s), if any, provider identification number(s) and/or supplier number(s), if any; and the name and address of each Medicare contractor to which Arizant currently submits claims, if any;

13. a description of Arizant's corporate structure, including identification of any parent and sister companies, subsidiaries, and their respective lines of business; and
14. the certifications required by Section V.C.

B. Annual Reports. Arizant shall submit to OIG annually a report with respect to the status of, and findings regarding, Arizant's compliance activities for each of the 5 Reporting Periods (Annual Report).

Each Annual Report shall include, at a minimum:

1. any change in the identity, position description, or other noncompliance job responsibilities of the Compliance Officer and any change in the membership of the Compliance Committee described in Section III.A;
2. a summary of any significant changes or amendments to the Policies and Procedures required by Section III.B and the reasons for such changes (e.g., change in contractor policy) and copies of any compliance-related Policies and Procedures;
3. the number of individuals required to complete the Code of Conduct certification required by Section III.B.1, the percentage of individuals who have completed such certification, and an explanation of any exceptions (the documentation supporting this information shall be available to OIG, upon request);
4. the following information regarding each type of training required by Section III.C:

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

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

5. a complete copy of all Sales and Marketing Engagement Reports prepared pursuant to Section III.D, along with a copy of the IRO's engagement letter (if applicable);
6. Arizant's response and corrective action plan(s) related to any issues raised by the reports prepared pursuant to Section III.D;
7. summary and description of any and all current and prior engagements and agreements between Arizant and the IRO, if different from what was submitted as part of the Implementation Report;
8. a certification from the IRO regarding its professional independence and/or objectivity with respect to Arizant;
9. a summary of Reportable Events (as defined in Section III.H) identified during the Reporting Period and the status of any corrective and preventative action relating to all such Reportable Events;
10. a summary of the disclosures in the disclosure log required by Section III.E that relate to Federal health care programs;
11. any changes to the process by which Arizant fulfills the requirements of Section III.F regarding Ineligible Persons;
12. the name, title, and responsibilities of any person who is determined

to be an Ineligible Person under Section III.F; the actions taken by Arizant in response to the screening and removal obligations set forth in Section III.F; and the actions taken to identify, quantify, and repay any overpayments to Federal health care programs relating to items or services relating to items or services furnished, ordered or prescribed by an Ineligible Person;

13. a summary describing any ongoing investigation or legal proceeding required to have been reported pursuant to Section III.G. The summary shall include a description of the allegation, the identity of the investigating or prosecuting agency, and the status of such investigation or legal proceeding;
14. a description of all changes to the most recently provided list of Arizant's locations (including addresses) as required by Section V.A.11; the corresponding name under which each location is doing business; the corresponding phone numbers and fax numbers; each location's Medicare provider number(s), provider identification number(s), and/or supplier number(s), if any; and
15. the certifications required by Section V.C.

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

C. Certifications. The Implementation Report and Annual Reports shall include a certification by the Compliance Officer that:

- (1) to the best of his or her knowledge, except as otherwise described in the applicable report, Arizant is in compliance with all of the requirements of this CIA;
- (2) he or she has reviewed the Report and has made reasonable inquiry regarding its content and believes that the information in the Report is accurate and truthful; and
- (3) Arizant has complied with its obligations under the Settlement

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

D. Designation of Information. Arizant 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. Arizant 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

Arizant:

David Westlin  
Compliance Officer  
Arizant Inc.  
10393 West 70th Street  
Eden Prairie, MN 55344  
Telephone: (952) 947-1277  
Facsimile: (952) 918-5277

Unless otherwise specified, all notifications and reports required by this CIA may be made by certified mail, overnight mail, hand delivery, or other means, provided that there is proof that such notification was received. For purposes of this requirement, internal facsimile confirmation sheets do not constitute proof of receipt.

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

In addition to any other rights OIG may have by statute, regulation, or contract, OIG or its duly authorized representative(s) may examine or request copies of Arizant's books, records, and other documents and supporting materials and/or conduct on-site reviews of any of Arizant's locations for the purpose of verifying and evaluating: (a) Arizant's compliance with the terms of this CIA; and (b) Arizant's compliance with the requirements of the Federal health care programs in which it participates. The documentation described above shall be made available by Arizant to OIG or its duly authorized representative(s) at all reasonable times for inspection, audit, or reproduction. Furthermore, for purposes of this provision, OIG or its duly authorized representative(s) may interview any of Arizant's employees, contractors, or agents who consent to be interviewed at the individual's place of business during normal business hours or at such other place and time as may be mutually agreed upon between the individual and OIG. Arizant shall assist OIG or its duly authorized representative(s) in contacting and arranging interviews with such individuals upon OIG's request. Arizant's employees may elect to be interviewed with or without a representative of Arizant present.

**VIII. DOCUMENT AND RECORD RETENTION**

Arizant shall maintain for inspection all documents and records relating to reimbursement from the Federal health care programs, or to compliance with this CIA, for 6 years.

## **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 Arizant prior to any release by OIG of information submitted by Arizant pursuant to its obligations under this CIA and identified upon submission by Arizant as trade secrets, or information that is commercial or financial and privileged or confidential, under the FOIA rules. With respect to such releases, Arizant shall have the rights set forth at 45 C.F.R. § 5.65(d). Nothing in this CIA, or any communication or report made pursuant to this CIA, shall constitute a waiver of, or be construed to require Arizant to waive, Arizant's attorney-client, work product, or other applicable privileges. Notwithstanding that fact, the existence of any such privilege shall not affect Arizant's obligation to comply with the provisions of this CIA, e.g., by providing all documents necessary to determine whether Arizant is in compliance with the terms of the CIA.

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

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

A. Stipulated Penalties for Failure to Comply with Certain Obligations. As a contractual remedy, Arizant 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 Arizant fails to establish and implement any of the following obligations as described in Section III:

- a. a Compliance Officer;
- b. a Compliance Committee;
- c. a written Code of Conduct;
- d. written Policies and Procedures;

- e. the training of Covered Persons;
- f. a Disclosure Program;
- g. Ineligible Persons screening and removal requirements; and
- h. Notification of Government Investigations or Legal Proceedings.

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 Arizant fails to engage an IRO, as required in Section III.D and Appendix A.

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 Arizant fails to submit the Implementation Report or the Annual Reports to OIG in accordance with the requirements of Section V by the deadlines for submission.

4. A Stipulated Penalty of \$2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day Arizant fails to submit the annual Sales and Marketing Engagement Report in accordance with the requirements of Section III.D and Appendix A.

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

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

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

Stipulated Penalty under Subsections 1-6 of this Section.

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

C. Payment of Stipulated Penalties.

1. *Demand Letter*. Upon a finding that Arizant has failed to comply with any of the obligations described in Section X.A and after determining that Stipulated Penalties are appropriate, OIG shall notify Arizant of: (a) Arizant's failure to comply; and (b) OIG's exercise of its contractual right to demand payment of the Stipulated Penalties (this notification is referred to as the "Demand Letter").

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

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



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

D. Exclusion for Material Breach of this CIA.

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

- a. a failure by Arizant to report a Reportable Event and take corrective action, as required in Section III.H;
- b. a repeated or flagrant violation of the obligations under this CIA, including, but not limited to, the obligations addressed in Section X.A;
- c. a failure to respond to a Demand Letter concerning the payment of Stipulated Penalties in accordance with Section X.C; or
- d. a failure to engage and use an IRO in accordance with Section III.D.

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

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

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

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

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

#### E. Dispute Resolution

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

2. *Stipulated Penalties Review.* Notwithstanding any provision of Title 42 of the United States Code or Title 42 of the Code of Federal Regulations, the only issues in a proceeding for Stipulated Penalties under this CIA shall be: (a) whether Arizant was

in full and timely compliance with the obligations of this CIA for which OIG demands payment; and (b) the period of noncompliance. Arizant 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 Arizant to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable 20 days after the ALJ issues such a decision unless Arizant requests review of the ALJ decision by the DAB. If the ALJ decision is properly appealed to the DAB and the DAB upholds the determination of OIG, the Stipulated Penalties shall become due and payable 20 days after the DAB issues its decision.

3. *Exclusion Review.* Notwithstanding any provision of Title 42 of the United States Code or Title 42 of the Code of Federal Regulations, the only issues in a proceeding for exclusion based on a material breach of this CIA shall be:

- a. whether Arizant was in material breach of this CIA;
- b. whether such breach was continuing on the date of the Exclusion Letter; and
- c. whether the alleged material breach could not have been cured within the 30-day period, but that: (i) Arizant had begun to take action to cure the material breach within that period; (ii) Arizant has pursued and is pursuing such action with due diligence; and (iii) Arizant provided to OIG within that period a reasonable timetable for curing the material breach and Arizant has followed the timetable.

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

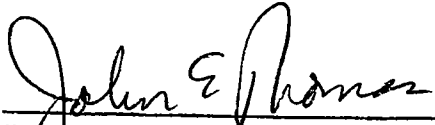
4. *Finality of Decision.* The review by an ALJ or DAB provided for above shall not be considered to be an appeal right arising under any statutes or regulations. Consequently, the parties to this CIA agree that the DAB's decision (or the ALJ's decision if not appealed) shall be considered final for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

#### **XI. EFFECTIVE AND BINDING AGREEMENT**

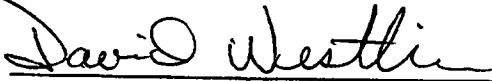
Consistent with the provisions in the Settlement Agreement pursuant to which this CIA is entered, and into which this CIA is incorporated, Arizant and OIG agree as follows:

- A. This CIA shall be binding on the successors, assigns, and transferees of Arizant;
- B. This CIA shall become final and binding on the date the final signature is obtained on the CIA;
- C. Any modifications to this CIA shall be made with the prior written consent of the parties to this CIA;
- D. The undersigned Arizant signatories represent and warrant that they are authorized to execute this CIA. The undersigned OIG signatory represents that he is signing this CIA in his official capacity and that he is authorized to execute this CIA.

ON BEHALF OF ARIZANT

  
\_\_\_\_\_  
JOHN E. THOMAS  
President and Chief Executive Officer

May 7, 2004  
DATE

  
\_\_\_\_\_  
DAVID WESTLIN  
Compliance Officer

MAY 7, 2004  
DATE

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JOHN T. BOESE, ESQ.  
Counsel for Arizant Inc.

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DATE

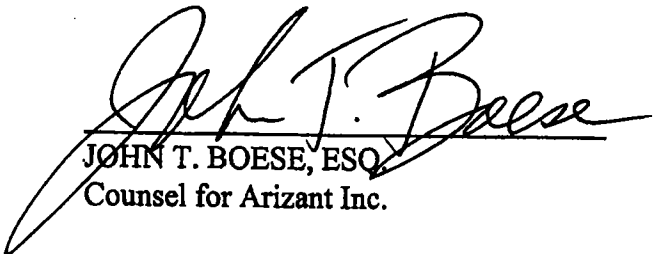
**ON BEHALF OF ARIZANT**

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JOHN E. THOMAS  
President and Chief Executive Officer

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DATE

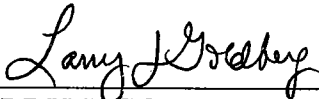
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DAVID WESTLIN  
Compliance Officer

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JOHN T. BOESE, ESQ.  
Counsel for Arizant Inc.

5/7/04  
\_\_\_\_\_  
DATE

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



\_\_\_\_\_  
LARRY J. GOLDBERG

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

7 May 2004  
DATE

## APPENDIX A INDEPENDENT REVIEW ORGANIZATION

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

### A. IRO Engagement.

Arizant 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/or objective fashion, as set forth in Paragraph D. Within 30 days after OIG receives written notice of the identity of the selected IRO, OIG will notify Arizant if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, Arizant may continue to engage the IRO.

If Arizant engages a new IRO during the term of the CIA, this IRO shall also meet the requirements of this Appendix. If a new IRO is engaged, Arizant shall submit the information identified in Section V.A.8 to OIG within 30 days of engagement of the IRO. Within 30 days after OIG receives written notice of the identity of the selected IRO, OIG will notify Arizant if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, Arizant may continue to engage the IRO.

### B. IRO Qualifications.

The IRO shall:

1. assign individuals to conduct the Sales and Marketing Engagement who have expertise in the billing, coding, reporting, and other reimbursement requirements applicable to medical products and devices and in the general requirements of the Federal health care programs from which Arizant's customers seek reimbursement.
2. have sufficient staff and resources to conduct the reviews required by the CIA on a timely basis.

### C. IRO Responsibilities.

The IRO shall:

1. follow all applicable Medicare, Medicaid and other Federal health care programs rules and reimbursement guidelines in making assessments in Sales and Marketing Engagement;



2. if in doubt of the application of a particular Medicare, Medicaid or other Federal health care program policy or regulation, request clarification from the appropriate authority (e.g., fiscal intermediary or carrier);
3. respond to all OIG inquires in a prompt, objective, and factual manner; and
4. prepare timely, clear, well-written reports.

D. IRO Independence/Objectivity.

The IRO must perform the Sales and Marketing Engagement in a professionally independent and/or objective fashion, as appropriate to the nature of the engagement, taking into account any other business relationships or engagements that may exist between the IRO and Arizant.

E. IRO Removal/Termination.

1. *Arizant.* If Arizant terminates its IRO during the course of the engagement, Arizant must submit a notice explaining its reasons to OIG no later than 30 days after termination. Arizant must engage a new IRO in accordance with Paragraph A of this Appendix.

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

Prior to requiring Arizant to engage a new IRO, OIG shall notify Arizant of its intent to do so and provide a written explanation of why OIG believes such a step is necessary. To resolve any concerns raised by OIG, Arizant may request a meeting with OIG to discuss any aspect of the IRO's qualifications, independence or performance of its responsibilities and to present additional information regarding these matters. Arizant shall provide any additional information as may be requested by OIG under this Paragraph in an expedited manner. OIG will attempt in good faith to resolve any differences regarding the IRO with Arizant prior to requiring Arizant to terminate the IRO. However, the final determination as to whether or not to require Arizant to engage a new IRO shall be made at the sole discretion of OIG.