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**SECURITIES AND EXCHANGE COMMISSION**  
WASHINGTON, D.C. 20549

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**FORM 8-K**

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**CURRENT REPORT**

**PURSUANT TO SECTION 13 OR 15(d) OF THE  
SECURITIES EXCHANGE ACT OF 1934**

**Date of Report (Date of earliest event reported): February 1, 2010**

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**ATRICURE, INC.**

(Exact name of registrant as specified in charter)

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**Delaware**  
(State or other jurisdiction  
of incorporation)

**000-51470**  
(Commission  
File Number)

**34-1940305**  
(IRS Employer  
Identification No.)

**6217 Centre Park Drive**  
**West Chester, OH**  
(Address of principal executive offices)

**45069**  
(Zip Code)

**Registrant's telephone number, including area code: (513) 755-4100**

**6033 Schumacher Park Drive, West Chester, OH 45069**  
(Former name or former address, if changed since last report)

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Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
  - Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
  - Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
  - Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))
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**Item 1.01. Entry into a Material Definitive Agreement.**

On February 2, 2010, AtriCure, Inc. (the “Company”) entered into a Settlement Agreement among the Company, the Department of Justice (“DOJ”), the Office of Inspector General of the Department of Health and Human Services (“OIG”) and the relator in the previously disclosed investigation and *qui tam* complaint which Settlement Agreement definitively resolves all claims related to the DOJ investigation. The Company has not admitted nor will it admit to any wrongdoing in connection with the settlement. The *qui tam* complaint will be formally dismissed when the court approves the submission of the settlement papers and the notice of dismissal that has been prepared by the DOJ.

In its Form 10-Q for the nine months ended September 30, 2009, the Company disclosed that it had reached a tentative settlement to resolve these matters. The terms of the Settlement Agreement are substantially identical to the terms disclosed by the Company in the Form 10-Q.

The Settlement Agreement provides that the Company will pay a settlement amount of \$3,766,623 (plus interest at 3.125% per year) and legal fees to counsel to the relator of \$200,000. Payment of the settlement amount will be made over a five year period with \$500,000 to be paid within 10 days after execution of the Settlement Agreement and a majority of the amount being payable in the fourth and fifth years. Payment of the legal fees will be made in ratable quarterly payments over four years.

As part of the resolution, the Company also entered into a five year Corporate Integrity Agreement with OIG. The Corporate Integrity Agreement acknowledges the existence of the Company’s corporate compliance program and provides for certain other compliance-related activities during the five year term of the agreement. Those activities include specific written standards, monitoring, training, education, independent review, disclosure and reporting requirements.

The foregoing description of the Settlement Agreement and the Corporate Integrity Agreement is not complete and is qualified in its entirety by reference to such agreements, which are attached as Exhibits 10.1 and 10.2, respectively, and are incorporated by reference in this Form 8-K.

This Current Report on Form 8-K contains “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements include statements that address activities, events or developments that the Company expects, believes or anticipates will or may occur in the future, such as earnings estimates, other predictions of financial performance, launches by the Company of new products and market acceptance of the Company’s products. Forward-looking statements are based on the Company’s experience and perception of current conditions, trends, expected future developments and other factors it believes are appropriate under the circumstances and are subject to numerous risks and uncertainties, many of which are beyond the Company’s control. These risks and uncertainties include the rate and degree of market acceptance of the Company’s products, the Company’s ability to develop and market new and enhanced products, the timing of and ability to obtain and maintain regulatory clearances and approvals for its products, the timing of and ability to obtain reimbursement of procedures utilizing the Company’s products, competition from existing and new products and procedures or the Company’s ability to effectively react to other risks and uncertainties described from time to time in the Company’s SEC filings, such as fluctuation of quarterly financial results, reliance on third party manufacturers and suppliers, litigation (including the purported class action lawsuits) or other proceedings, government regulation and stock price volatility. The Company does not guarantee any forward-looking statement, and actual results may differ materially from those projected. The Company undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events or otherwise.

**Item 9.01. Financial Statements and Exhibits.**

(d) Exhibits.

- 10.1 Settlement Agreement as of February 2, 2010 by and among the United States of America, acting through the United States Department of Justice and on behalf of the Office of Inspector General of the Department of Health and Human Services, the Company and the Relator. (the identity of the relator has been omitted because it remains under seal with the applicable court)
- 10.2 Corporate Integrity Agreement between the Office of Inspector General of the Department of Health and Human Services and AtriCure, Inc.

**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

ATRICURE, INC.

Date: February 5, 2010

By: \_\_\_\_\_ /s/ JULIE A. PITON  
**Julie A. Piton**  
**Vice President, Finance and**  
**Administration and Chief Financial Officer**

**SETTLEMENT AGREEMENT****I. PARTIES**

This Settlement Agreement (Agreement) is entered into among the United States of America, acting through the United States Department of Justice and on behalf of the Office of Inspector General of the Department of Health and Human Services (OIG-HHS) (collectively the "United States"); Atricure, Inc. ("Atricure"); and ("Relator") (hereafter referred to collectively as "the Parties"), through their authorized representatives.

**II. PREAMBLE**

As a preamble to this Agreement, the Parties agree to the following:

A. Atricure is a Delaware corporation headquartered in West Chester, Ohio that manufactures and distributes medical devices.

B. On August 21, 2007, Relator filed a qui tam action in the United States District Court for the Southern District of Texas captioned United States ex rel. \_\_\_\_\_ v. Atricure, Inc., Civil Action No. 07-2705 (S.D. Tex.) (hereinafter "the Civil Action").

C. In the Civil Action, Relator alleges that Atricure submitted or caused to be submitted false or fraudulent claims for payment to the Medicare Program ("Medicare"), Title XVIII of the Social Security Act, 42 U.S.C. § § 1395- 1395hhh, by engaging in the following conduct (the "Covered Conduct") from September 2005 through October 2008:

(1) Relator alleges that Atricure caused false claims to be submitted by improperly instructing hospitals and other healthcare providers to code minimally invasive procedures using the Atricure Ablation System, the Atricure Bipolar System, and the Atricure Transpolar System (collectively, "Ablation Devices") as "open" procedures when it knew such procedure codes were not correct;

(2) Relator alleges that Atricure promoted the sale and use of its Ablation Devices for the treatment of atrial fibrillation when it knew that such treatment was not medically necessary and knowingly caused false and/or fraudulent claims to be submitted to Medicare for such treatment;

(3) Relator alleges that Atricure caused false claims to be submitted by knowingly inducing hospitals to purchase its Ablation Devices by providing free or discounted marketing services and loaning or selling generators and disposable equipment to hospitals at less than fair market value; and

(4) Relator alleges that Atricure knowingly promoted the sale and use of its Ablation Devices for the treatment of atrial fibrillation, a use that has not been approved by the United States Food and Drug Administration, in violation of the Food, Drug and Cosmetic Act, 21 U.S.C. §§ 331(a).

D. The United States contends that it has certain civil claims, as specified in Paragraph 3, below, against Atricure for engaging in the Covered Conduct.

E. The United States also contends that it has certain administrative claims against Atricure for the Covered Conduct under the provisions for permissive exclusion from Medicare, Medicaid and other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)) under 42 U.S.C. § 1320a-7(b), the provisions for permissive exclusion from TRICARE under 32 C.F.R. § 199.9, and the provisions for civil monetary penalties under 42 U.S.C. § 1320a-7a.

F. Atricure denies the contentions set forth in Paragraph C and the claims and allegations made in the Civil Action. This Agreement represents a compromise to avoid continued litigation and associated risks and is neither an admission of liability or wrongdoing by Atricure nor a concession by the United States that its claims are not well founded.

G. To avoid the delay, uncertainty, inconvenience, and expense of protracted litigation of the above claims, the Parties reach a full and final settlement pursuant to the Terms and Conditions below.

### III. TERMS AND CONDITIONS

NOW, THEREFORE, in reliance on the representations contained herein and in consideration of the mutual promises, covenants, and obligations in this Agreement, and for good and valuable consideration, receipt of which is hereby acknowledged, the Parties agree as follows:

1. Atricure shall pay to the United States the sum of Three Million, Seven Hundred and Sixty-Six Thousand, Six Hundred and Twenty Three dollars (\$3,766,623) (the "Settlement Amount"). On the Effective Date of this Agreement, this sum shall constitute a debt due and immediately owing to the United States. Atricure further agrees to pay Relator \$200,000 for expenses and attorneys' fees and costs (the "Relator's Attorneys' Fees Amount"). The foregoing payments shall be made as follows:

a. Atricure shall pay to the United States the Settlement Amount plus interest accrued thereon at the rate of 3.125% per annum, in accordance with the payment schedule attached hereto as Exhibit A ("Payment Schedule"). Within 10 days after the Effective Date of this Agreement, Atricure shall pay the United States the initial fixed payment in the amount of \$500,000 ("Initial Payment") and thereafter make principal payments with interest according to the schedule in Exhibit A.

b. All payments set forth in Paragraph 1(a) shall be made to the United States by electronic funds transfer pursuant to written instructions to be provided by the Civil Division of the Department of Justice, The entire balance of the Settlement Amount, or any portion thereof,

plus any interest accrued on the principal as of the date of any prepayment, may be prepaid without penalty.

c. Contingent upon the United States receiving the Initial Payment from Atricare and as soon as feasible after receipt, the United States agrees to pay \$82,950 to Relator, Contingent upon the United States receiving each additional payment from Atricare identified in the schedule in Exhibit A and as soon as feasible after receipt of each payment, the United States agrees to make the corresponding additional payment to the Relator according to the schedule in Exhibit A.

d. In addition to the Settlement Amount, Atricare agrees to pay the Relator's Attorneys' Fees Amount, in accordance with the payment schedule attached hereto as Exhibit B ("Relator Attorneys' Fees Payment Schedule"), in full satisfaction of Relator's right to fees and costs authorized by 31 U.S.C. § 3730(d). Within five (5) business days after receiving notice that the Federal Civil Action has been dismissed, Atricare shall pay \$12,500 ("Initial Relator Attorneys' Fees Payment") to Relator, by check payable to her counsel, and thereafter make payments according to the schedule in Exhibit B.

2. If Atricare fails to make any of the payments described in Paragraph l(a) above at the specified time, upon written notice to Atricare of this default, Atricare shall have ten (10) calendar days to cure the default. If the default is not cured within the ten-day period: (a) the remaining unpaid principal portion of the Settlement Amount shall become accelerated and immediately due and payable, with interest at a simple rate of 3.125% from the Effective Date of this Agreement to the date of default, and at a simple rate of 12% per annum, from the date of default until the date of payment; (b) the United States may pursue any and all actions for collection as it may choose, including, without limitation, filing an action for specific

performance of this Agreement; and (c) the United States may offset the remaining unpaid balance of the Settlement Amount (inclusive of interest) from any amounts due and owing to Atricare by any department, agency, or agent of the United States. Atricare agrees not to contest any collection action undertaken by the United States pursuant to this Paragraph 2, and to pay the United States all reasonable costs incurred in any such collection action, including attorney's fees and expenses.

3. Subject to the exceptions in Paragraph 6 (concerning excluded claims), below, in consideration of the obligations of Atricare in this Agreement and the Corporate Integrity Agreement (CIA) entered into between OIG-HHS and Atricare, conditioned upon Atricare's full payment of the Settlement Amount, and subject to Paragraph 20, below (concerning bankruptcy proceedings commenced within 91 days of the Effective Date of this Agreement or any payment made under this Agreement), the United States (on behalf of itself, its officers, agents, agencies, and departments) agrees to release Atricare from any civil and administrative monetary claims the United States has or may have for the Covered Conduct under the False Claims Act, 31 U.S.C. §§ 3729-3733; the Food Drug and Cosmetic Act, 21 U.S.C. §§ 331(a) and 332; the Civil Monetary Penalties Law, 42 U.S.C. § 1320a-7a; the Program Fraud Civil Remedies Act, 31 U.S.C. §§ 3801-3812; or the common law theories of payment by mistake, unjust enrichment, and fraud. No individuals are released by this Agreement.

4. Subject to the exceptions in Paragraph 6 (concerning excluded claims), below, in consideration of the obligations of Atricare in this Agreement, conditioned upon Atricare's full payment of the Settlement Amount, and subject to Paragraph 20, below (concerning bankruptcy proceedings commenced within 91 days of the Effective Date of this Agreement or any payment made under this Agreement), Relator, for herself and for her heirs, successors, attorneys, agents,



and assigns, agrees to release Atricare from any civil monetary claim the United States has or may have for the Covered Conduct under the False Claims Act, 31 U.S.C. §§ 3729-3733.

5. In consideration of the obligations of Atricare in this Agreement and the Corporate Integrity Agreement (CIA), entered into between OIG-HHS and Atricare, conditioned upon Atricare's full payment of the Settlement Amount, and subject to Paragraph 20, below (concerning bankruptcy proceedings commenced within 91 days of the Effective Date of this Agreement or any payment made under this Agreement), the OIG-HHS agrees to release and refrain from instituting, directing, or maintaining any administrative action seeking exclusion from Medicare, Medicaid, and other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)) against Atricare under 42 U.S.C. § 1320a-7a (Civil Monetary Penalties Law) or 42 U.S.C. § 1320a-7(b)(7) (permissive exclusion for fraud, kickbacks, and other prohibited activities) for the Covered Conduct, except as reserved in Paragraph 6 (concerning excluded claims), below, and as reserved in this Paragraph. The OIG-HHS expressly reserves all rights to comply with any statutory obligations to exclude Atricare from Medicare, Medicaid, and other Federal health care programs under 42 U.S.C. § 1320a-7(a) (mandatory exclusion) based upon the Covered Conduct. Nothing in this Paragraph precludes the OIG-HHS from taking action against entities or persons, or for conduct and practices, for which claims have been reserved in Paragraph 6, below. Notwithstanding the foregoing, in the event of default as defined in Paragraph 2, above, OIG-HHS may, after providing written notice, exclude Atricare from participating in all Federal health care programs until Atricare pays the Settlement Amount and reasonable costs as set forth in Paragraph 1, above. Atricare waives any further notice of the exclusion under 42 U.S.C. § 1320a-7(b)(7), and agrees not to contest such exclusion either administratively or in any state or federal court. Reinstatement to program participation is not

automatic. If at the end of the period of exclusion Atricare wishes to apply for reinstatement, Atricare must submit a written request for reinstatement to OIG-HHS in accordance with the provisions of 42 C.F.R. §§ 1001.3001-.3005. Atricare will not be reinstated unless and until OIG-HHS approves such request for reinstatement.

6. Notwithstanding any term of this Agreement, specifically reserved and excluded from the scope and terms of this Agreement as to any entity or person (including Atricare and Relator) are the following claims of the United States: (a) any civil, criminal, or administrative liability arising under Title 26, U.S. Code (Internal Revenue Code); (b) any criminal liability; (c) except as expressly provided in this Agreement, any administrative liability, including mandatory and/or permissive exclusion from Federal health care programs; (d) any liability to the United States (or its agencies) for any conduct other than the Covered Conduct; (e) any liability based upon such obligations as are created by this Agreement; (f) any liability for express or implied warranty claims or other claims for defective or deficient products or services, including quality of goods and services; (g) any liability for failure to deliver goods or services due; or (h) any liability of individuals, including directors, officers and employees.

7. Relator and her heirs, successors, attorneys, agents, and assigns agree not to object to this Agreement and agree and confirm that this Agreement is fair, adequate, and reasonable under all the circumstances, pursuant to 31 U.S.C. § 3730(c)(2)(B) and, conditioned upon receipt of Relator's share, Relator, for herself individually, and for her heirs, successors, agents, and assigns, fully and finally releases, waives, and forever discharges the United States, its officers, agents, and employees, from any claims arising from or relating to 31 U.S.C. § 3730; from any claims arising from the filing of the Civil Action; and from any other claims for a share of the Settlement Amount; and in full settlement of any claims Relator may have under this Agreement.

This Agreement does not resolve or in any manner affect any claims the United States has or may have against the Relator arising under Title 26, U.S. Code (Internal Revenue Code), or any claims arising under this Agreement.

8. In consideration of the obligations of Atricure in this Agreement, conditioned upon the full payment of the Settlement Amount and Relator's Legal Fees, Relator, for herself and for her heirs, successors, agents, and assigns, agrees to generally release, acquit, waive, and forever discharge Atricure and all the current and former officers and directors, employees, agents, attorneys, owners and shareholders of Atricure from any and all rights, claims, expenses, debts, liabilities, demands, obligations, costs, damages, injuries, actions and causes of action of every nature, whether known or unknown, suspected or unsuspected, in law or in equity from the beginning of the world to the Effective Date of this Agreement including but not limited to those she advanced or could have advanced in the Civil Action or otherwise under the False Claims Act, 31 U.S.C. §§3729-3733, for expenses or attorneys' fees and costs under 31 U.S.C. § 3730(h), or under 31 U.S.C. § 3730(h) for employment decisions by Atricure and/or other statutory or common law doctrines of payment by mistake, unjust enrichment, breach of contract, fraud, or the like. The foregoing sentence is intended to be interpreted as a general release. Furthermore, Relator covenants not to sue Atricure, its current and former officers and directors, employees, agents, attorneys and shareholders of Atricure with respect to any and all rights, claims, expenses, debts, liabilities, demands, obligations, costs, damages, injuries, actions and causes of action of every nature, whether known or unknown, suspected or unsuspected, in law or in equity, including those, for attorneys' fees and costs arising prior to the Effective Date of this Agreement.

9. Defendant and Relator release and forever discharge each other from any and all claims, actions, causes of action, suits, debts dues, payments, demands, rights, damages, losses, expenses, costs, fees, accounts, accountings, obligations, arbitrations, judgments, executions, injunctions, awards, rights of contribution, indemnification and apportionment, attorneys' fees and any and all other liabilities of any nature or amount, whether presently known or unknown, asserted or unasserted, accrued or unaccrued, which Defendant or Relator ever had or now have against each other from the beginning of time up to and including the date of this Agreement. This general mutual release includes, but is not limited to, all claims arising from or during Relator's employment with Defendant or relating in any way to Relator's Civil Action

10. Atricure has provided sworn financial disclosure statements (Financial Statements) to the United States and the United States has relied on the accuracy and completeness of those Financial Statements in reaching this Agreement, Atricure warrants that the Financial Statements are complete, accurate, and current. If the United States learns of asset(s) in which Atricure had an interest at the time of this Agreement that were not disclosed in the Financial Statements, or if the United States learns of any misrepresentation by Atricure on, or in connection with, the Financial Statements and if such nondisclosure or misrepresentation changes the estimated net worth set forth in the Financial Statements by \$300,000 or more the United States may at its option: (a) rescind this Agreement and file suit based on the Covered Conduct or (b) let the Agreement stand and collect the full Settlement Amount plus one hundred percent (100%) of the value of the net worth of Atricure previously undisclosed. Atricure agrees not to contest any collection action undertaken by the United States pursuant to this provision and immediately to pay the United States all reasonable costs incurred in such an action, including attorney's fees and expenses.

11. In the event that the United States, pursuant to Paragraph 10 (concerning disclosure of assets), above, opts to rescind this Agreement, Atricare agrees not to plead, argue, or otherwise raise any defenses under the theories of statute of limitations, laches, estoppel, or similar theories, to any civil or administrative claims that (a) are filed by the United States within 90 calendar days of written notification to Atricare that this Agreement has been rescinded, and (b) relate to the Covered Conduct, except to the extent these defenses were available on August 21, 2007.

12. Atricare waives and shall not assert any defenses Atricare may have to any criminal prosecution or administrative action relating to the Covered Conduct that may be based in whole or in part on a contention that, under the Double Jeopardy Clause in the Fifth Amendment of the Constitution, or under the Excessive Fines Clause in the Eighth Amendment of the Constitution, this Agreement bars a remedy sought in such criminal prosecution or administrative action. Nothing in this paragraph or any other provision of this Agreement constitutes an agreement by the United States concerning the characterization of the Settlement Amount for purposes of the Internal Revenue laws, Title 26 of the United States Code.

13. Atricare fully and finally releases the United States, its agencies, employees, servants, and agents from any claims (including attorney's fees, costs, and expenses of every kind and however denominated) that Atricare has asserted, could have asserted, or may assert in the future against the United States, its agencies, employees, servants, and agents, related to the Covered Conduct and the United States' investigation and prosecution thereof.

14. The Settlement Amount shall not be decreased as a result of the denial of claims for payment now being withheld from payment by any Medicare carrier or intermediary or any state payer, related to the Covered Conduct; and Atricare agrees not to resubmit to any Medicare

carrier or intermediary or any state payer any previously denied claims related to the Covered Conduct, and agrees not to appeal any such denials of claims.

15. Atricure agrees to the following:

a. Unallowable Costs Defined: that all costs (as defined in the Federal Acquisition Regulation, 48 C.F.R. § 31.205-47; and in Titles XVIII and XIX of the Social Security Act, 42 U.S.C. §§ 1395-1395hhh and 1396-1396v; and the regulations and official program directives promulgated thereunder) incurred by or on behalf of Atricure, its present or former officers, directors, employees, shareholders, and agents in connection with the following shall be “Unallowable Costs” on government contracts and under the Medicare, Medicaid, TRICARE, Veterans Affairs (“VA”), or FEHBP programs:

(1) the matters covered by this Agreement;

(2) the United States’ audit(s) and civil investigation(s) of the matters covered by this Agreement;

(3) Atricure’s investigation, defense, and corrective actions undertaken in response to the United States’ audit(s) and civil investigation(s) in connection with the matters covered by this Agreement (including attorney’s fees);

(4) the negotiation and performance of this Agreement;

(5) the payment Atricure makes to the United States pursuant to this Agreement and any payments that Atricure may make to Relator, including costs and attorneys fees; and

(6) the negotiation of and obligations undertaken pursuant to the CIA to: (i) retain an independent review organization to perform reviews as described in the CIA; and (ii) prepare and submit reports to OIG-HHS. However, nothing in this paragraph 15(a)(6) that

may apply to the obligations undertaken pursuant to the CIA affects the status of costs that are not allowable based on any other authority applicable to Atricare. (All costs described or set forth in this Paragraph 15(a) are hereafter "Unallowable Costs,")

b. Future Treatment of Unallowable Costs: These Unallowable Costs shall be separately determined by Atricare, and Atricare shall not charge such Unallowable Costs directly or indirectly to any contracts with the United States or any State Medicaid program, or seek payment for such Unallowable Costs through any cost report, cost statement, information statement, or payment request submitted by Atricare or any of its subsidiaries or affiliates to the Medicare, Medicaid, TRICARE, VA or FEHBP programs.

c. Treatment of Unallowable Costs Previously Submitted for Payment: Atricare further agrees that within 90 days of the Effective Date of this Agreement it shall identify to applicable Medicare and TRICARE fiscal intermediaries, carriers, and/or contractors, and Medicaid and FEHBP fiscal agents, any Unallowable Costs (as defined in this Paragraph) included in payments previously sought from the United States, or any State Medicaid program, including, but not limited to, payments sought in any cost reports, cost statements, information reports, or payment requests already submitted by Atricare or any of its subsidiaries or affiliates, and shall request, and agree, that such cost reports, cost statements, information reports, or payment requests, even if already settled, be adjusted to account for the effect of the inclusion of the unallowable costs. Atricare agrees that the United States, at a minimum, shall be entitled to recoup from Atricare any overpayment plus applicable interest and penalties as a result of the inclusion of such Unallowable Costs on previously-submitted cost reports, information reports, cost statements, or requests for payment.

Any payments due after the adjustments have been made shall be paid to the United States pursuant to the direction of the Department of Justice and/or the affected agencies. The United States reserves its rights to disagree with any calculations submitted by Atricure or any of its subsidiaries or affiliates on the effect of inclusion of Unallowable Costs (as defined in this Paragraph) on Atricure or any of its subsidiaries or affiliates' cost reports, cost statements, or information reports.

d. Nothing in this Agreement shall constitute a waiver of the rights of the United States to audit, examine; or re-examine Atricure's books and records to determine that no Unallowable Costs have been claimed in accordance with the provisions of this Paragraph.

16. Atricure agrees to cooperate fully and truthfully with the United States' investigation of individuals and entities not released in this Agreement. Upon reasonable notice, Atricure shall encourage, and agrees not to impair, the cooperation of its directors, officers, and employees, and shall use its best efforts to make available, and encourage the cooperation of former directors, officers, and employees for interviews and testimony, consistent with the rights and privileges of such individuals. Atricure agrees to furnish to the United States, upon request, complete and unredacted copies of all non-privileged documents, reports, memoranda of interviews, and records in its possession, custody, or control concerning any investigation of the Covered Conduct that it has undertaken, or that has been performed by its counsel or other agent.

17. This Agreement is intended to be for the benefit of the Parties only. The Parties do not release any claims against any other person or entity, except to the extent provided for in Paragraphs 8 and 9 (Atricure and relator release paragraphs), above, and Paragraph 18 (waiver for beneficiaries paragraph), below.



18. Atricure agrees that it waives and shall not seek payment for any of the health care billings covered by this Agreement from any health care beneficiaries or their parents, sponsors, legally responsible individuals, or third party payors based upon the claims defined as Covered Conduct.

19. Atricure warrants that it has reviewed its financial situation and that it currently is solvent within the meaning of 11 U.S.C. §§ 547(b)(3) and 548(a)(1)(B)(ii)(I), and shall remain solvent following payment to the United States of the Initial Payment. In addition, by making each subsequent payment to the United States identified in the Payment Schedule, Atricure warrants that it shall remain solvent following that payment. Further, the Parties warrant that, in evaluating whether to execute this Agreement, they (a) have intended that the mutual promises, covenants, and obligations set forth constitute a contemporaneous exchange for new value given to Atricure, within the meaning of 11 U.S.C. § 547(c)(1); and (b) conclude that these mutual promises, covenants, and obligations do, in fact, constitute such a contemporaneous exchange. Further, the Parties warrant that the mutual promises, covenants, and obligations set forth herein are intended to and do, in fact, represent a reasonably equivalent exchange of value that is not intended to hinder, delay, or defraud any entity to which Atricure was or became indebted to on or after the date of this transfer, within the meaning of 11 U.S.C. § 548(a)(1).

20. If within 91 days of the Effective Date of this Agreement or of any payment made under this Agreement, Atricure commences, or a third party commences, any case, proceeding, or other action under any law relating to bankruptcy, insolvency, reorganization, or relief of debtors (a) seeking to have any order for relief of Atricure's debts, or seeking to adjudicate Atricure as bankrupt or insolvent; or (b) seeking appointment of a receiver, trustee, custodian, or other

similar official for Atricare or for all or any substantial part of Atricare's assets, Atricare's agrees as follows:

a. Atricare's obligations under this Agreement may not be avoided pursuant to 11 U.S.C. § 547, and Atricare shall not argue or otherwise take the position in any such case, proceeding, or action that: (i) Atricare's obligations under this Agreement may be avoided under 11 U.S.C. § 547; (ii) Atricare was insolvent at the time this Agreement was entered into, or became insolvent as a result of the payment made to the United States; or (iii) the mutual promises, covenants, and obligations set forth in this Agreement do not constitute a contemporaneous exchange for new value given to Atricare.

b. If Atricare's obligations under this Agreement are avoided for any reason, including, but not limited to, though the exercise of a trustee's avoidance powers under the Bankruptcy Code, the United States, at its sole option, may rescind the releases in this Agreement and bring any civil and/or administrative claim, action, or proceeding against Atricare for the claims that would otherwise be covered by the releases provided in Paragraph 3, above, and Atricare agrees that (i) any such claims, actions, or proceedings brought by the United States (including any proceedings to exclude Atricare from participation in Medicare, Medicaid, or other Federal health care programs) are not subject to an "automatic stay" pursuant to 11 U.S.C. § 362(a) as a result of the action, case, or proceedings described in the first clause of this Paragraph, and Atricare shall not argue or otherwise contend that the United States' claims, actions, or proceedings are subject to an automatic stay; (ii) Atricare shall not plead, argue, or otherwise raise any defenses under the theories of statute of limitations, laches, estoppel, or similar theories, to any such civil or administrative claims, actions, or proceeding that are brought by the United States within 60 calendar days of written notification to Atricare that the

releases have been rescinded pursuant to this Paragraph, except to the extent such defenses were available on August 21, 2007; and (iii) the United States has a valid claim against Atricare in an amount not less than \$11,857,980, and the United States may pursue its claim in the case, action, or proceeding referenced in the first clause of this Paragraph, as well as in any other case, action, or proceeding.

c. Atricare acknowledges that its agreements in this Paragraph are provided in exchange for valuable consideration provided in this Agreement.

21. Upon receipt of the Initial Payment described in Paragraph 1, above, the United States shall file in the Civil Action a Notice of Intervention and the United States and Relator shall file a Joint Stipulation of Dismissal with prejudice of the Civil Action pursuant to the terms and conditions of this Agreement.

22. Except as expressly provided to the contrary in this Agreement, each Party shall bear its own legal and other costs incurred in connection with this matter, including the preparation and performance of this Agreement.

23. Atricare represents that this Agreement is freely and voluntarily entered into without any degree of duress or compulsion whatsoever.

24. Relator represents that this Agreement is freely and voluntarily entered into without any degree of duress or compulsion whatsoever.

25. This Agreement is governed by the laws of the United States. The Parties agree that the exclusive jurisdiction and venue for any dispute arising between and among the Parties under this Agreement is the United States District Court for the Southern District of Texas, except that disputes arising under the CIA shall be resolved exclusively under the dispute resolution provisions in the CIA.

26. For purposes of construction, this Agreement shall be deemed to have been drafted by all Parties to this Agreement and shall not, therefore, be construed against any Party for that reason in any subsequent dispute.

27. This Agreement constitutes the complete agreement between the Parties. This Agreement may not be amended except by written consent of the Parties.

28. The individuals signing this Agreement on behalf of Atricare represent and warrant that they are authorized by Atricare to execute this Agreement. The individual(s) signing this Agreement on behalf of Relator represent and warrant that they are authorized by Relator to execute this Agreement. The United States signatories represent that they are signing this Agreement in their official capacities and that they are authorized to execute this Agreement.

29. This Agreement may be executed in counterparts, each of which constitutes an original and all of which constitute one and the same Agreement.

30. This Agreement is binding on Atricare's successors, transferees, heirs, and assigns.

31. This Agreement is binding on Relator's successors, transferees, heirs, and assigns.

32. All parties consent to the United States' disclosure of this Agreement, and information about this Agreement, to the public.

33. This Agreement is effective on the date of signature of the last signatory to the Agreement (Effective Date of this Agreement). Facsimiles of signatures shall constitute acceptable, binding signatures for purposes of this Agreement.

**THE UNITED STATES OF AMERICA**

DATED: 2/2/10

BY: /s/ Edward C. Crooke  
EDWARD C. CROOKE  
Trial Attorney  
Commercial Litigation Branch  
Civil Division  
United States Department of Justice

DATED: 1/29/10

BY: /s/ Michelle Zingaro  
MICHELLE ZINGARO  
Assistant United States Attorney  
United States Attorney's Office  
for the Southern District of Texas

DATED: 1/29/10

BY: /s/ Gregory E. Demske  
GREGORY E. DEMSKE  
Assistant Inspector General for Legal Affairs  
Office of Counsel to the Inspector General  
Office of Inspector General  
United States Department of Health and Human Services

**ATRICURE, INC.**

DATED: 1/28/10

BY: /s/ David Drachman  
DAVID DRACHMAN  
President, Chief Executive Officer, and Director  
Atricare, Inc.

DATED: 1/28/10

BY: /s/ Stuart Gerson  
STUART GERSON  
Epstein, Becket, & Green, LLP  
Counsel to Atricum, Inc.

**RELATOR**

DATED: 2/1/2010

BY: /s/

Relator

DATED: 1/31/2010

BY: /s/ Mitchell Kreindler

MITCHELL KREINDLER  
Kreindler & Associates  
Counsel to Relator

DATED: 2/1/2010

BY: /s/ David W. Sanford

DAVID W. SANFORD  
Sanford, Wittels & Heisler, LLP  
Counsel to Relator

DATED: 2/1/2010

BY: /s/ Grant Morris

GRANT MORRIS  
Law Offices of Grant Morris  
Counsel to Relator

**EXHIBIT A**

SETTLEMENT AND RELATOR SHARE PAYMENT SCHEDULE  
(U.S. DOLLARS)

<u>Quarter</u>	<u>Payment</u>	<u>Relator's Share</u>
At signing	500,000	82,950
11/30/2010	125,000	20,738
02/28/2011	125,000	20,738
05/31/2011	125,000	20,738
08/31/2011	125,000	26,959
11/30/2011	162,500	26,959
02/28/2012	162,500	26,959
05/31/2012	162,500	26,959
08/31/2012	162,500	26,959
11/30/2012	250,000	41,475
02/28/2013	250,000	41,475
05/31/2013	250,000	41,475
08/31/2013	250,000	41,475
11/30/2013	375,000	62,213
02/28/2014	375,000	62,213
05/31/2014	375,000	62,213
08/31/2014	375,000	62,213



**EXHIBIT B**

**RELATOR ATTORNEYS' FEES PAYMENT SCHEDULE  
(U.S. DOLLARS)**

<b><u>Quarter</u></b>	<b><u>Payment</u></b>
<b>Initial Relator Attorneys'</b>	
<b>Fees Payment</b>	<b>\$12,500</b>
06/30/10	\$12,500
09/30/10	\$12,500
12/31/10	\$12,500
03/31/11	\$12,500
06/30/11	\$12,500
09/30/11	\$12,500
12/31/11	\$12,500
03/31/12	\$12,500
06/30/12	\$12,500
09/30/12	\$12,500
12/31/12	\$12,500
03/31/13	\$12,500
06/30/13	\$12,500
09/30/13	\$12,500
12/31/13	\$12,500

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

**I. PREAMBLE**

AtriCure, Inc. hereby enters into this Corporate Integrity Agreement (CIA) with the Office of Inspector General (OIG) of the United States Department of Health and Human Services (HHS) to promote compliance with the statutes, regulations, and written directives of Medicare, Medicaid, and all other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)) (Federal health care program requirements). Contemporaneously with this CIA, AtriCure 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 AtriCure, Inc. under this CIA shall be five 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, IX, X, and XI shall expire no later than 120 days after OIG's receipt of: (1) AtriCure, Inc.'s final annual report; or (2) any additional materials submitted by AtriCure, Inc. pursuant to OIG's request, whichever is later.

CORPORATE INTEGRITY AGREEMENT  
ATRICURE, INC.

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

1. "Covered Persons" includes:

- a. all owners of AtriCure, Inc. who are natural persons (other than shareholders who: (1) have an ownership interest of less than 5%; and (2) acquired the ownership interest through public trading);
- b. all officers, directors, and employees of AtriCure, Inc. who are based in the United States or have job responsibilities in the United States, except as carved out below in this Section II.C.2; and
- c. all contractors, subcontractors, agents, and other persons who perform Promotion and Product Services Related Functions (as defined below in Section II.C.3) on behalf of AtriCure, Inc.

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. "Government Reimbursed Products" refers to all AtriCure, Inc. products that are reimbursed by Federal health care programs.

3. The term "Promotional and Product Services Related Functions" includes: (a) the selling, detailing, marketing, advertising, promoting, or branding of Government Reimbursed Products; and (b) the preparation or dissemination of materials or information about, or the provision of services relating to, Government Reimbursed Products that are distributed in the United States.

4. "Relevant Promotional and Product Services Covered Persons" includes all Covered Persons whose job responsibilities relate to Promotional and Product Services Related Functions.

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### III. CORPORATE INTEGRITY OBLIGATIONS

AtriCure, Inc. shall establish and maintain a Compliance Program that includes the following elements:

#### A. Compliance Officer and Committee.

1. *Compliance Officer.* Within 90 days after the Effective Date, AtriCure, Inc. shall appoint an individual to serve as its Compliance Officer and shall maintain a Compliance Officer for the term of the CIA. The Compliance Officer shall be responsible for developing and implementing policies, procedures, and practices designed to ensure compliance with the requirements set forth in this CIA and with Federal health care program requirements. The Compliance Officer shall be a member of senior management of AtriCure, Inc., shall report directly to the Chief Executive Officer of AtriCure, Inc., shall make periodic (at least quarterly) reports regarding compliance matters directly to the Board of Directors of AtriCure, Inc., 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 AtriCure, Inc. as well as for any reporting obligations created under this CIA. Any non-compliance job responsibilities of the Compliance Officer must not interfere with the Compliance Officer's ability to perform the duties outlined in this CIA.

AtriCure, Inc. 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 the change.

2. *Compliance Committee.* Within 90 days after the Effective Date, AtriCure, Inc. shall appoint a Compliance Committee. The Compliance Committee shall, at a minimum, include the Compliance Officer and other members of senior management necessary to meet the requirements of this CIA (e.g., senior executives of relevant departments, such as legal, human resources, sales and marketing). 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).

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ATRICURE, INC.

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

3. *Board of Directors Compliance Obligations.* A Committee of the Board of Directors (Committee) shall be responsible for the review and oversight of matters related to compliance with Federal health care program requirements, FDA requirements, and the obligations of this CIA. The Committee shall, at a minimum, be responsible for the following:

a. The Committee shall meet at least quarterly to review and oversee AtriCure, Inc.'s Compliance Program, including but not limited to evaluating its effectiveness and receiving updates about the activities of the Compliance Officer and other compliance personnel.

b. The Committee shall consist of at least three members, at least one of whom shall be an independent director. The Compliance Officer is required to make at least four reports a year to the Committee or more often, if requested by the Committee or the Compliance Officer.

c. The Committee shall arrange for the performance of a review on the effectiveness of AtriCure, Inc.'s Compliance Program (Compliance Program Review) for each Reporting Period of the CIA and shall review the results of the Compliance Program Review as part of the review and assessment of AtriCure, Inc.'s Compliance Program. A copy of the Compliance Program Review Report shall be provided to OIG in each Annual Report submitted by AtriCure, Inc.

d. For each Reporting Period of the CIA, the Committee shall adopt a resolution, signed by each individual member of the Committee, summarizing its review and oversight of AtriCure, Inc.'s compliance with Federal health care program requirements, FDA requirements, and the obligations of this CIA.

At minimum, the resolution shall include the following language:

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“The **[insert name of Committee]** Committee of the Board of Directors has made a reasonable inquiry into the operations of AtriCure, Inc.’s Compliance Program, including but not limited to evaluating its effectiveness and receiving updates about the activities of its Compliance Officer and other compliance personnel. The Board also has arranged for the performance of, and reviewed the results of, the Compliance Program Review. Based on its inquiry, the Committee has concluded that, to the best of its knowledge, AtriCure, Inc. has implemented an effective Compliance Program to meet Federal health care program requirements, FDA requirements, and the obligations of the CIA.”

If the Committee is unable to provide such a conclusion in the resolution, the Committee 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 assure implementation by AtriCure, Inc. of an effective Compliance Program.

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

The Board of Directors may by resolution reserve to itself the powers and responsibilities assigned to the Committee under this CIA. In that event, all references in this CIA to the Committee shall be deemed to be references to the Board of Directors.

4. *Management Accountability and Certifications:* In addition to the responsibilities set forth in this CIA for all Covered Persons, certain AtriCure, Inc. employees (“Certifying Employees”) are specifically expected to monitor and oversee activities within their areas of authority and shall annually certify, in writing or electronically, that the applicable AtriCure, Inc. component is compliant with Federal health care program requirements, FDA requirements, and the obligations of this CIA. These Certifying Employees shall include, at a minimum, the following individuals from AtriCure, Inc.:

- David Drachman, President and CEO
- Michael Rogge, Director of Marketing
- Stewart Strong, VP, Domestic Sales
- Tim Palmer, Director, Sales (East Region)

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- Kevin Henderson, Director, Sales (West Region)

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 [department or functional area], an area under my supervision. My job responsibilities include ensuring compliance with regard to the [insert name of the department or functional area.] To the best of my knowledge, except as otherwise described herein, the [insert name of department or functional area] of AtriCure, Inc. is in compliance with all applicable Federal health care program requirements, FDA requirements, and the obligations of the CIA.”

**B. Written Standards.**

1. *Code of Conduct.* Within 90 days after the Effective Date, AtriCure, Inc. shall develop, implement, and distribute a written Code of Conduct to all Covered Persons. AtriCure, Inc. 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. AtriCure, Inc.’s commitment to full compliance with all Federal health care program and FDA requirements, including its commitment to market, sell, promote, research, develop, provide information about, and advertise its products in accordance with Federal health care program and FDA requirements and to prepare and submit accurate claims consistent with such requirements;
- b. AtriCure, Inc.’s requirement that all of its Covered Persons shall be expected to comply with all Federal health care program and FDA requirements and with AtriCure, Inc.’s own Policies and Procedures;
- c. the requirement that all of AtriCure, Inc.’s Covered Persons shall be expected to report to the Compliance Officer, or other appropriate individual designated by AtriCure, Inc., suspected violations of any Federal health care program and FDA requirements and of AtriCure, Inc.’s own Policies and Procedures; and

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d. the right of all individuals to use the Disclosure Program described in Section III.E, and AtriCure, Inc.'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 AtriCure, Inc.'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.

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

2. *Policies and Procedures.* Within 90 days after the Effective Date, AtriCure, Inc. shall implement written Policies and Procedures regarding the operation of AtriCure, Inc.'s compliance program, including the compliance program requirements outlined in this CIA, and AtriCure, Inc.'s compliance with Federal health care program and FDA 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. appropriate ways to conduct Promotional and Product Services Related Functions in compliance with all applicable Federal healthcare program requirements, including, but not limited to the Federal anti-kickback statute (codified at 42 U.S.C. § 1320a-7b), and the False Claims Act (codified at 31 U.S.C. §§ 3729-3733);
- c. appropriate ways to conduct Promotional and Product Services Related Functions in compliance with all applicable FDA requirements, including FDA regulatory approval requirements;

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d. the materials and information that may be distributed by AtriCure, Inc. sales representatives and account executives about AtriCure, Inc.'s Government Reimbursed Products and the manner in which AtriCure, Inc. sales representatives and account executives respond to requests for information about non-FDA approved (or "off-label") uses of AtriCure, Inc.'s Government Reimbursed Products; the form and content of information disseminated by AtriCure, Inc. in response to such requests; and the internal review process for the information disseminated.

The Policies and Procedures shall include a requirement that AtriCure, Inc. develop a database to track requests for information about AtriCure, Inc.'s Government Reimbursed Products that involve non-FDA approved (or "off-label") uses. This database shall be referred to as the "Inquiries Database." The Inquiries Database shall include the following items of information for each unique inquiry (Inquiry) received for information about AtriCure, Inc.'s products: 1) date of Inquiry; 2) form of Inquiry (e.g., fax, phone, etc.); 3) name of the requesting HCP or HCI; 4) nature and topic of request (including exact language of the Inquiry if made in writing); 5) nature/form of the response from AtriCure, Inc. (including a record of the materials provided to the HCP or HCI in response to the request); and 6) the name of the AtriCure, Inc. representative who called on or interacted with the HCP or HCI. Any response from AtriCure, Inc. to an HCP or HCI shall identify whether the information provided addresses an indication that is part of the approved product label. The status and findings of any follow-up review conducted by AtriCure, Inc. in situations in which it appears that the Inquiry may have related to improper off-label promotion shall be maintained by the Compliance Officer and the information shall be included in the Inquiry Reports further discussed in Section III.A.2 of Appendix B;

e. review of AtriCure, Inc.'s launch and marketing plans and the use of Prolifiq, a centrally-controlled system to distribute information to AtriCure, Inc. customers. During the term of the CIA, AtriCure, Inc.

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will continue to mandate the use of the “Prolifiq” system for reviewing and tracking information requested by AtriCure, Inc. customers, and to disseminate such information. The policy governing the use of “Prolifiq” shall continue to ensure that AtriCure, Inc. is promoting its Government Reimbursed Products in a manner that complies with all applicable Federal health care program and FDA requirements and is consistent with representations made by AtriCure, Inc. to the FDA. The review of AtriCure’s launch and marketing plans and compliance with AtriCure’s Prolifiq system requirements shall occur at least annually and shall also occur each time when the FDA approves a new or additional indication for a Government Reimbursed Product;

f. review of all promotional and written materials and information intended to be disseminated outside AtriCure, Inc., including promotional and written materials and information related to the coding of Government Reimbursed Products by health care professionals and health care institutions, to ensure that legal, regulatory, and medical concerns are properly addressed during AtriCure, Inc.’s review and approval process and are elevated when appropriate. The Policies and Procedures shall be designed to ensure that such materials and information, as approved, comply with all applicable Federal health care program and FDA requirements;

g. Medical device reporting procedures, including those procedures required by 21 U.S.C. § 360i and 21 C.F.R. Part 803;

h. Post-approval medical device reporting procedures, including those required by 21 U.S.C. §§ 360i and 360l and 21 C.F.R. §§ 814.80, 814.82, and 814.84;

i. Policies and procedures for the protections of human subjects required by 45 C.F.R. § Part 46;

j. Policies and procedures for seeking approval of devices and uses of devices consistent with FDA statutes and regulations, including

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Investigational Device Exemption policies and procedures, required by 21 U.S.C. § 360j(g) and 21 C.F.R. Part 812; and

k. disciplinary policies and procedures for violations of AtriCure, Inc.'s Policies and Procedures, including policies relating to Federal health care program and FDA requirements.

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

At least annually (and more frequently, if appropriate), AtriCure, Inc. shall assess and update, as necessary, the Policies and Procedures. Within 30 days after the effective date of any revisions, any such revised Policies and Procedures shall be 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, AtriCure, Inc. shall provide at least two hours of General Training to each Covered Person. This training, at a minimum, shall explain AtriCure, Inc.'s:

- a. CIA requirements; and
- b. AtriCure, Inc.'s Compliance Program (including the Code of Conduct).

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

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

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- a. all applicable Federal health care program and FDA requirements relating to Promotional and Product Services Related Functions;
- b. all AtriCure, Inc. Policies and Procedures and other requirements applicable to Promotional and Product Services Related Functions;
- c. the personal obligation of each individual involved in Promotional and Product Services Related Functions to comply with all applicable Federal health care program and FDA requirements and all other applicable legal requirements, as well as AtriCure, Inc.'s Policies and Procedures;
- d. the legal sanctions for violations of the applicable Federal health care program and FDA requirements, the False Claims Act, and the Anti-kickback statute;
- e. examples of proper and improper practices related to Promotional and Product Services Related Functions;
- f. the dissemination of information regarding Federal health care program requirements concerning the accurate coding and submission of claims; and
- g. the legal sanctions to both AtriCure, Inc. and Relevant Covered Promotional and Product Services Persons of failure to comply with Federal health care program and FDA requirements and with AtriCure Inc.'s own Policies and Procedures and the failure to report such non-compliance.

New Relevant Promotional and Product Services Covered Persons shall receive this training within 90 days after the beginning of their employment or becoming a Relevant Promotional and Product Services Covered Person, or within 90 days after the Effective Date, whichever is later. An AtriCure, Inc. employee who has completed the Specific Training shall review or supervise (as applicable) a new Relevant Promotional and Product Services Covered Person's work, to the extent that the work relates to

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Promotional and Product Services Related Functions, until such time as the new Relevant Promotional and Product Services Covered Person completes his or her Specific Training.

After receiving the initial Specific Training described in this Section, each Relevant Promotional and Product Services Covered Person shall receive at least three hours of Specific Training in each subsequent Reporting Period.

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 of the training, including applicable Federal health care program and FDA requirements. The training and education required under this Section III.C may be provided by supervisory employees, knowledgeable staff, and/or outside consultant trainers selected by AtriCure, Inc., or may be satisfied by relevant continuing education programs provided they cover the topics outlined above in Section III.C.2.

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

6. *Computer-based Training.* AtriCure, Inc. may provide the training required under this CIA through appropriate computer-based training approaches. If AtriCure, Inc. 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 Covered Persons receiving such training.

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D. Review Procedures.

1. *General Description.*

a. *Engagement of Independent Review Organization.* Within 90 days after the Effective Date, AtriCure, Inc. shall engage an entity (or entities), such as an accounting, auditing, or consulting firm (hereinafter “Independent Review Organization” or “IRO”), to perform reviews to assist AtriCure, Inc. in assessing and evaluating its Promotional and Product Services Related Functions. The applicable requirements relating to the IRO are outlined in Appendix A to this CIA, which is incorporated by reference.

Each IRO engaged by AtriCure, Inc. shall have expertise in applicable Federal health care program and FDA requirements as may be appropriate to the Review for which the IRO is retained. Each IRO shall assess, along with AtriCure, Inc., whether it can perform the engagement in a professionally independent and objective fashion, as appropriate to the nature of the review, taking into account any other business relationships or other engagements that may exist.

The IRO(s) shall conduct reviews that assess AtriCure, Inc.’s systems, processes, policies, procedures, and practices relating to Promotional and Product Services Related Functions (Promotional and Product Services Reviews).

b. *Frequency and Brief Description of Reviews.* As set forth more fully in Appendix B, the Promotional and Product Services Review shall consist of two components - a Systems Review and a Transactions Review. The Systems Review shall assess AtriCure, Inc.’s systems, processes, policies, and procedures relating to Promotional and Product Services Related Functions. If there are no material changes in AtriCure, Inc.’s systems, processes, policies, and procedures relating to Promotional and Product Services Related Functions, the Promotional and Product Services Systems Review shall be performed for the periods covering the first and fourth

Reporting Periods. If AtriCure, Inc. materially changes its systems, processes, policies, and procedures relating to Promotional and Product Services Related Functions, the IRO shall perform a Systems Review for the Reporting Period in which such changes were made in addition to conducting the Systems Review for the first and fourth Reporting Periods.

The Promotional and Product Services Transactions Review shall be performed annually and shall cover each of the five Reporting Periods. The IRO(s) shall perform all components of each annual Transaction Review. As set forth more fully in Appendix B, the Transactions Review shall include several components, including a review relating to AtriCure, Inc.'s marketing and outreach efforts concerning atrial fibrillation, AtriCure, Inc.'s product-approval efforts, and a review of records relating to information disseminated regarding the correct or proper coding of AtriCure, Inc.'s Government Reimbursed Products.

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

2. *IRO Review Reports.* The IRO(s) shall prepare a report (or reports) based upon each Review performed. The information and content to be included in the report is described in Appendix B, which is incorporated by reference.

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

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Prior to initiating a Validation Review, OIG shall notify AtriCure, Inc. 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, AtriCure, Inc. may request a meeting with OIG to: (a) discuss the results of any Review submissions or findings; (b) present any additional information to clarify the results of the applicable Review or to correct the inaccuracy of the Review; and/or (c) propose alternatives to the proposed Validation Review. AtriCure, Inc. agrees to provide any additional information as may be requested by OIG under this Section III.D.3 in an expedited manner. OIG will attempt in good faith to resolve any Review issues with AtriCure, Inc. 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 and Objectivity Certification.* The IRO shall include in its report(s) to AtriCure, Inc. a certification or sworn affidavit that it has evaluated its professional independence and objectivity, as appropriate to the nature of the engagement, with regard to the applicable Review and that it has concluded that it is, in fact, independent and objective.

E. Disclosure Program.

Within 90 days after the Effective Date, AtriCure, Inc. 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 AtriCure, Inc.'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. AtriCure, Inc. 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

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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, AtriCure, Inc. shall conduct an internal review of the allegations set forth in the disclosure and ensure that proper follow-up is conducted.

The Compliance Officer (or designee) shall maintain a disclosure log, which shall include a record and summary of each disclosure received (whether anonymous or not), the status of the respective internal reviews, and any corrective action taken in response to the internal reviews. 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 scope of 42 U.S.C. § 1320a-7(a), but has not yet been excluded, debarred, suspended, or otherwise declared ineligible.
- b. “Exclusion Lists” include:
  - i. the HHS/OIG List of Excluded Individuals/Entities (available through the Internet at <http://www.oig.hhs.gov>); and
  - ii. the General Services Administration’s List of Parties Excluded from Federal Programs (available through the Internet at <http://www.epls.gov>).

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

- a. AtriCure, Inc. shall screen all prospective and current Covered Persons against the Exclusion Lists prior to engaging their services and, as part of the hiring or contracting process, shall require such Covered Persons to disclose whether they are Ineligible Persons.
- b. AtriCure, Inc. shall screen all Covered Persons against the Exclusion Lists within 90 days after the Effective Date and on an annual basis thereafter.
- c. AtriCure, Inc. shall implement a policy requiring all Covered Persons to disclose immediately any debarment, exclusion, suspension, or other event that makes that person an Ineligible Person.

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

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

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4. *Pending Charges and Proposed Exclusions.* If AtriCure, Inc. 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, AtriCure, Inc. shall take all appropriate actions to ensure that the responsibilities of that Covered Person have not and shall not adversely affect the quality of care rendered to any beneficiary, patient, or resident, or any claims submitted to any Federal health care program.

G. Notification of Government Investigation or Legal Proceedings.

Within 30 days after discovery by senior management at AtriCure, Inc., AtriCure, Inc. shall notify OIG, in writing, of any ongoing investigation or legal proceeding known to AtriCure, Inc. conducted or brought by a governmental entity or its agents involving an allegation that AtriCure, Inc. 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. AtriCure, Inc. 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:

- i. a matter that a reasonable person would consider a probable violation of criminal, civil, or administrative laws applicable to any Federal health care program and/or applicable to any FDA requirements relating to the promotion of AtriCure, Inc. Government Reimbursed Products for which penalties or exclusion may be authorized; or
- ii. the filing of a bankruptcy petition by AtriCure, Inc.

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

b. *Reporting of Reportable Events.* If AtriCure, Inc. determines (after a reasonable opportunity to conduct an appropriate review or investigation of the allegations) through any means that there is a Reportable Event, AtriCure, Inc. 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 and/or FDA authorities implicated;
- ii. a description of AtriCure, Inc.'s actions taken to correct the Reportable Event; and
- iii. any further steps AtriCure, Inc. plans to take to address the Reportable Event and prevent it from recurring.
- iv. If the Reportable Event involves the filing of a bankruptcy petition, the report to the OIG shall include documentation of the filing and a description of any Federal health care program authorities and/or FDA authorities implicated.
- v. AtriCure, Inc. shall not be required to report as a Reportable Event any matter previously disclosed under Section III.G.

I. Notification of Communications with FDA.

Within 30 days after the date of any written report, correspondence, or communication between AtriCure, Inc. and the FDA that materially discusses AtriCure, Inc.'s or a Covered Person's actual or potential unlawful or improper promotion of AtriCure, Inc.'s products (including any improper dissemination of information about unapproved uses), AtriCure, Inc. shall provide a copy of the report, correspondence, or communication to the OIG. AtriCure, Inc. shall also provide written notice to the OIG

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within 30 days after the resolution of any such disclosed matter, and shall provide the OIG with a description of the findings and/or results of the matter, if any.

Within 30 days after the date of any written report, correspondence, or communication between AtriCure, Inc. and the FDA that materially discusses the status of AtriCure, Inc.'s application for FDA approvals of Government Reimbursed Products, including the status of studies related to the FDA approval process, AtriCure, Inc. shall provide the OIG with a description of such written report, correspondence, or communication.

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

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

B. Purchase or Establishment of New Unit or Location. In the event that, after the Effective Date, AtriCure, Inc. 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, AtriCure, Inc. shall notify OIG at least 30 days prior to such purchase or the operation of the new business unit or location. This notification shall include the address of the new business unit or location, phone number, fax number, Federal health care program provider or supplier number (if applicable), and the name and address of the contractor that issued each number (if applicable). Each new business unit or location and all Covered Persons at each new business unit or location shall be subject to the applicable requirements of this CIA.

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

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**V. IMPLEMENTATION AND ANNUAL REPORTS**

A. Implementation Report. Within 120 days after the Effective Date, AtriCure, Inc. 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 members of the Committee of the Board referenced in Section III.A.3
4. the names and positions of the Certifying Employees required by Section III.A.4;
5. a copy of AtriCure, Inc.'s Code of Conduct required by Section III.B.1;
6. a copy of all Policies and Procedures required by Section III.B.2;
7. 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);
8. the following information regarding each type of training required by Section III.C:
  - a. a description of the initial and annual training, including a summary of the topics covered, the length of sessions, and a schedule of training sessions; and

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

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

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

10. the following information regarding the IRO(s): (a) identity, address, and phone number; (b) a copy of the engagement letter; and (c) a summary and description of any and all current and prior engagements and agreements between AtriCure, Inc. and the IRO;

11. a certification from the IRO regarding its professional independence and objectivity with respect to AtriCure, Inc.;

12. a description of the process by which AtriCure, Inc. fulfills the requirements of Section III.F regarding Ineligible Persons;

13. 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;

14. a list of all of AtriCure, Inc.'s U.S. locations (including locations and mailing addresses) at which it performs Promotional and Product Services Related Functions; the corresponding name under which each location is doing business; the corresponding phone numbers and fax numbers; each location's Federal health care program provider or supplier number(s) (if applicable), and the name and address of each Federal health care program contractor to which AtriCure, Inc. currently submits claims (if applicable);

15. a description of AtriCure, Inc.'s corporate structure, including identification of any parent and sister companies, subsidiaries, and their respective lines of business; and

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16. the certifications required by Section V.C.

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

Each Annual Report shall include, at a minimum:

1. an explanation of any change in the identity, position description, or other non-compliance job responsibilities of the Compliance Officer and any change in the membership of the Compliance Committee, the compliance Committee of the Board of Directors, or the group of Certifying Employees described in Section III.A.4, and a copy of the Compliance Program Review Report described in Section III.A.3;

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);

3. the number of Covered Persons 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 the initial and annual training, including a summary of the topics covered, the length of sessions, and a schedule of training sessions; and

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

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

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5. a complete copy of all reports prepared pursuant to Section III.D, along with a copy of the IRO's engagement letter (if applicable);
6. AtriCure, Inc.'s response to the reports prepared pursuant to Section III.D, along with corrective action plan(s) related to any issues raised by the reports;
7. a summary and description of any and all current and prior engagements and agreements between AtriCure, Inc. 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 objectivity with respect to AtriCure, Inc.;
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 AtriCure, Inc. 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; and the actions taken by AtriCure, Inc. in response to the screening and removal obligations set forth in Section III.F;
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 AtriCure, Inc.'s locations (including addresses) as required by Section V.A.12; the corresponding name under which each location is doing business; and the corresponding phone numbers and fax numbers;

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15. a summary describing any written communication with the FDA required to have been reported pursuant to Section III.I. This summary shall include a description of the matter and the status of the matter;

16. 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 following certifications shall be included in the Implementation Report and each Annual Report:

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

2. Compliance Officer: In the Implementation Report and Annual Reports, AtriCure, Inc. shall include the following individual certification by the Compliance Officer:

a. 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;

b. to the best of his or her knowledge, except as otherwise described in the report, AtriCure, Inc. is in compliance with the Federal health care program and FDA requirements and the obligations of the CIA;

c. to the best of his or her knowledge, AtriCure, Inc. 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. AtriCure, Inc.'s: 1) Policies and Procedures as referenced in

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Section III.B.2 above; 2) templates for standardized contracts and other similar documents; and 3) the training materials used for purposes of Section III.C all have been reviewed by competent legal counsel and/or legal personnel working at their direction and have been found to be in compliance with all applicable Federal health care program and FDA requirements. In addition, AtriCure, Inc.'s promotional materials containing claims or information about Government Reimbursed Products and other materials and information intended to be disseminated outside AtriCure, Inc. have been reviewed by competent regulatory, medical, and/or legal personnel in accordance with applicable Policies and Procedures to ensure that legal, medical, and regulatory concerns are properly addressed and are elevated when appropriate, and that the materials and information when finally approved are in compliance with all applicable Federal health care program and FDA requirements. If the applicable legal requirements have not changed, after the initial review of the documents listed above, only material changes to the documents must be reviewed by competent regulatory, medical, and/or legal personnel. The certification shall include a description of the document(s) reviewed and approximately when the review was completed. The documentation supporting this certification shall be available to OIG, upon request; and

e. AtriCure, Inc.'s launch and marketing plans for Government Reimbursed Products were reviewed at least once during the Reporting Period (consistent with Section III.B.2.e) and, for each product the plans were found to be consistent with AtriCure, Inc.'s policy objectives as referenced above in Section III.B.2.e.

f. AtriCure, Inc. is making good-faith efforts to obtain all necessary approvals for each of its Government Reimbursed Products.

D. Designation of Information. AtriCure, Inc. 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. AtriCure, Inc. 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:

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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

AtriCure: Jim Lucky  
VP, Quality Assurance & Regulatory Affairs  
Compliance Officer  
AtriCure, Inc.  
6033 Schumacher Park Drive  
West Chester, Ohio 45069  
Phone: 513.755.4100

Unless otherwise specified, all notifications and reports required by this CIA may be made by certified mail, overnight mail, hand delivery, or other means, provided that there is proof that such notification was received. For purposes of this requirement, internal facsimile confirmation sheets do not constitute proof of receipt. Upon request by OIG, AtriCure, Inc. may be required to provide OIG with an electronic copy of each notification or report required by this CIA in searchable portable document format (.pdf), either instead of or in addition to, a paper copy.

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

In addition to any other rights OIG may have by statute, regulation, or contract, OIG or its duly authorized representative(s) may examine or request copies of AtriCure, Inc.'s books, records, and other documents and supporting materials and/or conduct on-site reviews of any of AtriCure, Inc.'s locations for the purpose of verifying and evaluating: (a) AtriCure, Inc.'s compliance with the terms of this CIA; and (b) AtriCure, Inc.'s compliance with the requirements of the Federal health care programs and FDA applicable to its Government Reimbursed Products. The documentation described above shall be made available by AtriCure, Inc. to OIG or its duly authorized representative(s) at all reasonable times for inspection, audit, or reproduction. Furthermore, for purposes

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of this provision, OIG or its duly authorized representative(s) may interview any of AtriCure, Inc.'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. AtriCure, Inc. shall assist OIG or its duly authorized representative(s) in contacting and arranging interviews with such individuals upon OIG's request. AtriCure, Inc.'s employees may elect to be interviewed with or without a representative of AtriCure, Inc. present.

**VIII. DOCUMENT AND RECORD RETENTION**

AtriCure, Inc. shall maintain for inspection all documents and records relating to reimbursement from the Federal health care programs, or to compliance with this CIA, for six 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 AtriCure, Inc. prior to any release by OIG of information submitted by AtriCure, Inc. pursuant to its obligations under this CIA and identified upon submission by AtriCure, Inc. as trade secrets, or information that is commercial or financial and privileged or confidential, under the FOIA rules. With respect to such releases, AtriCure, Inc. shall have the rights set forth at 45 C.F.R. § 5.65(d).

**X. BREACH AND DEFAULT PROVISIONS**

AtriCure, Inc. 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, AtriCure, Inc. 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 AtriCure, Inc. fails to establish and

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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 and Relevant Covered Persons;
- f. a Disclosure Program;
- g. Ineligible Persons screening and removal requirements;
- h. notification of Government investigations or legal proceedings; and
- i. 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 AtriCure, Inc. fails to engage an IRO, as required in Section III.D and Appendices A and B.

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

4. A Stipulated Penalty of \$2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day AtriCure, Inc. fails to submit the annual IRO Review Report(s) in accordance with the requirements of Section III.D and Appendices A and B.

5. A Stipulated Penalty of \$2,000 (which shall begin to accrue on the date the failure to comply began) for each day AtriCure, Inc. employees or contracts with an

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Ineligible Person and that person: (i) has responsibility for, or involvement with, AtriCure, Inc.'s business operations related to Federal health care programs; or (ii) is in a position for which the person's salary or the items or services rendered or ordered by the person are paid in whole or part, directly or indirectly, by Federal health care programs or otherwise with Federal funds (the Stipulated Penalty described in this paragraph shall not be demanded for any time period during with AtriCure, Inc. can demonstrate that it did not discover the person's exclusion or other ineligibility after making a reasonable inquiry (as described in section III.F) as to the status of the person.

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

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

8. A Stipulated Penalty of \$1,000 for each day AtriCure, Inc. fails to comply fully and adequately with any obligation of this CIA. OIG shall provide notice to AtriCure, Inc. stating the specific grounds for its determination that AtriCure, Inc. has failed to comply fully and adequately with the CIA obligation(s) at issue and steps AtriCure, Inc. shall take to comply with the CIA. (This Stipulated Penalty shall begin to accrue 10 days after AtriCure, Inc. 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 1-7 of this Section.

B. Timely Written Requests for Extensions. AtriCure, Inc. 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 AtriCure, Inc. 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

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business days after AtriCure, Inc. 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 AtriCure, Inc. 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 AtriCure, Inc. of: (a) AtriCure, Inc.'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, AtriCure, Inc. 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 AtriCure, Inc. elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until AtriCure, Inc. cures, to OIG's satisfaction, the alleged breach in dispute. Failure to respond to the Demand Letter in one of these two manners within the allowed time period shall be considered a material breach of this CIA and shall be grounds for exclusion under Section X.D.

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

4. *Independence from Material Breach Determination.* Except as set forth in Section X.D.1.c, these provisions for payment of Stipulated Penalties shall not affect or otherwise set a standard for OIG's decision that AtriCure, Inc. 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.

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D. Exclusion for Material Breach of this CIA.

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

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

2. *Notice of Material Breach and Intent to Exclude.* The parties agree that a material breach of this CIA by AtriCure, Inc. constitutes an independent basis for AtriCure, Inc.'s exclusion from participation in the Federal health care programs. Upon a determination by OIG that AtriCure, Inc. has materially breached this CIA and that exclusion is the appropriate remedy, OIG shall notify AtriCure, Inc. of: (a) AtriCure, Inc.'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.* AtriCure, Inc. 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. AtriCure, Inc. 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) AtriCure, Inc. has begun to take action to cure

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the material breach; (ii) AtriCure, Inc. is pursuing such action with due diligence; and (iii) AtriCure, Inc. has provided to OIG a reasonable timetable for curing the material breach.

4. *Exclusion Letter.* If, at the conclusion of the 30-day period, AtriCure, Inc. fails to satisfy the requirements of Section X.D.3, OIG may exclude AtriCure, Inc. from participation in the Federal health care programs. OIG shall notify AtriCure, Inc. in writing of its determination to exclude AtriCure, Inc. (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 AtriCure, Inc.’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, AtriCure, Inc. 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 AtriCure, Inc. 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, AtriCure, Inc. 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 AtriCure, Inc. was in full and timely compliance with the obligations of this CIA for which OIG demands payment; and (b) the period of noncompliance. AtriCure, Inc. shall have the burden of proving its full and timely compliance and the steps taken to cure the

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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 AtriCure, Inc. to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable 20 days after the ALJ issues such a decision unless AtriCure, Inc. 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 AtriCure, Inc. 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) AtriCure, Inc. had begun to take action to cure the material breach within that period; (ii) AtriCure, Inc. has pursued and is pursuing such action with due diligence; and (iii) AtriCure, Inc. provided to OIG within that period a reasonable timetable for curing the material breach and AtriCure, Inc. 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 AtriCure, Inc., only after a DAB decision in favor of OIG. AtriCure, Inc.'s election of its contractual right to appeal to the DAB shall not abrogate OIG's authority to exclude AtriCure, Inc. 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 AtriCure, Inc. 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. AtriCure, Inc. 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

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AtriCure, Inc., AtriCure, Inc. 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**

AtriCure, Inc. and OIG agree as follows:

- A. This CIA shall be binding on the successors, assigns, and transferees of AtriCure, Inc.;
- B. This CIA shall become final and binding on the date the final signature is obtained on the CIA;
- C. This CIA constitutes the complete agreement between the parties and may not be amended except by written consent of the parties to this CIA;

D. OIG may agree to a suspension of AtriCure, Inc.'s obligations under the CIA in the event of AtriCure, Inc.'s cessation of participation in Federal health care programs. If AtriCure, Inc. ceases participating in Federal health care programs and is relieved of its CIA obligations by OIG, AtriCure, Inc. shall notify OIG at least 30 days in advance of AtriCure, Inc.'s intent to resume participating as a provider or supplier with any Federal health care program. Upon receipt of such notification, OIG shall evaluate whether the CIA should be reactivated or modified.

E. The undersigned AtriCure, Inc. signatories represent and warrant that they are authorized to execute this CIA. The undersigned OIG signatory represents that he is signing this CIA in his official capacity and that he is authorized to execute this CIA.

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

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ON BEHALF OF ATRICURE, INC.

/s/ David Drachman  
\_\_\_\_\_  
DAVID DRACHMAN  
Chief Executive Officer  
AtriCure, Inc.

2/1/2010  
\_\_\_\_\_  
DATE

/s/ Stuart M. Gerson  
\_\_\_\_\_  
STUART M. GERSON  
Epstein Becker & Green, P.C.

1/20/2010  
\_\_\_\_\_  
DATE

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

/s/ Gregory E. Demske

1/27/2010

GREGORY E. DEMSKE

DATE

Assistant Inspector General for Legal Affairs

Office of Inspector General

U. S. Department of Health and Human Services

CORPORATE INTEGRITY AGREEMENT

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**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**

AtriCure, Inc. shall engage an IRO that possesses the qualifications set forth in Paragraph B, below, to perform the responsibilities in Paragraph C, below. The IRO shall conduct the review in a professionally independent and objective fashion, as set forth in Paragraph D. Within 30 days after OIG receives written notice of the identity of the selected IRO, OIG will notify AtriCure, Inc. if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, AtriCure, Inc. may continue to engage the IRO.

If Atricure, Inc. 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, Atricure, Inc. shall submit the information identified in Section V.A.10 of the CIA 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 Atricure, Inc. if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, Atricure, Inc. may continue to engage the IRO.

**B. IRO Qualifications.**

The IRO shall:

1. assign individuals to conduct the Promotional and Product Services Review who have expertise in all applicable Federal health care program and FDA requirements relating to Promotional and Product Services Related Functions. The assigned individuals shall also be knowledgeable about the general requirements of the Federal health care program(s) under which Atricure, Inc. products are reimbursed;

2. assign individuals to design and select the samples for the Transaction Reviews who are knowledgeable about the appropriate statistical sampling techniques; and

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

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C. IRO Responsibilities.

The IRO shall:

1. perform each Promotional and Product Services Review in accordance with the specific requirements of the CIA;
2. follow all applicable Federal health care program and FDA requirements in making assessments in each Promotional and Product Services Review;
3. if in doubt of the application of a particular Federal health care program or FDA requirement, policy, or regulation, request clarification from the appropriate authority (e.g., CMS or FDA);
4. respond to all OIG inquiries in a prompt, objective, and factual manner; and
5. prepare timely, clear, well-written reports that include all the information required by Appendix B to the CIA.

D. IRO Independence and Objectivity.

The IRO must perform the Promotional and Product Services Review in a professionally independent and 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 Atricare, Inc.

E. IRO Removal/Termination.

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

Prior to requiring Atricare, Inc. to engage a new IRO, OIG shall notify Atricare, Inc. 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, Atricare, Inc. may request a

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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. Atricare, Inc. 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 Atricare, Inc. prior to requiring Atricare, Inc. to terminate the IRO. However, the final determination as to whether or not to require Atricare, Inc. to engage a new IRO shall be made at the sole discretion of OIG.

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**Appendix B to CIA for AtriCure, Inc.  
Promotional and Product Services Review**

I. Promotional and Product Services Review, General Description

As specified more fully below, AtriCure, Inc. (AtriCure) shall retain an Independent Review Organization (IRO) to perform reviews to assist AtriCure in assessing and evaluating its systems, processes, policies, procedures, and practices related to AtriCure's Promotional and Product Services Related Functions (Promotional and Product Services Review). The Promotional and Product Services Review shall consist of two components - a systems review (the "Promotional and Product Services Systems Review" or "Systems Review"), and a transactions review (the "Promotional and Product Services Transactions Review" or "Transactions Review") as described more fully below. AtriCure may engage, at its discretion, a single IRO to perform both components of the Promotional and Product Services Review provided that the entity has the necessary expertise and capabilities to perform both.

If there are no material changes in AtriCure's systems, processes, policies, and procedures relating to Promotional and Product Services Related Functions, the IRO shall perform the Promotional and Product Services Systems Review for the first and fourth Reporting Periods. If AtriCure materially changes its systems, processes, policies, and procedures relating to Promotional and Product Services Related Functions, the IRO shall perform a Promotional and Product Services Systems Review for the Reporting Period(s) in which such changes were made in addition to conducting the Review for the first and fourth Reporting Periods. The additional Systems Review(s) shall consist of: 1) an identification of the material changes; 2) an assessment of whether other systems, processes, policies, and procedures previously reported did not materially change; and 3) a review of the systems, processes, policies, and procedures that materially changed. The IRO shall conduct the Promotional and Product Services Transactions Review for each Reporting Period of the CIA.

II. Promotional and Product Services Systems Review

A. Description of Reviewed Policies and Procedures

The Promotional and Product Services Systems Review shall be a review of AtriCure's systems, processes, policies, and procedures (including the controls on those systems, processes, policies, and procedures) relating to certain Promotional and Product Services Related Functions. Where practical, AtriCure personnel may compile documentation, schedule and organize interviews, and undertake other efforts to assist the IRO in performing the Systems Review. The IRO is not

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required to undertake a de novo review of the information gathered or activities undertaken by AtriCure pursuant to the preceding sentence.

Specifically, the IRO shall review AtriCure's systems, processes, policies, and procedures associated with the following (hereafter "Reviewed Policies and Procedures"):

- 1) AtriCure's systems, policies, processes, and procedures applicable to the manner in which AtriCure representatives (including sales representatives and marketing personnel) handle requests or inquiries relating to information about the uses of AtriCure products (including non-FDA-approved (i.e., off-label) uses) and the dissemination of materials relating to off-label uses of products. This review includes:
  - a) the manner in which AtriCure sales representatives and marketing personnel handle requests for information about off-label uses of AtriCure products;
  - b) the form and content of information and materials related to AtriCure's products disseminated to physicians, pharmacists, or other health care professionals (collectively "HCPs") or health care institutions ("HCIs") by AtriCure;
  - c) AtriCure's systems, processes, and procedures (including the Inquiries Database) to track requests for information about off-label uses of products and responses to those requests;
  - d) the manner in which AtriCure collects and supports information reported in any systems used to track and respond to requests for product information, including its Inquiries Database;
  - e) the processes and procedures by which the Compliance Officer (and other appropriate individuals within AtriCure) identify situations in which it appears that improper off-label promotion may have occurred; and
  - f) AtriCure's processes and procedures for investigating, documenting, resolving, and taking appropriate disciplinary action for potential situations involving off-label promotion;
- 2) AtriCure's systems, policies, processes, and procedures relating to AtriCure's internal review and approval of information and

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materials related to AtriCure's products disseminated to HCPs or HCIs by AtriCure;

3) AtriCure's systems, policies, processes and procedures relating to incentive compensation for Covered Persons who are sales representatives, with regard to whether the systems, policies, processes, and procedures are designed to ensure that financial incentives do not inappropriately motivate such individuals to engage in the improper promotion, sales, and marketing of AtriCure's products. This shall include a review of the bases upon which compensation is determined and the extent to which compensation is based on product performance;

4) AtriCure's systems, policies, processes and procedures relating to its efforts to obtain FDA-required approvals for its Government Reimbursed Products; and

5) AtriCure's systems, processes, policies, and procedures relating to the development and review of launch and marketing plans for AtriCure's products. This shall include a review of the bases upon which HCPs and HCIs belonging to specified medical specialties are included in, or excluded from, AtriCure's launch and marketing plans based on expected utilization of AtriCure products for FDA-approved uses or non-FDA-approved uses.

**B. Promotional and Product Services Systems Review Report**

The IRO shall prepare a report based upon each Systems Review. For each of the Reviewed Policies and Procedures identified in Section II.A above, the report shall include the following items:

1) a description of the documentation (including policies) reviewed and any personnel interviewed;

2) a detailed description of AtriCure's systems, policies, processes, and procedures relating to the items identified in Sections II.A.1-5 above, including a general description of AtriCure's control and accountability systems (e.g., documentation and approval requirements, and tracking mechanisms) and written policies regarding the Reviewed Policies and Procedures;

3) a description of the manner in which the control and accountability systems and the written policies relating to the items

identified in Sections II.A.1-5 above are made known or disseminated within AtriCure;

4) a detailed description of any system(s) used to track and respond to requests for information about AtriCure's products (including the Inquiries Database);

5) a detailed description of AtriCure's incentive compensation system for Covered Persons who are sales representatives, including a description of the bases upon which compensation is determined and the extent to which compensation is based on product performance. To the extent that AtriCure may establish compensation differently for individual products, the IRO shall report separately on each such type of compensation arrangement;

6) findings and supporting rationale regarding any weaknesses in AtriCure's systems, processes, policies, and procedures relating to the Reviewed Policies and Procedures, if any; and

7) recommendations to improve any of the systems, policies, processes, or procedures relating to the Reviewed Policies and Procedures, if any.

### III. Promotional and Product Services Transaction Review

As described more fully below in Sections III.A-D, the Promotional and Product Services Transactions Review shall include: (1) a review of a sample of Inquiries reflected in the Inquiries Database; (2) a review of AtriCure's launch and marketing plans and AtriCure's plan review process; (3) a review of records relating to AtriCure's good-faith efforts to obtain FDA approval for its Government Reimbursed Products; and (4) a review of the coding information AtriCure provides to HCPs and HCIs. The IRO shall report on all aspects of its reviews in the Promotional and Product Services Transactions Review Reports.

#### A. Review of Inquiries and Inquiries Database

##### 1) Description of Inquiries Database

As set forth in Section III.B.2.d of the CIA, AtriCure shall establish a database to track information relating to requests for information received by AtriCure about its products (hereafter "Inquiries"). Specifically, AtriCure shall document and record all Inquiries received from HCPs or HCIs regarding AtriCure's products in a

database (the "Inquiries Database"). AtriCure shall record in the Inquiries Database the following information for each Inquiry received: 1) date of Inquiry; 2) form of Inquiry (e.g., fax, phone, medical information request form); 3) name of requesting HCP or HCI; 4) nature and topic of request (including exact language of the Inquiry if made in writing); 5) nature/form of the response from AtriCure (including a record of any materials provided in response to the request); and 6) the name of the AtriCure sales representative or marketing department employee who called upon or interacted with the HCP or HCI. Any response from AtriCure to an HCP or HCI shall identify whether the information provided addresses an indication that is part of an approved product label. The status and findings of any follow-up review conducted by AtriCure in situations in which improper off-label promotion is suspected shall be maintained by Global Compliance.

2) Internal Review of Inquiries Database

On a semi-annual basis, the Compliance Officer or other appropriate personnel shall review the Inquiries Database and related information, as appropriate, and shall generate a report summarizing the items of information outlined in Section III.A.1 above for each Inquiry received during the preceding two quarters ("Inquiry Report"). The Compliance Officer or other appropriate personnel shall review the Inquiry Reports to assess whether the information contained in the report suggests that improper off-label promotion may have occurred in connection with any Inquiry(ies). If the Compliance Officer or other appropriate personnel, in consultation with other appropriate AtriCure personnel, suspects that improper off-label promotion may have occurred in connection with any Inquiry, the Compliance Officer or other appropriate personnel shall undertake a follow-up review of the Inquiry (Off-Label Review), make specific findings based on his/her Off-Label Review, and take all appropriate responsive action (including disciplinary action of the Covered Person and reporting of the conduct, including disclosing Reportable Events pursuant to Section III.H of the CIA, if applicable).

3) IRO Review of Inquiries Reflected in Inquiries Database

The IRO shall select and review a random sample of 20 Inquiries from among the Inquiries reflected in the Inquiries Database for each Reporting Period. Ten of the Inquiries reviewed by the IRO shall be

Inquiries for which AtriCure conducted an Off-Label Review, and the other 10 shall be Inquiries for which AtriCure did not conduct an Off-Label Review. For each Inquiry reviewed, the IRO shall determine:

- a) Whether each item of information listed above in Section III.A.1 is reflected in the Inquiries Database for each reviewed Inquiry; and
- b) For each Inquiry for which the Compliance Officer or other appropriate personnel conducted an Off-Label Review, the basis for suspecting that improper off-label promotion may have occurred; the steps undertaken as part of the Off-Label Review; the findings of the Compliance Officer or other appropriate personnel as a result of the Off-Label Review; and any follow-up actions taken by AtriCure based on the Off-Label Review findings.

**B. IRO Review of AtriCure's Launch and Marketing Plans and Plan Review Process**

The IRO shall conduct a review and assessment of AtriCure's review of its launch and marketing plans for Government Reimbursed Products and compliance with the mandated use of the Prolifig system as set forth in Section III.B.2.e of the CIA. AtriCure shall provide the IRO with: i) a list of products promoted by AtriCure during the Reporting Period; ii) information about the FDA-approved uses for each AtriCure product; and iii) the launch and marketing plans for each product. AtriCure shall also provide the IRO with information about the reviews of launch and marketing plans that AtriCure conducted during the Reporting Period and any modifications to the plans made as a result of AtriCure's reviews.

The IRO shall select a sample of 10 of the HCPs and HCIs who were recipients of information derived from AtriCure's launch and marketing plans. For each plan, the IRO shall compare the sampled HCPs and HCIs against the criteria (e.g., medical specialty or practice area) used by AtriCure in conducting its review and/or modification of the plan in order to determine whether AtriCure followed its criteria and Policies and Procedures in reviewing and modifying the launch and marketing plan and distributing related information through Prolifig.

The IRO shall note any instances in which it appears that the sampled HCPs and HCIs are inconsistent with AtriCure's criteria relating to the launch or marketing plan and/or AtriCure's Policies and Procedures. The IRO shall also note any

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instances in which it appears that AtriCure failed to follow its criteria or Policies and Procedures.

C. IRO Review of AtriCure Materials Concerning Coding of Government Reimbursed Products

The IRO shall conduct a review and assessment of AtriCure's documents and materials related to the coding of its Government Reimbursed Products. AtriCure shall provide the IRO with: i) a list of Government Reimbursed Products promoted by AtriCure during the Reporting Period; ii) information about the CMS-approved coding for each AtriCure product; and iii) any materials produced or disseminated to HCIs and HCPs by AtriCure regarding coding for each product.

D. IRO Review of AtriCure's Efforts To Obtain FDA Approval for Government Reimbursed Products

The IRO shall conduct a review and assessment of AtriCure's efforts to obtain all necessary approvals to market from the FDA for each of its Government Reimbursed Products for any use. AtriCure shall provide the IRO with sufficient information for the IRO to assess whether AtriCure has adequate approvals to support its marketing for each of its Government Reimbursed Products. If AtriCure does not have adequate approvals, AtriCure shall further provide the IRO with sufficient information for the IRO to assess whether AtriCure 1) has set realistic internal goals and timelines to obtain FDA approvals; 2) is making a good-faith effort to initiate studies or other clinical trials necessary to obtain FDA approvals; and 3) is marketing its products in a manner consistent with each product's then-current certification by the FDA.

E. Promotional and Product Services Transactions Review Report

For each Reporting Period, the IRO shall prepare a report based on its Promotional and Product Services Transactions Review. The report shall include the following:

1) General Elements to Be Included in Report

- a) Review Objectives: A clear statement of the objectives intended to be achieved by each part of the review;
- b) Review Protocol: A detailed narrative description of the procedures performed and a description of the sampling unit and universe utilized in performing the procedures for each sample reviewed; and

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- c) Sources of Data: A full description of documentation and other information, if applicable, relied upon by the IRO in performing the Promotional and Product Services Transactions Review.
- 2) Results to be Included in Report
- The following results shall be included in each Promotional and Product Services Review Report:
- (Relating to the Review of Inquiries)
- a) in connection with the review of Inquiries, a description of each type of sample unit reviewed, including the number of each type of sample units reviewed (e.g., the number of Inquiries) and an identification of the types of documents and information reviewed for the Inquiries;
  - b) for each Inquiry sample unit, the IRO shall summarize the information about the Inquiry contained in the Inquiries Database;
  - c) for each Inquiry sample unit, findings and supporting rationale as to whether: (i) each item of information listed in Section III.A.1 is reflected in the Inquiries Database; and (ii) for each Inquiry for which an Off-Label Review was conducted, the basis for suspecting that improper off-label promotion may have occurred; the steps undertaken as part of the Off-Label Review; the findings of the Compliance Officer as a result of the Off-Label Review; and any follow-up actions taken by AtriCure as a result of the Compliance Officer's findings;
  - d) the findings and supporting rationale regarding any weaknesses in AtriCure's systems, processes, policies, procedures, and practices relating to the Inquiries, and the Inquiries Database, if any;
  - e) recommendations for improvement in AtriCure's systems, processes, policies, procedures, and practices relating to the Inquiries and the Inquiries Database, if any;

(Relating to the Launch and Marketing Plan Reviews)

- f) a list of the products promoted by AtriCure during the Reporting Period and a summary of the FDA-approved uses for such products;
- g) for each AtriCure product: i) a description of the criteria used by AtriCure in developing or reviewing the launch and marketing plans and for including or excluding specified types of HCPs or HCIs from the plans; ii) a description of the review conducted by AtriCure of the plans and an indication of whether AtriCure reviewed the plans as required by Section III.B.3.e of the CIA; iii) a description of all instances for each plan in which it appears that the HCPs and HCIs included on the plan are inconsistent with AtriCure's criteria relating to the plan and/or AtriCure's Policies and Procedures; and iv) a description of all instances in which it appears that AtriCure failed to follow its criteria or Policies and Procedures relating to plans or the review of the plans;
- h) the findings and supporting rationale regarding any weaknesses in AtriCure's systems, processes, policies, procedures, and practices relating to AtriCure's launch and marketing plans, the use of Prolifiq with respect to those plans, or review of the plans, if any;
- i) recommendations, if any, for changes in AtriCure's systems, processes, policies, procedures, and practices that would correct or address any weaknesses or deficiencies uncovered during the Transactions Review with respect to launch and marketing plans or the review of the plans;

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