

**INTEGRITY AGREEMENT
BETWEEN THE
OFFICE OF INSPECTOR GENERAL
OF THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND
LEONARD MCAULIFFE AND WINDSOR MEDICAL, INC.**

I. PREAMBLE

Leonard McAuliffe and Windsor Medical, Inc. (collectively, "McAuliffe") hereby agree to enter into this Integrity Agreement (the "IA") with the Office of Inspector General ("OIG") of the United States Department of Health and Human Services ("HHS") in an effort to ensure compliance with the requirements of Medicare, Medicaid and all other federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)) by McAuliffe, its directors, officers, employees, all third parties with whom McAuliffe may choose to engage to act as agents or consultants as well as any entities in which either Windsor Medical, Inc. or Leonard McAuliffe have an ownership or control interest as defined in 42 U.S.C. § 1320a-3(a)(3). On or about this date, McAuliffe is entering into a Plea Agreement with the United States Attorney's Office for the District of New Hampshire and this IA is incorporated by reference into that Plea Agreement.

II. TERM OF THE AGREEMENT

The period of the compliance obligations assumed by McAuliffe under this IA shall be 5 years from the effective date of this IA. The effective date of this IA is the date of the last signatory to the IA. Sections IV, VI, VII, VIII, IX and X shall remain in effect until OIG has completed its review of the final annual report and any additional materials submitted by McAuliffe pursuant to OIG's request.

III. INTEGRITY OBLIGATIONS

a. Policies and Notice. Within 60 days of the execution of this IA, McAuliffe will adopt and implement written policies, procedures and practices designed to ensure compliance with the requirements of Medicare, Medicaid and all other Federal health care programs for the sale and marketing of and billing for medical devices, instruments and other supplies. The policies and procedures shall be distributed to each employee who shall sign a certification that he or she has read, understands and will abide by the compliance policies and procedures. These certifications shall be made available to OIG upon request. In addition, McAuliffe shall post in a prominent place accessible to each employee a notice detailing its commitment to comply with all applicable statutes, regulations and directives applicable to Medicare, Medicaid and all other Federal health care programs in the conduct of its business. Each new employee shall read the policies

and procedures and execute the certifications described above within 2 weeks of beginning employment.

b. Training and Education.

Within 90 days of the execution of this IA, McAuliffe will develop and institute an information and education program designed to ensure that each officer, director, and employee who has any responsibility for activities related to the sale, marketing of or billing for medical devices, instruments or other medical supplies (including those employees who are directly involved in formulating, determining or implementing policies or procedures for the sale, marketing or promotion of medical devices, instruments or other supplies) are aware of: (1) all statutes, regulations, policies, procedures, and guidelines related to Medicare, Medicaid, and other Federal health care program and applicable to the marketing of or billing for the types of medical devices, instruments or supplies sold by McAuliffe; (2) McAuliffe's policies, procedures and practices (described in section III.a) and; (3) the standards of business conduct that such an individual is expected to follow and the consequences both to the individual and McAuliffe that will ensue from any violation of the requirements. Pursuant to this program, each officer, director and employee who has any responsibility for activities related to the sale, marketing of or billing for medical devices shall receive at least one hour of general training regarding these subjects. Subsequently, new employees shall receive such training within two weeks of beginning employment. Each person who

receives the training shall execute a certification that they have received training in accordance with the requirements of this section. These certifications shall be made available to OIG upon request.

c. Review and Disclosure.

(1) *Review of Practices.* On an annual basis, McAuliffe will have an experienced attorney with knowledge of the Federal health care statutes, regulations, policies, procedures, and guidelines, including those issued by the Health Care Financing Administration (HCFA) and its contractors: (i) review any proposed changes to McAuliffe's policies and procedures related to the sale, marketing of or billing for medical devices to Federal health care programs or their beneficiaries prior to any implementation of such changes by McAuliffe, (ii) annually review all of McAuliffe's practices related to the sale, marketing of or billing for medical devices to Federal health care programs or their beneficiaries and (iii) review all sales, promotional or marketing contracts or arrangements to determine if they comply all applicable Federal health care statutes, regulations, policies, procedures and written HCFA directives. Although the review may be subject to the attorney-client privilege, the underlying McAuliffe documents used in the reviews described in this section shall be maintained and available for OIG review and inspection for a minimum of 6 years. The first annual review shall be performed no later than 90 days after the effective date of this Agreement. Subsequent

annual reviews shall be performed no later than the anniversary date of the first annual review.

(2) *Material Deficiencies.*

(i) *Definition of a Material Deficiency.* For purposes of this IA, a “material deficiency” shall mean a matter that a reasonable person would consider a potential violation of criminal, civil, or administrative laws applicable to any Federal health care program for which penalties or exclusion may be authorized. A material deficiency may be the result of an isolated event or a series of occurrences.

(ii) *Reporting of Material Deficiencies.* If McAuliffe determines through any means that there is a Material Deficiency, McAuliffe shall notify OIG, in writing, within 30 days of making the determination that the Material Deficiency exists.

The report to the OIG shall include the following information:

- (A) a complete description of the Material Deficiency, including the relevant facts, persons involved, and legal and Federal health care program authorities implicated;
- (B) a description of McAuliffe’s actions taken to correct the Material Deficiency; and
- (C) any further steps McAuliffe plans to take to address the Material Deficiency and prevent it from recurring.

d. Ineligible Persons.

(1) *Definition.* For purposes of this IA, an “Ineligible Person” shall be any individual or entity who: (a) is currently excluded, debarred or otherwise ineligible to participate in the Federal health care programs or in Federal procurement or non-procurement programs; or (b) has been convicted of a criminal offense related to the provision of health care items or services, but has not yet been excluded, debarred or otherwise declared ineligible.

(2) *Screening Requirements.* McAuliffe shall not hire as employees or engage as contractors any Ineligible Person. To prevent hiring or contracting with any Ineligible Person, McAuliffe shall screen all prospective employees and prospective contractors prior to engaging their services by: (a) requiring applicants to disclose whether they are Ineligible Persons; and (b) reviewing the General Services Administration’s List of Parties Excluded from Federal Programs (available through the Internet at <http://epls.arnet.gov>) and the HHS/OIG List of Excluded Individuals/Entities (available through the Internet at <http://www.hhs.gov/oig>) (these lists will hereinafter be referred to as the “Exclusion Lists”).

(3) *Review and Removal Requirement.* Within 30 days of the effective date of this IA, McAuliffe shall review its list of current employees and contractors against the Exclusion Lists. Thereafter, McAuliffe shall review the Exclusion Lists semi-annually.

In addition, McAuliffe shall require employees and contractors to disclose immediately any debarment, exclusion or other event that makes the employee an Ineligible Person.

If McAuliffe has notice that an employee or contractor has become an Ineligible Person, McAuliffe shall remove such person from responsibility for, or involvement with, McAuliffe's business operations related to the Federal health care programs and shall remove such person from his or her position at least until such time as the person is reinstated into participation in the Federal health care programs.

(4) Pending Charges and Proposed Exclusions. If McAuliffe has notice that an employee or contractor is charged with a criminal offense related to any Federal health care program, or is proposed for exclusion during his or her employment or contract, the McAuliffe shall take all appropriate actions to ensure that the responsibilities of that employee or contractor have not and shall not adversely affect any Federal health care program.

e. Changes in Billing Status or Company Operations

As of the effective date of this Agreement, Leonard McAuliffe represents that he is the owner of Windsor Medical, Inc. which is in the business of selling medical instruments, devices and supplies to hospitals and other health care providers. Neither Leonard McAuliffe nor Windsor Medical, Inc. directly or indirectly, submits claims to the Medicare, Medicaid or other Federal health care programs. If Leonard McAuliffe, Windsor Medical, Inc. or any other entity in which either of them has an ownership or

control interest, as defined in 42 U.S.C. § 1320a-3(a)(3), intends to, directly or indirectly, submit claims for reimbursement to the Medicare, Medicaid or other Federal health care programs, Leonard McAuliffe must notify OIG of such intention at least 60 days prior to the submission of any claims. Leonard McAuliffe, Windsor Medical or another entity in which either has an ownership or control interest as described above agrees that it will enter into an amended Integrity Agreement, acceptable to OIG, which will reflect the change in billing status.

f. Notification of Government Investigation or Legal Proceedings.

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

IV. 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 McAuliffe's books,

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

V. IMPLEMENTATION AND ANNUAL REPORTS

McAuliffe shall report to the OIG regarding its implementation of the requirements of this IA.

a. Implementation Report. Within 120 days of the effective date of this IA, McAuliffe shall submit to OIG an Implementation Report which shall include the following:

(i) a copy of the policies, procedures, practices and notice required under section III.a;

(ii) a copy of all training materials used to comply with the information and education program required under section III.b; and

(iii) a certification by Leonard McAuliffe that:

(A) the policies and procedures have been distributed to all employees and they have completed the certifications required by section III.a; and

(B) all employees have completed the applicable training and executed the certification(s) required by section III.b.

The documentation supporting this certification shall be available to OIG, upon request.

b. Annual Reports. McAuliffe shall submit to OIG Annual Reports with respect to the status of and findings regarding McAuliffe's compliance activities for each of the five one-year periods beginning on the effective date of the IA. (The one-year period covered by each Annual Report shall be referred to as "the Reporting Period"). Each Annual Report shall include:

(i) any changes during the reporting period in the policies, procedures, practices and notice required under section III.a;

- (ii) any changes during the reporting period in the information and education program required under section III.b;
- (iii) a summary of Material Deficiencies (as defined in III.c) identified during the Reporting Period and the status of any corrective or preventative action relating to all such Material Deficiencies;
- (iv) a description of any personnel actions (other than hiring) taken by McAuliffe as a result of the obligations in section III.d;
- (v) a summary describing any ongoing investigation or legal proceeding required to have been reported pursuant to section III.f. 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;
- (vi) a certification by Leonard McAuliffe that:
 - (A) an attorney has conducted the review required in section III.c;
 - (B) all employees have received the policies and procedures and executed the certifications required by section III.a;
 - (C) all employees have completed the applicable training and executed the certification(s) required by section III.b;
 - (D) except as otherwise described in the Annual Report, McAuliffe is in compliance with all of the requirements of this IA; and

(E) he has reviewed the Report and has made reasonable inquiry regarding its content and believes that the information is accurate and truthful. The documentation supporting the certification shall be made available to OIG upon request.

The first Annual Report shall be received by the OIG no later than one year and 30 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.

VI. NOTIFICATIONS AND SUBMISSION OF REPORTS

Unless otherwise stated subsequent to the execution of this IA, all notifications and reports required under the terms of this IA shall be submitted to the entities listed below:

If to the OIG:

Civil Recoveries Branch - Compliance Unit
Office of Counsel to the Inspector General
Office of Inspector General
U.S. Department of Health and Human Services
Cohen Building, Room 5527
330 Independence Avenue, SW
Washington, DC 20201
Phone: 202.619.2078
Fax: 202.205.0604

If to McAuliffe:

Leonard McAuliffe
Windsor Medical, Inc.
914 Route 1, By-Pass North
Portsmouth, New Hampshire 03780
Tel: 1.800.732.1544
Fax:603.427.5434

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

VII. PRIVILEGES AND DISCLOSURES

Nothing in this IA shall constitute a waiver of the attorney-client privilege or the attorney work product doctrine, or shall require McAuliffe to waive such privileges and protections. Subject to HHS's Freedom of Information Regulations, set forth in 45 C.F.R. part 5, the OIG shall make a reasonable effort to notify McAuliffe prior to any release by the OIG of information submitted by McAuliffe pursuant to its obligations under this IA and identified upon submission as trade secrets or privileged or confidential commercial or financial information within the meaning of the Freedom of Information Act (FOIA), 5 U.S.C. § 552(b)(4), and HHS's Freedom of Information Regulations, 45 C.F.R. § 5.65. McAuliffe will refrain from identifying any information as trade secrets or privileged or

confidential commercial or financial information unless the information meets the criteria for exemption from disclosure under FOIA and HHS's Freedom of Information Regulations.

VIII. DOCUMENT AND RECORD RETENTION

McAuliffe shall maintain for inspection documents and records relating to reimbursement from the Federal health care programs or with compliance with this IA for 6 years after the effective date of this IA or until otherwise required to retain such records, whichever is later.

IX. BREACH AND DEFAULT PROVISIONS

McAuliffe's compliance with the terms and conditions in this IA shall constitute an element of McAuliffe's present responsibility with regard to participation in Federal health care programs. Full and timely compliance by McAuliffe shall be expected throughout the duration of the compliance period required by this IA with respect to all of the obligations herein agreed to by McAuliffe. All modifications to this IA (including changes to dates on which an obligation is due to be met) shall be requested in writing and agreed to by the OIG in writing prior to the date on which the modification is expected to take effect.

a. Stipulated Penalties for Failure to Comply with Corporate Integrity Obligations.

As a contractual remedy, McAuliffe and OIG hereby agree that failure to comply with

the obligations set forth in this IA may lead to the imposition of the following monetary penalties (hereinafter referred to as “stipulated penalties”).

(1) A stipulated penalty of \$1,500 (which shall begin to accrue on the date the obligation became due) for each day McAuliffe fails to have in place any of the following during the entire period beginning 90 days after the execution of this IA and concluding at the end of the term of this IA:

1. written Policies and Procedures;
- b. a training and education program.

(2) A stipulated penalty of \$1,500 (which shall begin to accrue on the date the obligation became due) for each day McAuliffe:

- (i) fails meet the deadlines set forth in section V to provide written Implementation and Annual Reports;
- (ii) fails to meet the deadlines set forth in section III.e to have an attorney perform an annual review.

(3) A stipulated penalty of \$1,500 (which shall begin to accrue on the date the failure to comply began) for each day McAuliffe employs or contracts with an individual after that individual has been listed by a Federal agency as excluded, debarred, suspended or otherwise ineligible for participation in the Medicare, Medicaid or any other Federal health care program (as defined in 42 U.S.C. § 1320a-7b(f)). This stipulated penalty shall not be demanded if McAuliffe can demonstrate that it did not discover the

individual's exclusion or other ineligibility after making a reasonable inquiry (as described in section III.d) as to the current or potential status of the employee or consultant engaged.

(4) A Stipulated Penalty of \$1,500 for each day McAuliffe fails to grant access to the information or documentation as required in section IV of this IA. (This Stipulated Penalty shall begin to accrue on the date McAuliffe fails to grant access.)

(5) A Stipulated Penalty of \$1,000 for each day McAuliffe fails to comply fully and adequately with any obligation of this IA. In its notice to McAuliffe, OIG shall state the specific grounds for its determination that McAuliffe has failed to comply fully and adequately with the IA obligation(s) at issue and steps the McAuliffe must take to comply with the IA. (This Stipulated Penalty shall begin to accrue 10 days after the date that OIG provides notice to McAuliffe of the failure to comply.) A Stipulated Penalty as described in this paragraph shall not be demanded for any violation for which the OIG has sought a Stipulated Penalty under paragraphs 1-4 of this section.

b. Payment of Stipulated Penalties.

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

(2). *Response to Demand Letter.* Within 10 days of the receipt of the Demand Letter, McAuliffe 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 IX d. In the event McAuliffe elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until McAuliffe 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 IA and shall be grounds for exclusion under section IX. c.

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

(4) *Timely Written Requests for Extensions.* McAuliffe may submit a timely written request for an extension of time to perform any act or file any notification or report required by this IA. Notwithstanding any other provision in this section, if OIG grants the timely written request, stipulated penalties shall not begin to accrue unless and until McAuliffe fails to meet the deadline granted by the extension. Notwithstanding any other provision in this section, if OIG denies a timely written request, stipulated penalties shall not begin to accrue until two business days following McAuliffe's receipt of OIG's

written denial of such a timely written request. A "timely written request" is defined as a request in writing received by OIG at least five business days prior to the date by which the act is due to be performed or notification or report is due to be filed.

(5) *Independence from Material Breach Determination.* Except as otherwise noted, these provisions for payment of stipulated penalties shall not affect or otherwise set a standard for the OIG's determination that McAuliffe has materially breached this IA, which decision shall be made at the OIG's discretion and governed by the provisions set forth below.

c. Exclusion for Material Breach.

(1) *Material Breach.* A material breach of this IA means:

- (i) a failure by McAuliffe to report a material deficiency and take corrective action as required in section III.c;
 - (ii) repeated or flagrant violations of the obligations under this IA, including, but not limited to, the obligations addressed in section IX.a;
 - (iii) failure to either pay stipulated penalties or request a hearing by an ALJ as required by IX.b;
 - (iv) failure to notify OIG and enter into an amended IA prior to billing the Federal health care programs, as required by section III.e;
- or

(v) failure to have an attorney perform the annual review required by section IIIc.

(2) *Notice of Material Breach and Intent to Exclude.* The parties agree that a material breach of this IA by McAuliffe constitutes an independent basis for McAuliffe's exclusion from participation in Medicare, Medicaid, and all other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)). Upon a determination by the OIG that McAuliffe has materially breached this IA and that exclusion should be imposed, the OIG shall notify McAuliffe, in accordance with section VI' of: (i) McAuliffe's material breach; and (ii) the 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 Letter").

(3) *Opportunity to Cure.* McAuliffe shall have 30 days from its receipt of the Notice of Material Breach and Intent to Exclude Letter to proceed as follows:

- (i) demonstrate to the OIG's satisfaction that McAuliffe has not committed a material breach of this IA;
- (ii) cure the alleged material breach; or
- (iii) demonstrate to the OIG's satisfaction that the alleged material breach cannot be cured within the 30-day period, but that (A) McAuliffe has begun to take action to cure the material breach; (B) McAuliffe is pursuing such action with due

diligence; and (C) McAuliffe has provided to the OIG a reasonable timetable for curing the material breach.

(4) *Exclusion Letter*. If at the conclusion of the 30-day period (or other specific period as subsequently agreed by OIG and McAuliffe), McAuliffe fails to meet the requirements of section IX.c(3) above, OIG may exclude McAuliffe from participation in the Medicare, Medicaid and any other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)). OIG will notify McAuliffe in writing of its determination to exclude McAuliffe (this letter shall be referred to hereinafter as the “Exclusion Letter”). Subject to the dispute resolution provisions in section IX.d, the exclusion shall go into effect 20 days after the date of the Exclusion Letter. The exclusion shall have national effect and will also apply to all other Federal procurement and non-procurement programs. If McAuliffe is excluded under the provisions of this IA, McAuliffe may seek reinstatement pursuant to the provisions at 42 C.F.R. §§ 1001.3001-.3004.

d. Dispute Resolution.

(1) *Review Rights*. Upon OIG’s delivery to McAuliffe 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, McAuliffe 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 of the receipt of the Demand Letter and the request for a hearing involving exclusion shall be made within 25 days of receipt of the Exclusion Letter.

(2) *Stipulated Penalties Review.* Notwithstanding any provision of Title 42 of the United States Code or Chapter 42 of the Code of Federal Regulations, the only issues in a proceeding for Stipulated Penalties under this IA shall be: (a) whether McAuliffe was in full and timely compliance with the obligations of this IA for which the OIG demands payment; and (b) the period of noncompliance. McAuliffe shall have the burden of proving its full and timely compliance and the steps taken to cure the noncompliance, if any. If the ALJ agrees with OIG with regard to a finding of a breach of this IA and orders McAuliffe to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable 20 days after the ALJ issues such a decision unless McAuliffe 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 Chapter 42 of the Code of Federal Regulations, the only issues in a proceeding for exclusion based on a material breach of this IA shall be:

- a. whether McAuliffe was in material breach of this IA;
- 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) McAuliffe had begun to take action to cure the material breach within that period;
 - (ii) McAuliffe has pursued and is pursuing such action with due diligence; and
 - (iii) McAuliffe provided to OIG within that period a reasonable timetable for curing the material breach and McAuliffe 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 the McAuliffe, only after a DAB decision in favor of OIG. McAuliffe's election of its contractual right to appeal to the DAB shall not abrogate the OIG's authority to exclude McAuliffe upon the issuance of an ALJ's decision in favor of the OIG. If the ALJ sustains the determination of the OIG and

determines that exclusion is authorized, such exclusion shall take effect 20 days after the ALJ issues such a decision, notwithstanding that McAuliffe 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.

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 IA agree that the DAB's decision (or the ALJ's decision if not appealed) shall be considered final for all purposes under this IA.

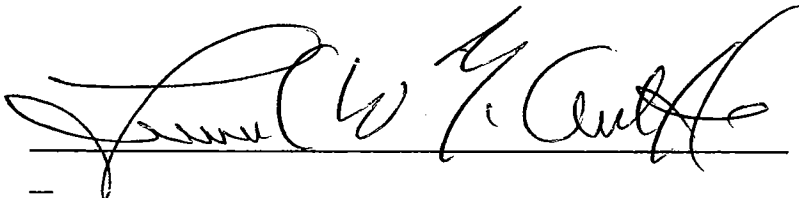
X. EFFECTIVE AND BINDING AGREEMENT

Consistent with the provisions in the settlement agreement pursuant to which this IA is entered, and into which this IA is incorporated, McAuliffe and the OIG agree as follows:

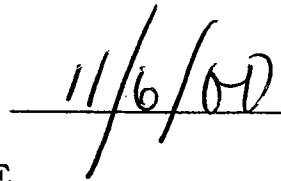
1. this IA shall be binding on the successors, assigns and transferees of McAuliffe;
2. this IA shall become final and binding upon signing by each respective party hereto;
3. any modifications to this IA shall be made with the prior written consent of the parties to this IA; and

4. the undersigned McAuliffe signatory represents and warrants that he is authorized to execute this IA. The undersigned OIG signatory represents that he is signing this IA in his official capacity and that he is authorized to execute this IA.

ON BEHALF OF LEONARD MCAULIFFE AND WINDSOR MEDICAL, INC.



LEONARD MCAULIFFE

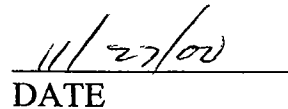


DATE

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



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



DATE