JOSH STEIN
ATTORNEY GENERAL

STATE OF NORTH CAROLINA
DEPARTMENT OF JUSTICE

SETH DEARMIN
CHIEF OF STAFF

December 2, 2019

North Carolina Senate President Pro Tempore Phil Berger
North Carolina House of Representatives Speaker Tim Moore
Co-Chairs, Joint Legislative Commission on Governmental Operations

Senator Danny Earl Britt, Jr.
Senator Warren Daniel
Senator Norman W. Sanderson
Representative James Boles, Jr.
Representative Ted Davis, Jr.
Representative Allen McNeill
Co-Chairs, Appropriations Subcommittee on Justice and Public Safety

North Carolina General Assembly
Raleigh, North Carolina 27601-1096

RE: G.S. §114-2.5; Report on Settlement Agreement for Avalign Technologies

Dear Members:

Section 114-2.5 of the North Carolina General Statutes requires the Attorney General to report to the Joint Legislative Commission on Governmental Operations and the Chairs of the Appropriations Subcommittees on Justice and Public Safety regarding all settlements and court orders which result in more than $75,000.00 being paid to the State. Pursuant to that statute, I am writing regarding the settlement of claims for Medicaid reimbursement to the state and federal governments in the above-referenced matter. Pursuant to federal law (42 C.F.R. § 433.320) recoveries in these cases are shared on a pro rata basis by the state and federal governments.

A settlement has been executed between Avalign and the State of North Carolina.

The settlement resolves allegations that from January 1, 2007 through December 31, 2014, Avalign sold medical devices to customers, who then sold directly to hospitals and other care providers for use in medical procedures, while knowing that the devices were not approved or cleared for marketing by the FDA.

Under the terms of North Carolina's settlement, the State of North Carolina will recover $113,543.50. Of that amount the federal government will receive $65,739.45 for North Carolina's federal portion of Medicaid recoveries. Pursuant to G.S. § 1-610, the qui tam plaintiffs whose whistleblower actions brought this matter to the government's attention will receive $9,957.88 of North Carolina's recovery. The North Carolina Medicaid Program will receive $17,948.97 as restitution and interest. In addition, pursuant to Article IX, Section 7 of the North Carolina Constitution and G.S. § 115C-457.1, the penalty portion of the settlement in the amount of $18,336,.96 will be paid to the Civil Penalty Forfeiture Fund for the support of North Carolina public schools. Pursuant to G.S. § 115C-457.2 and G.S. § 1-608(c), the North Carolina Department of Justice will receive $1,560.24 for investigative costs and costs of collection.

We will be happy to respond to any questions you may have regarding this report.

Sincerely,

Seth Dearmin
Chief of Staff

SD:ng

cc: John Poteat, NCGA Fiscal Research Division

STATE SETTLEMENT AGREEMENT

I. PARTIES

This Settlement Agreement (the "Agreement") is entered into between the State of North Carolina ("the State") and Avalign Technologies, Inc. ("Avalign") and Instrumed International, Inc. ("Instrumed") (collectively, "Defendants") collectively, "the Parties."

II. PREAMBLE

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

A. Each Defendant is a Delaware corporation with its principal place of business in Illinois. Avalign is the sole owner of Instrumed. At all relevant times, the Defendants manufactured, marketed, sold, and/or supplied medical devices in the United States, including to hospitals and other health care providers for use in medical procedures for which claims for reimbursement were submitted to federal and state health care programs.

B. On July 2, 2014, Mary Bixler Wood (the "Relator") filed a *qui tam* action in the United States District Court for the Southern District of New York captioned *United States of America et al., ex. rel Mary Bixler Wood et al. v. Avalign Technologies Inc., Instrumed International, Inc. and other entities et al.*, Civil Action No. 14-CV-4958. This *qui tam* action will be referred to as the "Civil Action." The Civil Action alleges that Defendants violated the False Claims Act ("FCA") (and corresponding state and local laws) by, among other things, selling medical devices to customers who then sold directly or indirectly to hospitals and other health care providers for use in medical procedures for which claims for reimbursement were submitted to

federal health care programs, while knowing that the devices were not approved or cleared for marketing by the United States Food and Drug Administration ("FDA") pursuant to the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301 *et seq.*, and were not exempt from the FDCA's premarket approval or clearance requirements as "pre-amendment devices" (*i.e.*, devices that were, among other things, legally marketed prior to the May 28, 1976, the effective date of the Medical Device Amendments of 1976);

C. On August 6, 2019, Defendants entered into a separate civil Stipulation and Order of Settlement and Dismissal (the "Federal Stipulation)") with the "United States of America" (the "United States") as that term is defined in the Federal Stipulation.

D. The State contends that the Defendants caused claims for payment to be submitted to the State's Medicaid Program (42 U.S.C. Chapter 7 Subchapter XIX).

E. The State contends that it has certain civil and administrative causes of action against the Defendants for engaging in the following conduct at various times between 2007 and 2014 (the "Covered Period"):

> Instrumed, a subsidiary of Avalign: (1) sold the medical devices listed in Rider 1, which Instrumed claimed qualified as "pre-amendment devices" and, thus, were exempt from the FDCA's premarket approval or clearance requirements; (2) knew that the devices did not in fact qualify as "pre-amendment devices;" and (3) caused the devices to be sold to customers, who then sold them to hospitals and other health care providers for use in medical procedures for which claims for reimbursement were submitted to Medicare and Medicaid. The conduct described in this Paragraph is the "Covered Conduct" for purposes of this Agreement.

F. Except where specifically stated, this Agreement is neither an admission of facts or liability by the Defendants, nor a concession by the State that its allegations are not well founded.

G. The Parties mutually desire to reach a full and final settlement for the Covered Conduct as set forth below.

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III. TERMS AND CONDITIONS

1. The Parties agree that this Court has subject matter jurisdiction over this action and consent to this Court's exercise of personal jurisdiction over each of them.

2. Defendants admit, acknowledge and accept responsibility for the following conduct:

a. Devices, as defined in 21 U.S.C. § 321(h), are subject to regulation by the FDA. Before certain devices can be marketed, they must be cleared by the FDA, pursuant to Section 510(k) of the FDCA. However, if a device qualifies as a "pre-amendment device," it is exempt from the Section 510(k) requirements.

b. According to FDA guidance, pre-amendment status may be established through (1) the direct proof method, e.g., submitting documents showing that the device was placed in interstate commerce and was actually labeled and promoted for a specific intended use prior to May 28, 1976; (2) the sworn statement method, e.g., submitting a sworn statement from a current or former company employee or other credible person that the device was in interstate commerce prior to May 28, 1976; or (3) some combination of those two methods. For a manufacturer such as Instrumed to claim that a particular device qualifies for the pre-amendment status exemption, the manufacturer must be able to demonstrate, among other things, that the device was legally marketed in the United States prior to May 28, 1976, and that the device had not been significantly changed or modified since then, and for which a classification regulation requiring premarket approval has not been issued by FDA.

c. In February 2009, Instrumed's then-head of Quality and Regulatory Affairs acknowledged in an email in response to an inquiry about an Instrumed device, that "we cannot claim pre-amendment because Instrumed was not selling/marketing this device before May 28, 1976."

d. By no later than April 2009, representatives of Instrumed and CareFusion Corporation ("CareFusion"), a customer of Instrumed pre-amendment devices and distributor of those devices, began exchanging correspondence regarding whether Instrumed and CareFusion could legitimately rely on Instrumed's invocation of the pre-amendment status exemption to market its devices. This exchange of correspondence continued for approximately one year.

e. Throughout these exchanges, CareFusion repeatedly informed Instrumed that the evidence Instrumed was relying on to justify its claim that certain devices qualified for the pre-amendment status exemption—evidence consisting of excerpts from a catalogue issued by the devices' original manufacturer, not Instrumed, and an affidavit from an Instrumed employee—was insufficient.

    i. Subsequently, in May 2010, CareFusion informed Instrumed that its affidavit was "too general to be of value."

    ii. In October 2010, CareFusion again informed Instrumed that its affidavit was insufficient, including because it lacked "[s]pecific device codes and associated product names" and "[a] statement, with any supporting documentation, of the specific intended uses for which the device was labeled and promoted."

iii. In further correspondence in November 2010, CareFusion reiterated its concerns about the affidavit to Instrumed, and noted that, "[i]n order for an affidavit to be useful, we would need someone to confirm that they are aware that you were making a specific product and the product you are currently selling has not substantially changed since May, 1976."

iv. In that same correspondence, CareFusion described having "several meetings" with Instrumed regarding the affidavit, and that "it was determined that we could not establish pre-amendment based on your documentation."

f. Instrumed never provided CareFusion a satisfactory affidavit to justify its claim that the devices qualified for the pre-amendment status exemption.

g. In 2012, Instrumed's Vice President of Quality and Regulatory Assurance at that time opened a Corrective and Preventative Action ("CAPA") that set forth a plan to compile supporting documentation because Instrumed had "[n]o evidence of selling devices claimed as pre-amendment."

h. The day after the CAPA was opened, the daughter of Instrumed's founder confirmed that she was unable to locate any documentation to show these devices had been marketed prior to May 28, 1976.

i. In March 2014, the FDA issued a warning letter indicating that it had determined that Instrumed's devices "are not pre-amendment devices that were legally on the market in the United States prior to May 28, 1976."

j. Instrumed responded to the warning letter by submitting to the FDA a "Pre-Amendment Device Determination Request" for some of the devices identified by the FDA, including copies of the previous manufacturer's catalogue pages to support pre-amendment status. After the FDA provided feedback to Instrumed in May 2014, Instrumed decided to discontinue sale of these products and conducted a recall of these products.

k. In May 2015, the FDA rejected Instrumed's determination requests as insufficient.

l. Throughout the Covered Period, Instrumed continued to sell the devices in Rider 1.

m. Some of the devices were then sold by Instrumed's customers to hospitals and other medical providers and were used in procedures for which providers submitted claims for reimbursement to federal health care programs.

3. The Defendants agree to pay to the United States and the Medicaid Participating States (as defined in sub-paragraph (c) and subject to the non-participating state deduction provision of sub-paragraph (d) below), collectively, the sum of $9,500,000.00 plus accrued interest (the "Settlement Amount"). The Settlement Amount shall constitute a debt immediately due and owing to the United States and the Medicaid Participating States on the "effective date" of the Federal Settlement Agreement, as defined therein and subject to the terms of this Agreement. The debt shall forever be discharged by payments to the United States and the Medicaid Participating States under the following terms and conditions:

(a) The Defendants shall pay to the United States the sum of $8,128,440.60 plus accrued interest pursuant to the terms of the Federal Stipulation.

(b) The total Medicaid recovery for the Covered Conduct is $3,135,000.00 consisting of $1,371,559.40 for the states pursuant to this Agreement and $1,763,440.60 for the United States pursuant to the Federal Stipulation. The Defendants shall pay to the Medicaid Participating States the sum of $1,371,559.40 plus accrued interest on that amount of 2.87% per annum commencing on May 30, 2019, and continuing to and include the day payment is made under this Agreement (the "Medicaid State Settlement Amount"), subject to the non-participating state deduction provision of sub-paragraph (d) below (the "Medicaid Participating State Settlement Amount"), no later than seven (7) business days after the expiration of the 60-day opt-in period for Medicaid Participating States described in sub-paragraph (c) below. The Medicaid Participating State Settlement Amount shall be paid and immediately deposited by electronic funds transfer to the New York State Attorney General's National Global Settlement Account pursuant to written instructions from the state negotiating team (the "State Team"), which written instructions shall be delivered to counsel for the Defendants. This electronic funds transfer shall constitute tender and negotiation of the State Amount as defined in Paragraph III.3.(d) below.

(c) The Defendants shall execute a State Settlement Agreement with any State that executes such an Agreement in the form to which the Defendants and the State Team have agreed, or in a form otherwise agreed to by the Defendants and an individual State. The State shall constitute a Medicaid Participating State provided this Agreement is fully executed by the State and delivered to the Defendants' attorneys within 60 days of receiving this Agreement. The

Defendants' offer to resolve this matter with the State shall become null and void absent written agreement between counsel for the Defendants and the State Team to extend the 60-day period.

(d) The total portion of the amount paid by the Defendants in settlement for the Covered Conduct for the State is $113,157.93, consisting of a portion paid to the State under this Agreement and another portion paid to the United States as part of the Federal Settlement Agreement. The amount allocated to the State under this Agreement is the sum of $47,418.48 plus applicable interest (the "State Amount"), of which $23,709.24 is restitution. If the State does not execute this Agreement within 60 days of receiving this Agreement, the State Amount shall be deducted from the Medicaid State Settlement Amount and shall not be paid by the Defendants absent written agreement between counsel for the Defendants and the State Team to extend the time period for executing this Agreement.

4. Contingent upon receipt of the State Amount, the State agrees to dismiss with prejudice any state law claims which the State has the authority to dismiss currently pending against the Defendants in State or Federal Courts for the Covered Conduct, including any supplemental state law claims asserted in the Civil Action. Contingent upon receipt of the State Amount, the State, if served with the Civil Action and otherwise liable to pay a relator's share, agrees to pay the Relator(s) the amount of $9,957.88 plus applicable interest. This amount is to be paid through the State Team and has been addressed via side letter with the Relator in the Civil Action.

5. Subject to the exceptions in Paragraph 6 below, in consideration of the obligations of the Defendants set forth in this Agreement, and conditioned upon tender and negotiation of the State Amount, the State agrees to release the Defendants, their predecessors and current and former parents, divisions, subsidiaries, affiliates, successors, transferees, heirs, and assigns (collectively,

the "Defendants Released Entities"), from any civil or administrative monetary cause of action that the State has for any claims submitted or caused to be submitted to the State's Medicaid Program as a result of the Covered Conduct.

6. Notwithstanding the releases given in Paragraph 5 of this Agreement, or any other term of this Agreement, the following claims of the State are specifically reserved and are not released:

(a) any criminal, civil, or administrative liability arising under state revenue codes;

(b) any criminal liability;

(c) any civil or administrative liability that any person or entity, including the Defendants Released Entities, has or may have to the State or to individual consumers or state program payors under any statute, regulation, or rule not expressly covered by the release in Paragraph 5 above, including, but not limited to, any and all of the following claims: (i) State or federal antitrust violations; and (ii) claims involving unfair and/or deceptive acts and practices and/or violations of consumer protection laws;

(d) any liability to the State for any conduct other than the Covered Conduct;

(e) any liability to the State arising from the Covered Conduct for claims submitted or caused to be submitted to any "managed care entities" as defined by 42 U.S.C. § 1396u-2;

(f) any liability based upon obligations created by this Agreement;

(g) except as explicitly stated in this Agreement, any administrative liability, including mandatory exclusions from the State's Medicaid Program;

(h) any liability for expressed or implied warranty claims or other claims for defective or deficient products and services, including quality of goods and services;

(i) any liability for personal injury or property damage or for other consequential damages arising from the Covered Conduct;

(j) any liability for failure to deliver goods or services due; or

(k) any liability of individuals.

7. The Defendants waive and shall not assert any defenses it may have to criminal prosecution or administrative action for the Covered Conduct, which defenses may be based in whole or in part on a contention, under the Double Jeopardy Clause of the Fifth Amendment of the U.S. Constitution or the Excessive Fines Clause of the Eighth Amendment of the U.S. Constitution, that this Agreement bars a remedy sought in such criminal prosecution or administrative action.

8. In consideration of the obligations of the State set forth in this Agreement, the Defendants Released Entities waive and discharge the State and any of its agencies, departments, and personnel including, but not limited to, officials, employees, and agents, whether current or former in their official and individual capacities from any causes of action (including attorneys' fees, costs, and expenses of every kind and however denominated) which the Defendants Released Entities have against the State and any of its agencies, departments, and personnel as previously referenced arising from the State's investigation and prosecution of the Covered Conduct.

9. The amount that the Defendants must pay to the State pursuant to Paragraph III.3.(d) above will not be decreased as a result of the denial of any claims for payment now being withheld from payment by the State's Medicaid Program, or any other state program payor, for the Covered Conduct; and the Defendants agree not to resubmit to the State's Medicaid Program or any other state program payor, any previously denied claims, which denials were based on the

Covered Conduct, and agrees to withdraw the appeal of, or not to appeal or cause the appeal of, any such denials of claims.

10. The Defendants shall not seek payment for any claims for reimbursement to the State's Medicaid Program covered by this Agreement from any health care beneficiaries or their parents, sponsors, legally responsible individuals, or third-party payors.

11. The Defendants expressly warrant that they have reviewed their financial condition and that they are currently solvent, meaning that a fair valuation of their property (exclusive of exempt property) exceeds the sum of their debts.

12. The Parties each represent that this Agreement is freely and voluntarily entered into without any degree of duress or compulsion whatsoever.

13. The Defendants agree to cooperate fully and truthfully with any State investigation of individuals or entities not released in this Agreement. Upon reasonable notice of such an investigation, the Defendants shall encourage, and agree not to impair, the cooperation of their directors, officers, and employees, and shall use their 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 and of the Defendants. Upon request, the Defendants agree to furnish to the State complete and unredacted copies of all non-privileged documents including, but not limited to, reports, memoranda of interviews, and records in its possession, custody or control, concerning any investigation of the Covered Conduct that they have undertaken, or that has been performed by another on their behalf, as well as complete and unredacted copies of any other non-privileged documents in their possession, custody, or control relating to the Covered Conduct.

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

15. Except as otherwise stated in this Agreement, this Agreement is intended to be for the benefit of the Parties only, and the Parties do not release any liability as to any other person or entity.

16. Nothing in this Agreement constitutes an agreement by the State concerning the characterization of the amounts paid hereunder for purposes of the State's revenue code.

17. In addition to all other payments and responsibilities under this Agreement, the Defendants agree to pay the State Team's reasonable expenses and fees, including travel costs, consultant expenses, and administrative fees. The Defendants will pay this amount by separate check made payable to the National Association of Medicaid Fraud Control Units, after the Medicaid Participating States execute their respective Agreements, or as otherwise agreed by the Parties.

18. This Agreement is governed by the laws of the State and venue for addressing and resolving any and all disputes relating to this Agreement shall be the state courts of appropriate jurisdiction of the State.

19. The undersigned Defendants' signatories represent and warrant that they are authorized as a result of appropriate corporate action to execute this Agreement. The undersigned State signatories represent that they are signing this Agreement in their official capacities and that they are authorized to execute this Agreement on behalf of the State through their respective agencies and departments.

20. The Effective Date of this Agreement shall be the date of signature of the last signatory to this Agreement. Facsimiles of signatures shall constitute acceptable binding signatures for purposes of this Agreement.

21. This Agreement shall be binding on all successors, transferees, heirs, and assigns of the Parties.

22. This Agreement constitutes the complete agreement between the Parties with respect to this matter and shall not be amended except by written consent of the Parties.

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

24. For purposes of construing this Agreement, this Agreement shall be deemed to have been drafted by the Parties to this Agreement and shall not, therefore, be construed against any of the Parties for that reason.

STATE OF NORTH CAROLINA

By: _____ Dated: 9-23-19

F. Edward Kirby, Jr.
Director, Medicaid Investigations Division
Office of the Attorney General

By: _____ Dated: 9/16/2019

DAVE RICHARD
Deputy Secretary, NC Medicaid
Division of Health Benefits

AVALIGN TECHNOLOGIES, INC. and INSTRUMED INTERNATIONAL, INC.

HYMAN, PHELPS & MCNAMARA

By: _____ Dated: 10/22/2019

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