UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (date of earliest event reported): October 13, 2020

Merit Medical Systems, Inc.

(Exact name of registrant as specified in its charter)

Utah	**0-18592**	**87-0447695**
(State or other jurisdiction of incorporation or organization)	(Commission File Number)	(I.R.S. Employer Identification No.)

1600 West Merit Parkway **South Jordan, Utah**	**84095**
(Address of principal executive offices)	(Zip Code)

(801) 253-1600

(Registrant's telephone number, including area code)

N/A

(Former name or former address, if changed since last report)

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:

☐ 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))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, no par value	MMSI	NASDAQ Global Select Market System

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 1.01. Entry into a Material Definitive Agreement.

On October 13, 2020, Merit Medical Systems, Inc. (the "Company) entered into agreements with the United States Department of Justice ("DOJ") and others to fully resolve the DOJ's investigation of certain marketing and promotional practices of the Company. The Company denies the DOJ's allegations, but has determined that avoiding protracted litigation and its associated costs will enable it to focus on its mission of being the most customer-focused company in healthcare. These agreements memorialize the agreement in principle that the Company previously disclosed in its press release on July 15, 2020 (a copy of the press release was also filed in a Form 8-K that same day).

Specifically, the Company entered into:

(i) a Settlement Agreement, a copy of which is attached hereto as Exhibit 10.1, effective October 13, 2020, with the DOJ, and on behalf of the Inspector General of the Department of Health and Human Services (the "OIG"), the Defense Health Agency ("DHA"), acting on behalf of the TRICARE Program, and the relator named therein; and

(ii) a Corporate Integrity Agreement, a copy of which is attached hereto as Exhibit 10.2, effective October 13, 2020, with the DOJ and OIG.

The DOJ asserted that the Company provided benefits, allegedly in the form of patient referrals advertising assistance, practice development, practice support, and educational grants to induce healthcare providers to purchase and use the Company's products in medical procedures performed on federal healthcare program beneficiaries, in violation of the Anti-Kickback Statute, 42 U.S.C. §1320a-7b(b), and caused the submission of false claims under the False Claims Act, 31 U.S.C. §3729 (as further described in the Settlement Agreement, the "Covered Conduct"). This settlement is neither an admission of fault or liability on the part of the Company nor a concession by the DOJ that its claims are unfounded.

Settlement Agreement

Under the terms of the Settlement Agreement, the Company will pay a total of $18,000,000 plus accrued interest from July 8, 2020 at a rate of 0.75% per annum (the "Settlement Payment"). The Settlement Payment consists of $15,210,000 (plus interest) paid to the United States no later than October 27, 2020, and $2,790,000 (plus interest) to be paid under the terms of separate agreements the Company will enter into with participating states to settle claims related to the Covered Conduct. The Company expects to make the portion of the Settlement Payment to the United States prior to its due date and the portion of the Settlement Payment to the states as those payments become due. Upon reaching an agreement in principle with the DOJ, the Company previously recorded a legal settlement expense of $18.2 million in the second quarter of 2020.

Conditioned upon payment of the Settlement Payment, and dismissal of certain actions against the government, the DOJ, OIG, DHA and the relator have agreed to release the Company and its subsidiaries from any civil or administrative monetary liability arising from the Covered Conduct; the DOJ and the relator have agreed to dismiss the civil action filed by the relator; and in consideration of the Company's obligations under the Corporate Integrity Agreement (as described below), the OIG has agreed to waive its permissive exclusion authority and refrain from instituting any administrative action seeking to exclude the Company from participating in Medicare, Medicaid or other Federal health care programs as a result of the Covered Conduct.

Corporate Integrity Agreement

In connection with the resolution of the investigated matters, and in exchange for the OIG's agreement not to exclude the Company from participating in federal health care programs, on October 13, 2020, the Company entered into a five-year Corporate Integrity Agreement with the OIG. The Corporate Integrity Agreement imposes compliance, monitoring, reporting, certification, oversight and training obligations on the Company, certain of which have previously been implemented. The Corporate Integrity Agreement requires, among other matters, that the Company (i) maintain a Compliance Officer, a Compliance Committee, board review and oversight of certain federal healthcare compliance matters, compliance programs, and disclosure programs; (ii) establish robust compliance policies and procedures to meet federal health care program and FDA requirements; (iii) provide management certifications and compliance training and education; (iv) engage an independent review organization to conduct a thorough review of the Company's systems,

policies, processes and procedures related to promotional materials, product evaluations, consulting agreements, trainings provided to healthcare professionals, sponsorships, grants and charitable contributions; (v) implement a risk assessment and internal review process; (vi) establish a disclosure program for whistleblowers; (vii) increase oversight of the interactions between its sales personnel and healthcare providers; and (viii) report or disclose certain events and physician payments.

The Company's failure to comply with its obligations under the Corporate Integrity Agreement could result in monetary penalties and the Company being excluded from participating in federal health care programs.

The foregoing descriptions of the Settlement Agreement and the Corporate Integrity Agreement are qualified in their entirety by the full terms of the Settlement Agreement and the Corporate Integrity Agreement, which are attached as Exhibit 10.1 and Exhibit 10.2 hereto, respectively, and incorporated herein by reference.

Item 2.03. Creation of a Direct Financial Obligation or an Obligation under an Off-Balance Sheet Arrangement of a Registrant.

The information set forth above under Item 1.01 regarding the Settlement Agreement and Settlement Payment is incorporated by reference into this Item 2.03.

Item 8.01. Other Events.

On October 13, 2020, the Company issued a press release announcing that it had finalized a settlement with the DOJ to fully resolve the DOJ's investigation of certain marketing and promotional practices.

A copy of the Company's press release is attached hereto as Exhibit 99.1 hereto and is incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Exhibit
10.1	Settlement Agreement, dated October 13, 2020, 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 ("OIG-HHS") of the Department of Health and Human Services ("HHS"), and the Defense Health Agency ("DHA"), acting on behalf of the TRICARE Program (collectively, the "United States"); the Company; and Charles J. Wolf, M.D. ("Relator"), through their authorized representatives.
10.2	Corporate Integrity Agreement, dated October 13, 2020, by and between the OIG-HHS and the Company.
99.1	Press Release, dated October 13, 2020, entitled "Merit Medical Finalizes Resolution with the Government."
101	The cover page from this Current Report on Form 8-K, formatted in Inline XBRL and incorporated as Exhibit 101
104	The cover page from this Current Report on Form 8-K, formatted in Inline XBRL.

SIGNATURES

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

MERIT MEDICAL SYSTEMS, INC.

Date: October 16, 2020

By: /s/ Brian G. Lloyd
Brian G. Lloyd
Chief Legal Officer and Corporate Secretary

SETTLEMENT AGREEMENT

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 ("OIG-HHS") of the Department of Health and Human Services ("HHS"), and the Defense Health Agency ("DHA"), acting on behalf of the TRICARE Program (collectively, the "United States"); Merit Medical Systems, Inc. ("Merit" or "Defendant"); and Charles J. Wolf, M.D. ("Relator"), through their authorized representatives. Collectively, all of the above will be referred to as "the Parties."

RECITALS

A. Merit, a publicly-held corporation with its principal place of business in South Jordan, Utah, is a medical device manufacturer that markets and sells its products throughout the United States. Among other things, Merit markets and sells embolotherapeutic devices used to treat arteriovenous malformations, symptomatic uterine fibroids, and hypervascular tumors.

B. In April 2016, Relator filed a *qui tam* action in the United States District Court for the District of New Jersey captioned *United States ex rel. Wolf v. Merit Medical Systems, Inc.*, Civ. A. No. 16-1855 (D.N.J.), pursuant to the provisions of the False Claims Act, 31 U.S.C. § 3730(b) (the "*Qui Tam* Action"). The United States intervened in the *Qui Tam* Action on June 12, 2020.

C. The United States contends that Merit caused to be submitted claims for payment to the Medicare Program, Title XVIII of the Social Security Act, 42 U.S.C. §§ 1395-1395lll ("Medicare"); the Medicaid Program, 42 U.S.C. §§ 1396–1396w-5 ("Medicaid"); and the TRICARE Program, 10 U.S.C. §§ 1071–1110b ("TRICARE").

D. The United States contends that it has certain civil claims against Merit arising from the following conduct from September 1, 2010, to March 31, 2017, by which Merit caused the submission of false or fraudulent claims to Medicare, Medicaid, and TRICARE:

The United States contends that under an internal program known as the Local Advertising Program, Merit offered and paid physicians, medical practices, and hospitals (collectively, "Healthcare Providers") millions of dollars in free advertising assistance, practice development, practice support, and purported unrestricted "educational" grants to induce the Healthcare Providers to purchase and use Merit products in medical procedures performed on federal healthcare program beneficiaries, in violation of the Anti-Kickback Statute ("AKS"), 42 U.S.C. § 1320a-7b(b).

The United States further contends that Merit executives and sales personnel selected which Healthcare Providers would benefit from Merit's Local Advertising Program payments, as reward for past sales, to induce future sales, and to steer business to Merit and away from Merit's competitors. In its subsidized advertising, Merit promoted the targeted Healthcare Providers by name, provided contact information for those Healthcare Providers, and did not mention Merit or Merit products. The United States contends that before agreeing to make the Local Advertising Program payments to benefit a targeted Healthcare Provider, Merit often estimated the "projected revenue" that it expected to receive from the Healthcare Provider's purchase of Merit products, and after making the payments, Merit often tracked the return on investment (ROI) based on the Healthcare Provider's purchase of Merit products.

Merit and its executives claimed that the purpose of the Local Advertising Program was to increase patient awareness of uterine fibroid embolization. In fact, the United States contends, Merit used the Local Advertising Program payments to induce its targeted Healthcare Providers to use Merit products by providing them financial support and patient referrals. In internal communications, Merit described using the Local Advertising Program payments as "leverage," a "bargaining chip," or as part of a "deal" to secure Merit business from Healthcare Providers. The

United States contends that Merit disregarded warnings that its conduct may violate the AKS, including from its Chief Compliance Officer.

The conduct set forth in Paragraph D is referred to below as the "Covered Conduct."

E. Merit denies the allegations and contentions of the United States and the Relator. This Settlement Agreement is neither an admission of liability by Merit nor a concession by the United States that its claims are not well founded.

F. Relator claims entitlement under 31 U.S.C. § 3730(d) to a share of the proceeds of this Settlement Agreement and to Relator's reasonable expenses, attorneys' fees, and costs.

G. Merit has entered into, or will be entering into, separate settlement agreements described below in Paragraph 1(b) ("Medicaid State Settlement Agreements") with the states ("Medicaid Participating States") in settlement of the conduct released in those separate Medicaid State Settlement Agreements. Relator claims entitlement under 31 U.S.C. § 3730(d), and State equivalents, to a share of the proceeds of the Medicaid State Settlement Agreements.

To avoid the delay, uncertainty, inconvenience, and expense of protracted litigation of the above claims, and in consideration of the mutual promises and obligations of this Settlement Agreement, the Parties agree and covenant as follows:

TERMS AND CONDITIONS

1. Merit shall pay to the United States and the Medicaid Participating States the sum of Eighteen Million Dollars ($18,000,000.00) plus interest at the rate of 0.75% per annum, calculated monthly, from July 8, 2020, and continuing until and including the date of payment ("Total Settlement Amount"). The Total Settlement Amount shall be paid, subject to the provisions of Paragraph 14 below, as follows:

a. Merit shall pay to the United States the sum of Fifteen Million Two Hundred Ten Thousand Dollars ($15,210,000.00), of which Seven Million Six Hundred Five Thousand

Dollars ($7,605,000.00) is restitution, plus accrued interest as set forth above ("Federal Settlement Amount"), no later than fourteen (14) calendar days after the Effective Date of this Agreement by electronic funds transfer pursuant to written instructions to be provided by the United States Attorney's Office for the District of New Jersey.

b. Merit shall collectively pay to the Medicaid Participating States the total sum of Two Million Seven Hundred Ninety Thousand Dollars ($2,790,000.00), of which One Million Three Hundred Ninety-Five Thousand Dollars ($1,395,000.00) is restitution, plus accrued interest as set forth above ("State Settlement Amount"), pursuant to written instructions from the National Association of Medicaid Fraud Control Units ("NAMFCU") State Team and under the terms and conditions of the separate agreements that Merit has entered into, or will enter into, with the Medicaid Participating States.

2. Conditioned upon the United States receiving the Federal Settlement Amount from Merit and as soon as feasible after receipt, the United States shall pay Two Million Six Hundred Fifty Thousand Dollars ($2,650,000.00) to Relator by electronic funds transfer to the trust account of Joseph Greenwald & Laake, P.A.

3. The Defendant and Relator and their heirs, successors, attorneys, agents, and assigns each retain all of their rights pursuant to 31 U.S.C. § 3730(d) on the issue of Relator's expenses, fees, and costs, and have not reached agreement on those issues to date. Relator and Defendant further agree that, should the Parties be unable to reach an agreement on amounts, Relator may file a motion for attorney's fees, costs and expenses in the District Court within sixty (60) days of the date of dismissal of the Civil Action. The Parties agree that the United States District Court for the District of New Jersey shall retain and have continuing jurisdiction with regard to any disputes over the amounts for expenses, attorney's fees and costs.

4. Subject to the exceptions in Paragraph 8 (concerning excluded claims) below, and conditioned upon Merit's full payment of the Total Settlement Amount and Merit's full and timely compliance with Paragraph 17 below, the United States releases Merit and Merit's current and former parent corporations, direct and indirect subsidiaries, and brother and sister corporations (collectively, the "Released Parties") from any civil or administrative monetary claim the United States has for the Covered Conduct under the False Claims Act, 31 U.S.C. §§ 3729-3733; 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.

5. Subject to Paragraph 3 and conditioned upon Merit's full payment of the Total Settlement Amount, Relator, for himself and for his heirs, successors, attorneys, agents, and assigns, releases, remises, and forever discharges Merit, together with its current and former employees, officers, owners, directors, shareholders, attorneys, agents, insurers, parents, subsidiaries, predecessors, successors, assigns, and affiliated and related entities (collectively, the "Merit Releasees") from any claims, rights, demands, controversies, allegations, causes of action, suits, obligations, judgments, debts, duties, and all other liabilities of any kind or nature whatsoever, known or unknown, suspected or unsuspected, accrued or not accrued, fixed or contingent, in law or in equity, in contract or in tort, under common law, under any federal or state statute or regulation (including without limitation any civil monetary claim the Relator has on behalf of the United States for the Covered Conduct under the False Claims Act, 31 U.S.C. §§ 3729-33), and whether or not asserted, that Relator or his respective heirs, successors, attorneys, agents, affiliates, and assigns otherwise would have standing to bring, have asserted, could have asserted, or may assert in the future against Merit or any of the Merit Releasees, from the beginning of time to the Effective Date of this Agreement.

6. The Relator covenants and warrants that the Relator and his attorneys and agents will within thirty (30) days of the Effective Date of this Agreement return to Merit and provide written certification that the Relator and his attorneys and agents have returned to Merit (a) all documents, records, files, data and other information that Relator obtained from Merit during his employment, or otherwise constitutes or contains the property of Merit, including but not limited to confidential or proprietary information, (b) all electronic equipment and electronic information storage devices (e.g., computers, cellular phones, PDAs, zip drives, thumb drives, disks, etc.) that constitutes or contains property of Merit, and (c) Merit credit cards, office keys, and any other property of Merit that the Relator and his attorneys and agents obtained or that were made available to the Relator as a consequence of the Relator's employment with Merit and/or that constitute or contain the rightful property of Merit, and that all electronic copies of the above have been permanently deleted from Relator's computers, electronic equipment, storage devices, and cloud-storage accounts. Merit agrees to retain all material returned under this paragraph until the Relator's claims pursuant to 31 U.S.C. § 3730(d) for expenses, fees, and costs, as described in paragraph 3, have been fully resolved.

7. In consideration of the obligations of Merit in this Agreement and the Corporate Integrity Agreement (CIA) entered into between OIG-HHS and Merit, and conditioned upon Merit's full payment of the Total Settlement Amount and Merit's full and timely compliance with Paragraph 17 below, the OIG-HHS agrees to release and refrain from instituting, directing, or maintaining any administrative action seeking exclusion from Medicare, Medicaid, and other Federal healthcare programs (as defined in 42 U.S.C. § 1320a-7b(f)) against Merit 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 this Paragraph and in Paragraph 8 (concerning excluded claims), below. The OIG-HHS

expressly reserves all rights to comply with any statutory obligations to exclude Merit from Medicare, Medicaid, and other Federal healthcare 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 8, below.

8. Notwithstanding the releases given in paragraphs 4 and 5 of this Agreement, or any other term of this Agreement, the following claims of the United States are specifically reserved and are not released:

a. Any liability arising under Title 26, U.S. Code (Internal Revenue Code);

b. Any criminal liability;

c. Except as explicitly stated in this Agreement, any administrative liability, including mandatory exclusion from Federal healthcare programs;

d. Any liability to the United States (or its agencies) for any conduct other than the Covered Conduct;

e. Any liability based upon obligations created by this Agreement;

f. Any liability of individuals;

g. Any liability for express or implied warranty claims or other claims for defective or deficient products or services, including quality of goods and services;

h. Any liability for failure to deliver goods or services due; and

i. Any liability for personal injury or property damage or for other consequential damages arising from the Covered Conduct.

9. Relator and his heirs, successors, attorneys, agents, and assigns shall not object to this Agreement but 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). Conditioned upon Relator's receipt of the payment described in Paragraph 2, Relator and his heirs, successors, attorneys, agents, and assigns fully and finally release, waive, and forever discharge the United States, its agencies, officers, agents, employees, and servants, from any claims arising from the filing of the *Qui Tam* Action or under 31 U.S.C. § 3730, and from any claims to a share of the proceeds of this Agreement and/or the *Qui Tam* Action.

10. Merit waives and shall not assert any defenses that Merit 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.

11. Each Released Party, listed in Paragraph 4, fully and finally releases the United States, its agencies, officers, agents, employees, and servants, from any claims (including attorneys' fees, costs, and expenses of every kind and however denominated) that the Released Party has asserted, could have asserted, or may assert in the future against the United States, its agencies, officers, agents, employees, and servants, related to the Covered Conduct and the United States' investigation and prosecution thereof.

12. Merit fully and finally releases the Relator from any claims (including attorneys' fees, costs, and expenses of every kind and however denominated) that Merit has asserted, could have asserted, or may assert in the future against the Relator, related to the Covered Conduct and the Relator's investigation and prosecution thereof, the pursuit and filing of the Civil Action, and any all claims brought pursuant to the *qui tam* complaint, and amended complaint.

13. The Total Settlement Amount shall not be decreased as a result of the denial of claims for payment now being withheld from payment by any Medicare contractor (e.g., Medicare

Administrative Contractor, fiscal intermediary, carrier), TRICARE carrier or payer, or any state payer, related to the Covered Conduct; and Merit agrees not to resubmit to any Medicare contractor, TRICARE carrier or payer, or any state payer any previously denied claims related to the Covered Conduct, agrees not to appeal any such denials of claims, and agrees to withdraw any such pending appeals.

14. Merit agrees to the following:

a. Unallowable Costs Defined: 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. §§ 1395-1395lll-1 and 1396-1396w-5; and the regulations and official program directives promulgated thereunder) incurred by or on behalf of Merit, its present or former officers, directors, employees, shareholders, and agents in connection with:

(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) Merit'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 attorneys' fees);

(4) the negotiation and performance of this Agreement;

(5) the payment Merit makes to the United States pursuant to this Agreement and any payments that Merit 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 annual reviews as

described in Section III of the CIA; and (ii) prepare and submit reports to the OIG-HHS;

are unallowable costs for government contracting purposes and under the Medicare Program, Medicaid Program, TRICARE Program, and Federal Employees Health Benefits Program ("FEHBP") (collectively, "Unallowable Costs"). However, nothing in paragraph 14(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 Merit.

b. Future Treatment of Unallowable Costs: Unallowable Costs shall be separately determined and accounted for by Merit, and Merit 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 Merit or any of its subsidiaries or affiliates to the Medicare, Medicaid, TRICARE, or FEHBP Programs.

c. Treatment of Unallowable Costs Previously Submitted for Payment: Merit further agrees that within ninety (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 Merit 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. Merit agrees that the United States, at a minimum, shall be entitled to recoup from Merit 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 Merit or any of its subsidiaries or affiliates on the effect of inclusion of Unallowable Costs (as defined in this Paragraph) on Merit 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 Merit's books and records to determine that no Unallowable Costs have been claimed in accordance with the provisions of this Paragraph.

15. This Agreement is intended to be for the benefit of the Parties, the Released Parties (as to Paragraph 4), and the Merit Releasees (as to Paragraph 5) only. The Parties do not release any claims against any other person or entity, except to the extent provided for in Paragraph 16 (waiver for beneficiaries paragraph), below.

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

17. Within three (3) business days of the Effective Date of this Agreement:

a. The United States and Merit shall sign and file a Joint Stipulation of Dismissal with Prejudice pursuant to Federal Rule of Civil Procedure 41(a)(1) in *Merit Medical Systems, Inc. v. United States of America et al.*, No. 19-mc-211 (D.N.J.);

b. Merit shall sign and file a Notice of Dismissal with Prejudice pursuant to Federal Rule of Civil Procedure 41(a)(1) in *Merit Medical Systems, Inc. v. Barr et al.*, No. 2:20-cv-6468 (D.N.J.); and

c. The United States and Merit shall sign and file a Joint Motion to Dismiss with Prejudice pursuant to Federal Rule of Appellate Procedure 42(b) in *Merit Medical Systems, Inc. v. United States of America*, No. 20-1449 (4th Cir.).

18. Upon receipt of the Total Settlement Amount and upon Merit's full and timely compliance with Paragraph 17 above, the United States and Relator shall promptly sign and file in the *Qui Tam* Action a Notice of Dismissal of the *Qui Tam* Action pursuant to Rule 41(a)(1) as follows:

a. The Notice of Dismissal shall be with prejudice as to the United States' and Relator's claims in the *Qui Tam* Action as to the Covered Conduct and consistent with the terms and conditions of this Agreement.

b. The Notice of Dismissal shall be without prejudice to the United States and with prejudice to the Relator as to any other claims in the *Qui Tam* Action except for those reserved by Relator and his attorneys in Paragraph 3.

19. Except for those reserved by Relator and his attorneys in Paragraph 3, each Party shall bear its own legal and other costs incurred in connection with the *Qui Tam* Action and the three actions referenced above in Paragraph 17, including the preparation and performance of this Agreement.

20. Each party and signatory to this Agreement represents that it freely and voluntarily enters into this Agreement without any degree of duress or compulsion.

21. This Agreement is governed by the laws of the United States. The exclusive jurisdiction and venue for any dispute relating to this Agreement is the United States District Court

for the District of New Jersey. For purposes of construing this Agreement, 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.

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

23. The undersigned counsel represent and warrant that they are fully authorized to execute this Agreement on behalf of the persons and entities indicated below.

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

25. This Agreement is binding on Merit's successors, transferees, heirs, and assigns.

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

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

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

[SIGNATURE PAGES FOLLOW]

THE UNITED STATES OF AMERICA

DATED: October 13, 2020 BY: /s/ Christopher Terranova
CHRISTOPHER TERRANOVA
Trial Attorney
Commercial Litigation Branch, Civil Division
United States Department of Justice

DATED: October 13, 2010 BY: /s/ Andrew A. Caffrey, III
ANDREW A. CAFFREY, III
Assistant United States Attorney
United States Attorney's Office
District of New Jersey

APPROVED:

/s/ Lee M. Cortex, Jr.
LEE M. CORTES, JR.
Chief, Health Care Fraud Unit
United States Attorney's Office
District of New Jersey

APPROVED:

/s/ Rachael A. Honig
RACHAEL A. HONIG
Attorney for the United States, Acting under Authority Conferred by 28 U.S.C. § 515
United States Attorney's Office
District of New Jersey

DATED: October 13, 2020 BY: /s/ Lisa M. Re
LISA M. RE
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

DATED: October 13, 2020 BY: /s/ Salvatore M. Maida
SALVATORE M. MAIDA
General Counsel
Defense Health Agency
United States Department of Defense

DATED: October 13, 2020 BY: /s/ Fred Lampropoulos
FRED LAMPROPOULOS
Chairman and Chief Executive Officer
Merit Medical Systems, Inc.

DATED: October 13, 2020 BY: /s/ Michael R. Pauze
MICHAEL R. PAUZÉ
King & Spalding LLP
Counsel for Merit Medical Systems, Inc.

DATED: October 13, 2020 BY: /s/ Lawrence S. Lustberg
LAWRENCE S. LUSTBERG
Gibbons P.C.
Counsel for Merit Medical Systems, Inc.

RELATOR

DATED: October 13, 2020 BY: /s/ Charles J. Wolf, M.D.
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CORPORATE INTEGRITY AGREEMENT BETWEEN THE OFFICE OF INSPECTOR GENERAL OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES AND MERIT MEDICAL SYSTEMS, INC.

I. PREAMBLE

Merit Medical Systems, Inc. (Merit) 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) and with the statutes, regulations, and written directives of the Food and Drug Administration (FDA requirements). Contemporaneously with this CIA, Merit is entering into a Settlement Agreement with the United States.

Merit represents that it has an established corporate compliance program (Compliance Program) which preceded the execution of this CIA. The Compliance Program includes a Compliance Officer, Compliance Committee, written policies and procedures, education and training programs, and a disclosure program. Merit will continue to operate its Compliance Program throughout the term of this CIA.

II. TERM AND SCOPE OF THE CIA

A. The period of the compliance obligations assumed by Merit under this CIA shall be five years from the effective date of this CIA. The "Effective Date" shall be the date on which the final signatory of this CIA executes this CIA. Each one-year period, beginning with the one-year period following the Effective Date, shall be referred to as a "Reporting Period."

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

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

1. For purposes of this CIA, the term "Covered Persons" includes: (a) all owners of Merit who are natural persons (other than shareholders who: (i) have an ownership interest of less than 5% and (ii) acquired the ownership interest through public trading) and all officers and directors of Merit; (b) all officers, directors and employees of Merit; and (c) all contractors, subcontractors, agents, and other persons who perform any of the Covered Functions on behalf of Merit.

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

2. "Government Reimbursed Products" refers to all Merit products that are: (a) marketed or sold by Merit in the United States (or pursuant to contracts with the United States) and (b) reimbursed by Federal health care programs.

3. The term "Covered Functions" includes: (a) the selling, marketing, advertising, promoting, or branding of Government Reimbursed Products; (b) the preparation or external dissemination of promotional materials or information about, or the provision of services relating to, Government Reimbursed Products; (c) contracting with health care professionals (HCPs) for consulting services (including but not limited to speaker programs, speaker training programs, training and education services, product development activities, presentations, consultant task force meetings, advisory boards, ad hoc advisory activities, research and any research-related activities, and authorship of articles or other publications relating to Government Reimbursed Products), or other fee-for service arrangements relating to Government Reimbursed Products; (d) contracting with HCPs or health care institutions (HCIs) for any Co-Marketing Activity; and (e) reviewing and/or approving requests for grants or charitable contributions involving HCPs or HCIs.

4. The term "Sponsorships" shall mean support for a program, event, or organization in return for the advertisement, or promotion of Merit products, including healthcare-related conventions and conference sponsorships, promotional booths, exhibit space, advertisements, memberships, signage rights, naming rights, and subscriptions.

5. The term "Third Party Educational Activity" shall mean any scientific, educational, or professional program, meeting, or event for HCPs conducted by

a third party and supported by Merit, including but not limited to, continuing medical education (CME), disease awareness, or sponsorship of symposia at medical conferences.

6. The term "Co-Marketing Activity" shall mean any marketing or other promotional activity that Merit performs with or on behalf of (in addition to itself) one or more HCPs or HCIs involving a Government Reimbursed Product.

III. CORPORATE INTEGRITY OBLIGATIONS

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

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

1. *Compliance Officer*. Within 90 days after the Effective Date, Merit shall appoint a Compliance Officer and shall maintain a Compliance Officer for the term of the CIA. The Compliance Officer shall be an employee and a member of senior management of Merit; shall report directly to the Chief Executive Officer of Merit; and shall not be, or be subordinate to, the General Counsel or Chief Financial Officer or have any responsibilities that involve acting in any capacity as legal counsel or supervising legal counsel functions for Merit. The Compliance Officer shall be responsible for, without limitation:

a. developing and implementing policies, procedures, and practices designed to ensure compliance with the requirements set forth in this CIA and with Federal health care program and FDA requirements;

b. making periodic (at least quarterly) reports regarding compliance matters in person to the Audit Committee of the Board of Directors of Merit (Audit Committee) and shall be authorized to report on such matters to the Audit Committee at any time. Written documentation of the Compliance Officer's reports to the Audit Committee shall be made available to OIG upon request; and

c. monitoring the day-to-day compliance activities engaged in by Merit as well as any reporting obligations created under this CIA.

Any noncompliance job responsibilities of the Compliance Officer shall be limited and must not interfere with the Compliance Officer's ability to perform the duties outlined in this CIA.

Merit 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 business days after such a change.

2. *Compliance Committee*. Within 90 days after the Effective Date, Merit 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 sales, marketing, legal, medical affairs/medical information, regulatory affairs, research and development, human resources, audit, finance, manufacturing, and operations). The Compliance Officer shall chair the Compliance Committee and the Compliance Committee shall support the Compliance Officer in fulfilling his/her responsibilities (e.g., shall assist in the analysis of Merit's risk areas and shall oversee monitoring of internal and external audits and investigations). The Compliance Committee shall meet at least quarterly. The minutes of the Compliance Committee meetings shall be made available to OIG upon request.

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

3. *Board Compliance Obligations*. The Audit 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 Audit Committee must include independent (i.e., non-employee and non-executive) members.

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

a. meeting at least quarterly to review and oversee Merit's Compliance Program, including but not limited to the performance of the Compliance Officer and Compliance Committee;

b. submitting to OIG a description of the documents and other materials it reviewed, as well as any additional steps taken, such as the engagement of an independent advisor or other third party resources, in its oversight of the compliance program and in support of making the resolution below during each Reporting Period; and

c. for each Reporting Period of the CIA, adopting a resolution, signed by each member of the Audit Committee, summarizing its review and oversight of Merit's compliance with Federal health care program requirements, FDA requirements, and the obligations of this CIA.

d. for the first and fourth Reporting Period of the CIA, the Audit Committee shall retain an individual or entity with expertise in compliance with Federal health care program and FDA requirements (Compliance Expert) to perform a review of the effectiveness of Merit's Compliance Program (Compliance Program Review). The Compliance Expert shall prepare a written report about the Compliance Program Review. The written report (Compliance Program Review Report) shall include a description of the Compliance Program Review and any recommendations with respect to Merit's compliance program. The Audit Committee shall review the Compliance Program Review Report as part of its review and oversight of Merit's compliance program. A copy of the Compliance Program Review report shall be provided to OIG in the first and fourth Annual Report submitted by Merit. In addition, copies of any materials provided to the Audit Committee by the Compliance Expert, along with minutes of any meetings between the Compliance Expert and the Audit Committee, shall be made available to OIG upon request.

At minimum, the resolution shall include the following language:

> "The Audit Committee has made a reasonable inquiry into the operations of Merit's Compliance Program including the performance of the Compliance Officer and the Compliance Committee. Based on its inquiry and review, the Audit Committee has concluded that, to the best of its knowledge, Merit

has implemented an effective Compliance Program to meet Federal health care program requirements, FDA requirements, and the obligations of the Corporate Integrity Agreement."

If the Audit Committee is unable to provide such a conclusion in the resolution, the Audit 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 implement an effective Compliance Program at Merit.

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

4. *Management Certifications*. In addition to the responsibilities set forth in this CIA for all Covered Persons, certain Merit employees (Certifying Employees) are specifically expected to monitor and oversee activities within their areas of authority and shall annually certify that the applicable Merit business unit is in compliance with applicable Federal health care program and FDA requirements and with the obligations of this CIA. These Certifying Employees shall include, at a minimum, the following: the Chief Financial Officer, the Executive Vice President – Commercial, the Chief Regulatory Affairs Officer, and the Vice President – US Sales. For each Reporting Period, each Certifying Employee shall sign a certification that states:

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

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

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

B. Written Standards

1. *Policies and Procedures.* Within 120 days after the Effective Date, Merit shall develop and implement written policies and procedures regarding the operation of its compliance program, including the compliance program requirements outlined in this CIA and Merit's compliance with Federal health care program and FDA requirements (Policies and Procedures). Throughout the term of this CIA, Merit shall enforce its Policies and Procedures and shall make compliance with its Policies and Procedures an element of evaluating the performance of all employees. The Policies and Procedures shall be made available to all Covered Persons. At a minimum, the Policies and Procedures shall address the following:

a. appropriate ways to conduct Covered Functions in compliance with all: (i) applicable Federal healthcare program requirements, including, but not limited to the Federal Anti-Kickback Statute (codified at 42 U.S.C. § 1320a-7b(b)) and the False Claims Act (codified at 31 U.S.C. §§ 3729-3733); and (ii) all applicable FDA requirements;

b. the development, implementation, and compliant use of promotional materials used by sales representatives (including any contract sales force) and other Merit representatives who promote and sell Government Reimbursed Products;

c. the development, implementation, and review of policies for the distribution of Government Reimbursed Products for evaluation purposes (Evaluation Product). This shall include a review of the bases upon, and circumstances under, which HCPs and HCIs belonging to specified medical specialties or types of clinical practice may receive Evaluation Product

from Merit (including, separately, from sales representatives, or through other channels);

d. consultant or other fee-for-service arrangements entered into with HCPs or HCIs (including but not limited to speaker programs, speaker training programs, training and education services, product development activities, presentations, consultant task force meetings, advisory boards, ad hoc advisory activities, research and research-related activities, authorship activities, and any other financial engagement or arrangement with an HCP or HCI) and all events and expenses relating to such engagements or arrangements. The Policies and Procedures shall include requirements about the content and circumstances of such arrangements and events;

e. agreements or arrangements with HCPs or HCIs for the purchase or licensing of intellectual property (including, but not limited to, patents, patent applications, and the payment of royalties);

f. programs by HCPs to educate sales representatives, including but not limited to presentations by HCPs at sales meetings, preceptorships, tutorials, and experience-based learning activities;

g. review and approval of, and payment for, travel and related expenses for HCPs including those in connection with HCP participation in educational, research, training, or other Merit-sponsored programs or activities;

h. sponsorship or funding of grants (including educational grants) or charitable contributions involving HCPs and HCIs;

i. funding of, or participation in, any Sponsorships, Third Party Educational Activity, or Co-Marketing Activity as defined in Sections II.C.4, II.C.5, and II.C.6 above;

j. compensation (including through salaries, bonuses, or other means) for Covered Persons who are sales representatives and their managers;

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

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

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

C. Training and Education

1. *Covered Persons Training.* Within 120 days after the Effective Date, Merit shall develop a written plan (Training Plan) that outlines the steps Merit will take to ensure that: (a) all Covered Persons receive at least annual training regarding Merit's CIA requirements and compliance program, and (b) all Covered Persons who engage in Covered Functions receive at least annual training regarding: (i) all applicable Federal health care program and FDA requirements relating to Covered Functions and (ii) all Merit Policies and Procedures and other requirements applicable to Covered Functions. The Training Plan shall include information regarding the following: training topics, categories of Covered Persons and required to attend each training session, length of the training session(s), schedule for training, and format of the training. Merit shall furnish training to its Covered Persons pursuant to the Training Plan during each Reporting Period.

2. *Board Training*. In addition to the training described in Section III.C.1, within 120 days after the Effective Date, each member of the Board of Directors shall receive training regarding the corporate governance responsibilities of board members, and the responsibilities of board members with respect to review and oversight of the Compliance Program. Specifically, the training shall address the unique responsibilities of health care board members, including the risks, oversight areas, and strategic approaches to conducting oversight of a health care entity. This training may be conducted by an outside compliance expert hired by the Board of Directors and should include a discussion of OIG's guidance on board member responsibilities.

New members of the Board of Directors shall receive the Board Training described above within 30 days after becoming a member or within 120 days after the Effective Date, whichever is later.

3. *Training Records*. Merit shall make available to OIG, upon request, training materials and records verifying that the training described in Sections III.C.1 and III.C.2 has been provided as required.

D. Risk Assessment and Internal Review Process

Within 120 days after the Effective Date, Merit shall develop and implement a centralized annual risk assessment and internal review process to identify and address risks associated with each Government Reimbursed Product, including risks associated with the Covered Functions. The Compliance Committee shall be responsible for implementation and oversight of the risk assessment and internal review process. The risk assessment and internal review process shall be conducted annually and shall require Merit to: (1) identify and prioritize risks, (2) develop internal audit work plans related to the identified risk areas, (3) implement the internal audit work plans, (4) develop corrective action plans in response to the results of any internal audits performed, and (5) track the implementation of the corrective action plans in order to assess the effectiveness of such plans. Merit shall maintain the risk assessment and internal review process for the term of the CIA.

E. Review Procedures

1. General Description.

a. *Engagement of Independent Review Organization*. Within 90 days after the Effective Date, Merit shall engage an entity (or entities), such as an accounting, auditing, or consulting firm (hereinafter "Independent Review Organization" or "IRO"), to perform the reviews listed in this Section III.E. The applicable requirements relating to the IRO are outlined in Appendix A to this CIA, which is incorporated by reference.

b. *Retention of Records*. The IRO and Merit shall retain and make available to OIG, upon request, all work papers, supporting documentation, correspondence, and draft reports

(those exchanged between the IRO and Merit) related to the reviews.

c. *Access to Records and Personnel*. Merit shall ensure the IRO has access to all records and personnel necessary to complete the reviews listed in this Section III.E., and that all records furnished to the IRO are accurate and complete.

2. *Systems and Transactions Reviews.* As set forth more fully in Appendix B, the IRO reviews shall consist of two components: Systems Reviews and Transactions Reviews relating to the Covered Functions.

a. *Systems Review*. The Systems Reviews shall assess Merit's systems, processes, policies, and procedures relating to the Covered Functions. If there are no material changes in Merit's relevant systems, processes, policies, and procedures, the Systems Reviews shall be performed for the first and fourth Reporting Periods. If Merit materially changes its relevant systems, processes, policies, and procedures, 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, as set forth more fully in Appendix B.

b. *Transactions Review.* The Transactions Reviews 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.

3. *IRO Review Reports*. The IRO shall prepare a report based upon each IRO review performed (IRO Review Report). Information to be included in the IRO Review Report is described in Appendices A-B.

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

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

F. Disclosure Program

Within 90 days after the Effective Date, Merit 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 Merit's policies, conduct, practices, or procedures with respect to a Federal health care program or an FDA requirement believed by the individual to be a potential violation of criminal, civil, or administrative law. Merit shall appropriately publicize the existence of the Disclosure Program and the disclosure mechanism (e.g., via periodic e- mails to employees, or by posting the information in prominent common areas).

The Disclosure Program shall emphasize a nonretribution, nonretaliation policy and shall include a reporting mechanism for anonymous communications for which appropriate confidentiality shall be maintained. The Disclosure Program also shall include a requirement that all of Merit's Covered Persons shall be expected to report suspected violations of any Federal health care program or FDA requirements to the Compliance Officer or other appropriate individual designated by Merit. Upon receipt of a disclosure, the Compliance Officer (or designee) shall gather all relevant information from the disclosing individual. The Compliance Officer (or designee) shall make a preliminary, good faith inquiry into the allegations set forth in every disclosure to ensure that he or she has obtained all of the information necessary to determine whether a further review should be conducted. For any disclosure that is sufficiently specific so that it reasonably: (1) permits a determination of the appropriateness of the alleged improper practice; and (2) provides an opportunity for taking corrective action, Merit 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 and shall record all disclosures, whether or not related to a potential violation of criminal, civil or administrative law related to Federal health care programs or FDA requirements, in the disclosure log within two business days of receipt of the disclosure. The disclosure log shall include a summary of each disclosure received (whether anonymous or not), the individual or department responsible for reviewing the disclosure, the status of the review, and any corrective action taken in response to the review.

G. Ineligible Persons

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

a. an "Ineligible Person" shall include an individual or entity who:

i. is currently excluded from participation in the Federal health care 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.

b. "Exclusion List" means the HHS/OIG List of Excluded Individuals/Entities (LEIE) (available through the Internet at http://www.oig.hhs.gov).

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

a. Merit shall screen all prospective Covered Persons against the Exclusion List prior to engaging their services and, as part of the hiring or contracting process, shall require such Covered Persons to disclose whether they are Ineligible Persons.

b. Merit shall screen all current Covered Persons against the Exclusion List within 90 days after the Effective Date and on a monthly basis thereafter.

c. Merit shall maintain a policy requiring all Covered Persons to disclose immediately if they become an Ineligible Person.

Nothing in this Section III.G affects Merit's responsibility to refrain from (and liability for) billing Federal health care programs for items or services furnished, ordered, or prescribed by an excluded person. Merit understands that items or services furnished, ordered, or prescribed by excluded persons are not payable by Federal health care

programs and that Merit may be liable for overpayments and/or criminal, civil, and administrative sanctions for employing or contracting with an excluded person regardless of whether Merit meets the requirements of Section III.G.

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

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

H. Notification of Government Investigation or Legal Proceeding

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

I. Reportable Events

1. *Definition of Reportable Event*. For purposes of this CIA, a "Reportable Event" means anything that involves:

a. a matter that a reasonable person would consider a probable violation of criminal, civil, or administrative laws applicable

to any Federal health care program for which penalties or exclusion may be authorized;

b. a matter that a reasonable person would consider a probable violation of FDA requirements relating to the promotion of Government Reimbursed Products, unless otherwise reported to the FDA in accordance with Section III.J below;

c. the employment of or contracting with a Covered Person who is an Ineligible Person as defined by Section III.G.1.a; or

d. the filing of a bankruptcy petition by Merit.

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

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

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

a. a complete description of all details relevant to the Reportable Event, including, at a minimum, the types of claims, transactions or other conduct giving rise to the Reportable Event, the period during which the conduct occurred, and the names of individuals and entities believed to be implicated, including an explanation of their roles in the Reportable Event;

b. a statement of the Federal criminal, civil or administrative laws that are probably violated by the Reportable Event, if any;

c. the Federal health care programs affected by the Reportable Event, if any;

d. a statement of the FDA requirements probably violated by the Reportable Event, if any; and

e. a description of Merit's actions taken to correct the Reportable Event and prevent it from recurring.

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

a. the identity of the Ineligible Person and the job duties performed by that individual;

b. the dates of the Ineligible Person's employment or contractual relationship;

c. a description of the Exclusion List screening that Merit completed before and/or during the Ineligible Person's employment or contract and any flaw or breakdown in the screening process that led to the hiring or contracting with the Ineligible Person;

d. a description of how the Ineligible Person was identified; and

e. a description of any corrective action implemented to prevent future employment or contracting with an Ineligible Person.

5. *Reportable Events under Section III.I.1.d*. For Reportable Events under Section III.I.1.d, the report to OIG shall include documentation of the bankruptcy filing and a description of any Federal health care program and/or FDA requirements implicated.

J. Notification of Communications with FDA

Within 30 days after the date of any written report, correspondence, or communication between Merit and the FDA that materially discusses Merit's or a Covered Person's actual or potential unlawful or improper promotion of Merit's products (including any improper dissemination of information about off-label indications), Merit shall provide a copy of the report, correspondence, or communication to OIG. Merit shall also provide written notice to OIG within 30 days after the resolution of any such

disclosed improper promotional matter, and shall provide OIG with a description of the findings and/or results of the matter, if any.

K. Requirements Relating to Certain Promotional Activities

Within 120 days following the Effective Date, Merit shall establish and implement the following requirements relating to: (1) arrangements with HCPs to serve as presenters on behalf of Merit or participate in training programs related to the safe and effective use of Government Reimbursed Products (Speaker Programs); and (2) arrangements for marketing or other promotional activity that Merit performs with or on behalf of one or more HCPs or HCIs involving a Government Reimbursed Product (Co-Marketing).

1. *Speaker Programs.* Merit shall establish and implement:

   a. A process to require all speakers to complete training and enter written agreements that describe the scope of work to be performed, the speaker fees to be paid, and compliance obligations for the speakers (including requirements regarding the use of Merit approved materials).

   b. A centralized, electronic system to initiate and track all speaker programs that includes controls designed to ensure that speaker programs are used for legitimate and lawful purposes in accordance with all applicable Federal health care program and FDA requirements.

   c. A process to ensure speakers are paid according to a centrally managed, pre-set rate structure determined based on an independent fair-market value analysis.

   d. A comprehensive list of speaker program attendees through its centralized system. In addition, Merit shall use its centralized system to handle all logistics and spending associated with speaker programs, including the tracking and review of the aggregate amount (including speaker fees, travel, and other expenses) paid to each speaker in connection with speaker programs.

   e. A requirement for certifications by sales representatives or

other Merit personnel that a speaker program complied with Merit requirements, or in the event of non-compliance, Merit shall require the identification of the policy violation and ensure appropriate follow up activity to address the violation.

2. *Co-Marketing Activities*. Merit shall establish and implement:

a. A process to ensure that a needs assessment has been complete for any Co-Marketing Activity. The needs assessment shall identify the business need for performing the Co-Marketing Activity and provide details about the Co- Marketing Activity (i.e., information about the type of Co- Marketing Activity and the role and contribution of each HCP or HCI involved in the Co-Marketing Activity);

b. A centralized, electronic system to track all Co-Marketing Activities;

c. A process to evaluate the fair market value of any Co-Marketing Activity;

d. A process to ensure that all arrangements to engage in Co-Marketing Activities are set forth in a written agreement that describes the scope of work to be performed by all parties to the arrangement, the fees to be paid, and any work product that will be produced.

L. Field Force Monitoring and Review Efforts

Within 120 days after the Effective Date, Merit shall establish a comprehensive Field Force Monitoring Program (FFMP) to evaluate and monitor its sales personnel's interactions with HCPs and HCIs. The FFMP shall be a formalized process designed to directly and indirectly observe the appropriateness of sales personnel's interactions with HCPs and HCIs and to identify potential improper conduct. As described in more detail below, the FFMP shall include: (1) direct field observations (Observations) of sales personnel and (2) the monitoring and review of other records relating to sales personnel's interactions with HCPs and HCIs (Records Reviews).

1. *Observations*. As a component of the FFMP, Monitoring Personnel shall conduct observations of sales representatives (including any contract sales personnel) to assess whether the messages delivered and materials distributed to HCPs and HCIs are consistent with applicable legal requirements and with Merit's Policies and Procedures. These observations shall be full day ride-alongs with sales representatives (Observations), and each Observation shall consist of directly observing all meetings between a sales representative and HCPs and HCIs during the workday. The Observations shall be scheduled throughout the year, judgmentally selected by Monitoring Personnel, and be conducted across the United States.

At the completion of each Observation, Monitoring Personnel shall prepare a report which includes:

1) the identity of the sales representative;
2) the identity of the Monitoring Personnel who conducted the Observation;
3) the date and duration of the Observation;
4) the product(s) promoted during the Observation;
5) an overall assessment of compliance with Merit Policies and Procedures; and
6) the identification of any potential improper conduct by the field sales representative.

Monitoring Personnel shall conduct at least 5 Observations during each Reporting Period. Monitoring Personnel shall have access to all relevant records and information necessary to assess sales representatives' interactions with HCPs and HCIs and to identify potential or actual compliance violations.

2. *Records Reviews*. As a component of the FFMP, Merit shall also review various types of records to assess sales representatives' interactions with HCPs and HCIs and to identify potential or actual compliance violations.

a. For each Reporting Period, Merit shall develop and implement a plan for conducting Records Reviews associated with at least five Government Reimbursed Products. The Records Reviews shall include a review of records relating to the activities of sales representatives in every separate district and/or region (as applicable) who promoted the products under review.

b. The Records Reviews shall include the monitoring and review of:

(i) records and systems associated with sales representatives' interactions with HCPs and HCIs (including records relating to Co-Marketing activities, consulting and other fee-for-service arrangements, speaker program activities, travel and entertainment, expense reports, any payments to HCPs or HCIs, and sales communications from managers);

(ii) records relating to requests for medical information about or inquiries relating to, the Government Reimbursed Products under review;

(iii) sales representative call notes;

(iv) sales representatives' e-mails and other electronic records; and

(v) recorded results of the Observations of sales force representatives, coaching guides, and manager notes.

3. *Reporting and Follow-up*. Results from the FFMP shall be compiled and reported to the Compliance Officer for review and remediation as appropriate.

M. Requirements Relating to Certain Non-Promotional Activities

Within 120 days after the Effective Date, Merit shall develop policies, procedures, and systems to implement the requirements outlined below relating to the following types of activities: (1) consultant arrangement activities; and (2) grant and charitable contribution activities involving HCPs and HCIs.

1. *Consulting Arrangement Activities*. To the extent that Merit engages HCPs for services other than for speaker programs (e.g., training and education services, product development activities, presentations, consultant task force meetings, advisory boards, ad hoc advisory activities, research and research-related activities, authorship activities, and any other financial engagement or arrangement with an HCP), such HCPs

shall be referred to herein as Consultants. Within 90 days of the Effective date, Merit shall:

a. Require all Consultants to enter written agreements describing the scope of work to be performed, the consultant fees to be paid, and compliance obligations for the Consultants. Consultants shall be paid according to a centrally managed, pre-set rate structure that is determined based on an independent fair-market value analysis.

b. Establish a process to develop an annual budgeting plan that specifies (i) the business needs for, and the estimated numbers of, the various Consultant engagements and activities to occur during the following year and (ii)the budgeted amounts to be spent on Consultant-related activities. Merit compliance personnel shall be involved in the review and approval of such plans, including any subsequent modification of an approved plan for the purpose of ensuring that Consultant arrangements and related events are used for legitimate and lawful purposes in accordance with applicable Federal health care program and FDA requirements and Merit Policies and Procedures.

c. Establish a process to ensure that a needs assessment has been completed to justify the retention of a Consultant prior to the retention of the Consultant. The needs assessment shall identify the business need for the retention of the Consultant and provide specific details about the consulting arrangement (e.g., information about the numbers and qualifications of the HCPs and HCIs to be engaged, the agenda for the proposed meeting, and a description of the proposed work to be done and the type of work product to be generated). Any deviations from the Consultant budgeting plans shall be documented in the needs assessment form and shall be subject to review and approval by Merit compliance personnel.

d. Amend its policies and procedures in a manner designed to ensure that each Consultant performs the work for which the

Consultant is engaged and that, as applicable, Merit receives the work product generated by the Consultant.

4. *Grant and Charitable Contribution Activities involving HCPs and HCIs.* Within 120 days of the Effective date, Merit shall:

a. Establish a centralized system which shall be the exclusive mechanism through which requestors may request or be awarded amounts for Third Party Educational Activities, other grant activities involving HCPs and HCIs (referred to below as "Grants"), and charitable contributions involving HCPs or HCIs (referred to below as "Contributions").

b. Establish a process to review requests for Grants and Contributions according to standardized, objective criteria developed by Merit (such as based upon the qualifications of the requestor, or the quality of the program funded by the Grant or Contribution) and to ensure that Grants and Contributions are provided only pursuant to a written agreement with the funding recipient and that payments to the funding recipient are consistent with the written agreement. Merit's sales and marketing personnel shall have no involvement in, or influence over, the review and approval of requests for Grants and Contributions.

N. Reporting of Physician Payments

1. *Reporting of Payment Information.* Within 90 days after the Effective Date, Merit shall post on its website a description of the types of Payments it makes to Covered Recipients and include a link to CMS's Open Payments Data website (www.openpaymentsdata.cms.gov). Merit also shall include on its website instructions regarding how to utilize the CMS Open Payments Data search tool to search for information regarding Payments provided to Covered Recipients from Merit.

2. *Definitions.* For purposes of this Section III.M, the terms "Payments" and "Covered Recipient" are defined as specified in 42 U.S.C. § 1320a-7h and the related regulations and guidance (including FAQs) published by CMS.

IV. SUCCESSOR LIABILITY

In the event that, after the Effective Date, Merit proposes to (a) sell any or all of its business, business units or locations (whether through a sale of assets, sale of stock or other type of transaction) that are subject to this CIA; or (b) purchases or establishes a new business, business unit or location related to or engaged in any of the Covered Functions, the CIA shall be binding on the purchaser of any business, business unit or location. Any such new business, business unit or location (and all Covered Persons at each new business, business unit or location) shall be subject to the applicable requirements of this CIA, unless otherwise determined and agreed to in writing by OIG. Merit shall give notice of such sale or purchase to OIG within 30 days following the closing of the transaction.

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

V. IMPLEMENTATION AND ANNUAL REPORTS

A. Implementation Report

Within 150 days after the Effective Date, Merit 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, business address, business phone number, and position description of the Compliance Officer required by Section III.A.1, 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.2;

3. the names of the Audit Committee members who are responsible for satisfying the Board compliance obligations described in Section III.A.3;

4. the names and positions of the Certifying Employees required by Section III.A.4 and a copy of the written process for Certifying Employees to follow in order to complete the certification required by Section III.A.4;

5. a list of the Policies and Procedures required by Section III.B.1;

6. the Training Plan required by Section III.C.1 and a description of the Board of Directors training required by Section III.C.2 (including a summary of the topics covered, the length of the training and when the training was provided);

7. a description of the risk assessment and internal review process required by Section III.D;

8. the following information regarding the IRO(s): (a) identity, address, and phone number; (b) a copy of the engagement letter; (c) information to demonstrate that the IRO has the qualifications outlined in Appendix A to this CIA; and (d) a certification from the IRO regarding its professional independence and objectivity with respect to Merit that includes a summary of all current and prior engagements between Merit and the IRO;

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

10. a description of the Ineligible Persons screening and removal process required by Section III.G;

11. a description of policies, procedures, and systems implemented pursuant to the Requirements Relating to Certain Promotional Activities outlined in Section III.K;

12. a description of the FFMP required by Section III.L;

13. a description of the policies, procedures, and systems implemented pursuant to the Requirements Relating to Certain Non-Promotional Activities outlined in Section III.M;

14. a certification from the Compliance Officer that information regarding Payments has been posted on Merit's website as required by Section III.N;

15. a list of all of Merit's locations (including locations and mailing addresses); the corresponding name under which each location is doing business; and the locations' Medicare and state Medicaid provider number and/or supplier number(s) if any;

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

17. the certifications required by Section V.C.

B. Annual Reports

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

1. any change in the identity, position description, or other noncompliance job responsibilities of the Compliance Officer; a current list of the Compliance Committee members; a current list of the Audit Committee members who are responsible for satisfying the Board compliance obligations; and a current list of the Certifying Employees, along with the identification of any changes made during the Reporting Period to the Compliance Committee, Audit Committee, and Certifying Employees;

2. a description of any changes to the written process for Certifying Employees to follow in order to complete the certification required by Section III.A.4;

3. the dates of each report made by the Compliance Officer to the Audit Committee (written documentation of such reports shall be made available to OIG upon request);

4. the Audit Committee resolution required by Section III.A.3, a description of the documents and other materials reviewed by the Audit Committee, as well as any additional steps taken, in its oversight of the compliance program and in support of making the resolution, and the Compliance Expert report as required in Section III.A.3.d.;

5. a list of any new or revised Policies and Procedures required by Section III.B.1 developed during the Reporting Period;

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

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

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

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

10. a certification from the IRO regarding its professional independence and objectivity with respect to Merit, including a summary of all current and prior engagements between Merit and the IRO;

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

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

13. a summary describing any ongoing investigation or legal proceeding required to have been reported pursuant to Section III.H. 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 summary of Reportable Events (as defined in Section III.I)

identified during the Reporting Period;

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

16. a summary of any changes to the policies, procedures, and systems relating to the Requirements for Certain Promotional Activities described in Section III.K, including the reasons for such changes;

17. the results of the FFMP required by Section III.L, including copies of the Observations for any instances in which it was determined that improper conduct occurred and a description of the action(s) that Merit took as a result of such determinations;

17. a summary of any changes to the policies, procedures, and systems relating to the Requirements for Certain Non-Promotional Activities described in Section III.M, including the reasons for such changes;

18. a certification from the Compliance Officer that information regarding Payments has been posted on Merit's website as required by Section III.N;

19. a description of all changes to the most recently provided list of Merit's locations (including addresses) as required by Section V.A.13;

20. a description of any changes to Merit's corporate structure, including any parent and sister companies, subsidiaries, and their respective lines of business; and

21. the certifications required by Section V.C.

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

C. Certifications

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

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

a. to the best of his or her knowledge, except as otherwise described in the report, Merit has implemented and is in compliance with all requirements of this CIA;

b. he or she has reviewed the report and has made reasonable inquiry regarding its content and believes that the information in the report is accurate and truthful; and

c. he or she understands that the certification is being provided to and relied upon by the United States.

D. Designation of Information

Merit 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. Merit shall refrain from identifying any information as exempt from disclosure if that information does not meet the criteria for exemption from disclosure under FOIA.

VI. NOTIFICATIONS AND SUBMISSION OF REPORTS

Unless otherwise stated in writing after the Effective Date, all notifications and reports required under this CIA shall be submitted to the following entities:

OIG:

Administrative and Civil Remedies Branch
Office of Counsel to the Inspector General
Office of Inspector General
U.S. Department of Health and Human Services
Cohen Building, Room 5527
330 Independence Avenue, S.W.
Washington, DC 20201
Telephone: 202.619.2078

Facsimile: 202.205.0604 Merit:

David Lewis
1600 West Merit Parkway South
Jordan, UT 84095 Telephone:
(801) 316-3835
Email Address: David.Lewis@merit.com

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

VII. OIG INSPECTION, AUDIT, AND REVIEW RIGHTS

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

VIII. DOCUMENT AND RECORD RETENTION

Merit shall maintain for inspection all documents and records relating to reimbursement from the Federal health care programs and to compliance with this CIA for six years (or longer if otherwise required by law) from the Effective Date.

IX. DISCLOSURES

Consistent with HHS's FOIA procedures, set forth in 45 C.F.R. Part 5, OIG shall make a reasonable effort to notify Merit prior to any release by OIG of information submitted by Merit pursuant to its obligations under this CIA and identified upon submission by Merit as trade secrets, or information that is commercial or financial and privileged or confidential, under the FOIA rules. With respect to such releases, Merit shall have the rights set forth at 45 C.F.R. § 5.42 (a).

X. BREACH AND DEFAULT PROVISIONS

Merit 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, Merit 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) per obligation for each day Merit fails to establish, implement or comply with any of the following obligations as described in Section III:

   a. a Compliance Officer;

   b. a Compliance Committee;

   c. the Board compliance obligations and the engagement of a Compliance Expert, the performance of a Compliance Program Review, and the preparation of a Compliance Program Review Report, as required by Section III.A.3;

d. the management certification obligations and the development and implementation of a written process for Certifying Employees, as required by Section III.A.4;

e. written Policies and Procedures;

f. the development of a written training plan and the training and education of Covered Persons and Board members;

g. a risk assessment and internal review process;

h. a Disclosure Program;

i. Ineligible Persons screening and removal requirements;

j. notification of Government investigations or legal proceedings;

k. reporting of Reportable Events;

l. notification of written communications with FDA;

m. the Requirements Relating to Certain Promotional Activities;

n. the FFMP;

n. the Requirements Relating to Certain Non-Promotional Activities; and,

o. posting of any Payment-related information.

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 Merit fails to engage and use an IRO as required by Section III.E and Appendix 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 Merit fails to timely submit (a) a complete Implementation Report or Annual Report, (b) a certification to OIG in

accordance with the requirements of Section V, or (c) a complete response to any request for information from OIG.

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 Merit fails to submit any IRO Review report in accordance with the requirements of Section III.E and Appendix B.

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

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

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

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

Merit 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 Merit fails to meet the revised deadline set by OIG. Notwithstanding any other provision in this Section, if OIG denies such a timely written request, Stipulated

Penalties for failure to perform the act or file the notification or report shall not begin to accrue until three business days after Merit 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 Merit 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 Merit of: (a) Merit'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 business days after the receipt of the Demand Letter, Merit 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 Merit elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until Merit 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.d, these provisions for payment of Stipulated Penalties shall not affect or otherwise set a standard for OIG's decision that Merit has materially breached this CIA, which decision shall be made at OIG's discretion and shall be governed by the provisions in Section X.D, below.

D. Exclusion for Material Breach of this CIA

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

a. repeated violations or a flagrant violation of any of the obligations under this CIA, including, but not limited to, the obligations addressed in Section X.A;

b. a failure by Merit to report a Reportable Event and take corrective action as required in Section III.I;

c. a failure to engage and use an IRO in accordance with Section III.E and Appendix 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 Merit constitutes an independent basis for Merit's exclusion from participation in the Federal health care programs. The length of the exclusion shall be in OIG's discretion, but not more than five years per material breach. Upon a determination by OIG that Merit has materially breached this CIA and that exclusion is the appropriate remedy, OIG shall notify Merit of: (a) Merit'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*. Merit 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. the alleged material breach has been cured; or

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

4. *Exclusion Letter*. If, at the conclusion of the 30 day period, Merit fails to satisfy the requirements of Section X.D.3, OIG may exclude Merit from participation in the Federal health care programs. OIG shall notify Merit in writing of its

determination to exclude Merit (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 Merit's receipt of the Exclusion Letter. The exclusion shall have national effect. Reinstatement to program participation is not automatic. At the end of the period of exclusion, Merit 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 Merit 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, Merit 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. The procedures relating to the filing of a request for a hearing can be found at http://www.hhs.gov/dab/divisions/civil/procedures/divisionprocedures.html.

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 Merit was in full and timely compliance with the obligations of this CIA for which OIG demands payment; and (b) the period of noncompliance. Merit shall have the burden of proving its full and timely compliance and the steps taken to cure the noncompliance, if any. OIG shall not have the right to appeal to the DAB an adverse ALJ decision related to Stipulated Penalties. If the ALJ agrees with OIG with regard to a finding of a breach of this CIA and orders Merit to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable 20 days after the ALJ issues such a decision unless Merit 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 whether Merit was in material breach of this CIA and, if so, whether:

a. Merit cured such breach within 30 days of its receipt of the Notice of Material Breach; or

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

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

Merit and OIG agree as follows:

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

B. This CIA constitutes the complete agreement between the parties and may not be amended except by written consent of the parties to this CIA.

C. All requirements and remedies set forth in this CIA are in addition to and do not affect (1) Merit's responsibility to follow all applicable Federal health care program and FDA requirements or (2) the government's right to impose appropriate remedies for failure to follow applicable Federal health care program or FDA requirements.

D. The undersigned Merit signatories represent and warrant that they are authorized to execute this CIA. The undersigned OIG signatories represent that they are signing this CIA in their official capacity and that they are authorized to execute this CIA.

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

ON BEHALF OF MERIT MEDICAL SYSTEMS, INC.

/s/ Fred Lampropoulos
FRED LAMPROPOULOS
Chief Executive Officer Merit Medical Systems, Inc.

October 13, 2020
DATE

/s/ Seth Lundy

/s/ Michael Pauze
SETH LUNDY
MICHAEL PAUZE
Counsel for Merit Medical Systems, Inc. King & Spalding LLP

October 13, 2020
DATE

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

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

October 13, 2020
DATE

/s/ Madeline J. Bainer
MADELINE J. BAINER
Senior Counsel
Administrative and Civil Remedies Branch
Office of Counsel to the Inspector General
U.S. Department of Health and Human Services

October 13, 2020
DATE

APPENDIX A
INDEPENDENT REVIEW ORGANIZATION

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

A. IRO Engagement

1. Merit shall engage an IRO that possesses the qualifications set forth in Paragraph B, below, to perform the responsibilities in Paragraph C, below. The IRO shall conduct the review in a professionally independent and objective fashion, as set forth in Paragraph E. Within 30 days after OIG receives the information identified in Section V.A.8 of the CIA or any additional information submitted by Merit in response to a request by OIG, whichever is later, OIG will notify Merit if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, Merit may continue to engage the IRO.

2. If Merit engages a new IRO during the term of the CIA, that IRO must also meet the requirements of this Appendix. If a new IRO is engaged, Merit shall submit the information identified in Section V.A.8 of the CIA to OIG within 30 days of engagement of the IRO. Within 30 days after OIG receives this information or any additional information submitted by Merit at the request of OIG, whichever is later, OIG will notify Merit if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, Merit may continue to engage the IRO.

B. IRO Qualifications

The IRO shall:

1. assign individuals to conduct the IRO Reviews who have expertise in the pharmaceutical industry and in all applicable Federal health care program and FDA requirements relating to the Covered Functions, including but not limited to expertise relating to marketing and promotional activities associated with pharmaceutical products and the Federal Anti-Kickback Statute and False Claims Act.

2. assign individuals to design and select the samples for the IRO Transactions 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.

C. IRO Responsibilities

The IRO shall:

1. perform each component of the IRO Reviews in accordance with the specific requirements of the CIA;

2. follow all applicable Federal health care program and FDA requirements in making assessments in the IRO Reviews;

3. respond to all OIG inquires in a prompt, objective, and factual manner; and

4. prepare timely, clear, well-written reports that include all the information required by Appendix B to the CIA.

D. Merit Responsibilities

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

E. IRO Independence and Objectivity

The IRO must perform each component of the IRO Reviews in a professionally independent and objective fashion, as defined in the most recent Government Auditing Standards issued by the U.S. Government Accountability Office.

F. IRO Removal/Termination

1. *Merit and IRO*. If Merit terminates its IRO or if the IRO withdraws from the engagement during the term of the CIA, Merit must submit a notice explaining (a) its reasons for termination of the IRO or (b) the IRO's reasons for its withdrawal to OIG, no later than 30 days after termination or withdrawal. Merit must engage a new IRO in accordance with Paragraph A of this Appendix and within 60 days of termination or withdrawal of the IRO.

2. *OIG Removal of IRO*. In the event OIG has reason to believe the IRO does not possess the qualifications described in Paragraph B, is not independent and objective as set forth in Paragraph E or has failed to carry out its responsibilities as described in Paragraph C, OIG shall notify Merit in writing regarding OIG's basis for determining that the IRO has not met the requirements of this Appendix. Merit shall have 30 days from the date of OIG's written notice to provide information regarding the IRO's

qualifications, independence or performance of its responsibilities in order to resolve the concerns identified by OIG. If, following OIG's review of any information provided by Merit regarding the IRO, OIG determines that the IRO has not met the requirements of this Appendix, OIG shall notify Merit in writing that Merit shall be required to engage a new IRO in accordance with Paragraph A of this Appendix. Merit must engage a new IRO within 60 days of its receipt of OIG's written notice. The final determination as to whether or not to require Merit to engage a new IRO shall be made at the sole discretion of OIG.

APPENDIX B
IRO REVIEWS

A. IRO Engagement, General Description

As specified more fully below, Merit shall retain an IRO to perform engagements to assist Merit in assessing and evaluating certain of its systems, processes, policies, and procedures related to Merit's Covered Functions (IRO Review). The IRO Review shall consist of two components—a systems review (Systems Review) and a transactions review (Transactions Review) as described more fully below. Merit may engage, at its discretion, a single entity to perform both components of the IRO Reviews, provided that the entity has the necessary expertise and capabilities to perform both.

If there are no material changes in Merit's systems, processes, policies, and procedures relating to Covered Functions, the IRO shall perform the Systems Review of certain systems, processes, policies and procedures relating to Covered Functions (as set forth below) for the first and fourth Reporting Periods. If Merit materially changes its systems, processes, policies, and procedures relating to Covered Functions, the IRO shall perform a Systems Review for the Reporting Period(s) in which such changes were made in addition to conducting the Review as set forth above. The additional Systems Review(s) shall consist of: (1) an identification of the material changes, and (2) a review of the systems, processes, policies, and procedures that materially changed. The IRO shall conduct the Transactions Review for each Reporting Period of the CIA.

B. IRO Systems Review

The Systems Review shall be a review of Merit's systems, processes, policies, and procedures (including the controls on those systems, processes, policies, and procedures) relating to Covered Functions. More specifically, the IRO shall review Merit's systems, processes, policies, and procedures associated with the following (hereafter "Reviewed Policies and Procedures"):

1. Merit's systems, policies, processes, and procedures relating to the development, implementation, and compliant use of promotional materials used by sales representatives (including any contract sales force) and other Merit representatives who promote and sell Government Reimbursed Products;

2. Merit's systems, policies, processes, and procedures relating to the development, implementation, and review of all policies for the distribution of Government Reimbursed Products for evaluation purposes (Evaluation Product). This shall include a review of the bases upon, and circumstances under, which HCPs and HCIs

belonging to specified medical specialties or types of clinical practice may receive Evaluation Product from Merit (including, separately, from sales representatives, or through other channels);

3. Merit's systems, policies, processes, and procedures relating to consultant or other fee-for-service arrangements entered into with HCPs or HCIs (including but not limited to speaker programs, speaker training programs, training and education services, product development activities, presentations, consultant task force meetings, advisory boards, ad hoc advisory activities, research and research-related activities, authorship activities, and any other financial engagement or arrangement with an HCP or HCI) and all events and expenses relating to such engagements or arrangements;

4. Merit's systems, policies, processes, and procedures relating to agreements or arrangements with HCPs or HCIs for the purchase or licensing of intellectual property (including, but not limited to, patents, patent applications, and payment of royalties);

5. Merit's systems, policies, processes, and procedures relating to programs by HCPs to educate sales representatives, including but not limited to presentations by HCPs at sales meetings, preceptorships, tutorials, and experience-based learning activities;

6. Merit's systems, policies, processes, and procedures relating to the review and approval of, and payment for, travel and related expenses for HCPs including those in connection with an HCP's participation in educational, research, training, or other Merit-sponsored programs or activities;

7. Merit's systems, policies, processes, and procedures relating to the sponsorship or funding of grants (including educational grants) or charitable contributions involving HCPs or HCIs;

8. Merit's systems, policies, processes, and procedures relating to funding of, or participation in, any Sponsorships, Third Party Educational Activity, or Co-Marketing Activity as defined in Sections II.C.4, II.C.5, and II.C.6 of the CIA;

9. Merit's systems, policies, processes, and procedures relating to compensation (including through salaries, bonuses, or other means) for Covered Persons who are sales representatives and their managers; and

10. Merit's systems, policies, processes, and procedures relating to disciplinary policies and procedures for violations of Merit's Policies and Procedures, including policies relating to Federal health care program and FDA requirements.

C. IRO Systems Review Report

The IRO shall prepare a report based upon each Systems Review performed. For each of the Reviewed Policies and Procedures identified in Section B 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 Merit's systems, policies, processes, and procedures relating to the items identified in Sections B.1-10 above, including a general description of Merit'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 B.1-10 above are made known or disseminated within Merit;

4. findings and supporting rationale regarding any weaknesses. in Merit's systems, processes, policies, and procedures relating to the Reviewed Policies and Procedures, if any; and

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

D. IRO Transactions Review

The Transactions Review shall include a review of: (1) a sample of consultant or other fee-for-service arrangements entered into with HCPs (including all events and expenses related to such engagements or arrangements), (2) a sample of Co-Marketing Activity agreements, (3) a sample of medical education grants and charitable contributions, and (4) a sample of Payments. The IRO shall report on all aspects of its reviews in the Transactions Review Report.

1. *Review of Consulting Activities.* For purposes of this Appendix B, the term "Consulting Activities" shall include all consulting and other fee for service arrangements entered with HCPs (including but not limited to speaker programs, speaker training programs, training and education services, product development activities, presentations, consultant task force meetings, advisory boards, ad hoc advisory activities, research and research-related activities, authorship and authorship-related activities, and any other financial engagement or arrangement with an HCP or HCI) and all events and expenses relating to such engagements or arrangements.

a. For the first Reporting Period, the IRO shall select and review a sample of 10 Consulting Activities entered into with HCPs and all related expenses. For the second and subsequent Reporting Periods, the IRO shall review a total of at least 10 Consulting Activities which shall include a review of specified numbers of each type of Consulting Activities as determined by OIG. Prior to the determination of the number of each type of Consulting Activity to be reviewed during the second and subsequent Reporting Periods, Merit shall provide to OIG the information specified below in the next paragraph within 60 days prior to the end of the applicable preceding Reporting Period.

b. The IRO shall select its sample of Consulting Activities for review in consultation with OIG after the provision of information about the Consulting Activities to the OIG. Merit shall provide the following information to the OIG: (1) a description of each type of Consulting Activity undertaken during the Reporting Period and a description of the services to be provided under each Consulting Activity; (2) the number of each type of Consulting Activity undertaken during the Reporting Period; and (3) the overall budgeted amount to be spent in connection with each type of Consulting Activity during the Reporting Period.

c. For each Consulting Activity reviewed, the IRO shall determine whether:

   i. a written agreement was in place for each Consulting Activity that describes the scope of work to be performed, the fees and related expenses to be paid for the Consulting Activity, and the compliance obligations for the Consultant;

   ii. the compensation to be paid for the Consulting Activity was determined in accordance with a centrally managed, pre-set rate structure established by Merit;

   iii. the rate structure was established based on an independent FMV analysis;

   iv. the Consulting Activity was identified in the annual Consultant budgeting plan developed by Merit;

   v. a needs assessment that identifies the business need for the Consulting Activity and provides details about the Consulting

Activity was completed prior to the initiation of the Consulting Activity;

vi. the Consulting Activity was reviewed and approved in accordance with Merit Policies and Procedures;

vii. Merit collected and retained a record of the specific activity performed by the HCP and, if applicable, a copy of the work product generated by the HCP in connection with the Consulting Activity; and

viii. the activity undertaken by the Consultant and/or the work product generated by the HCP was used by Merit in a manner consistent with the needs assessment that was completed prior to the initiation of the Consulting Activity.

2. *Review of Co-Marketing Activities*. If Merit engages in any Co-Marketing Activity during the term of the CIA, the IRO shall review such Co-Marketing Activity agreements entered into during the applicable Reporting Period. For each Co-Marketing Activity agreement, the IRO shall review:

a. How Merit determined the business need for performing Co-Marketing Activities with the HCP(s) and HCI(s);

b. How the targets or audience of each Co-Marketing Activity were selected and by whom;

c. The contributions of each party to each Co-Marketing Activity, and the financial value of those contributions;

d. How Merit determined that each party was contributing to and receiving fair market value from the Co-Marketing Activities;

e. Whether Merit reviewed and approved the Co-Marketing Activity agreement in accordance with Merit's Policies and Procedures; and

f. Whether Merit collected and retained records of the activities of each party to the Co-Marketing Activity agreement.

3. *Review of Grants and Charitable Contributions involving HCPs or HCIs*. For purposes of this Appendix B, the term "Grants" shall include any awarded amounts for Third Party Educational Activities (as defined in Section II.C.5 of the CIA) or other grant activities involving HCPs and HCIs, and the term "Contributions" shall include any

charitable contributions involving HCPs or HCIs provided by Merit. For each Reporting Period, the IRO shall review a sample of the greater of 10% or 5 Grants and Contributions to HCPs or HCIs.

a. The IRO shall select its sample of Grants and Contributions for review in consultation with OIG after the provision of information about each to OIG. Merit shall provide the following information to OIG: (1) a description of each type of Grant and Contribution provided during the Reporting Period and a description of the purpose of, and activity to be undertaken in connection with, each type of Grant and Contribution; (2) the number of each type of Grant and Contribution provided during the Reporting Period; and (3) the budgeted amount to be spent on each type of Grant and Contribution during the Reporting Period.

b. The IRO's review shall include, but not be limited to: proposal documents (including Grant and Contribution requests), approval documents, contracts, payments and materials relating to the centralized system's review of the requests, and documents and materials relating to the Grants and Contributions and any events or activities funded through the Grants and Contributions.

c. For each Grant and Contribution reviewed, the IRO shall determine whether:

    i. The request for the Grant or Contribution was submitted through Merit's centralized system and processed in accordance with standardized objective criteria;

    ii. The terms of the Grant or Contribution are reflected in a written agreement between Merit and the recipient of the grant or contribution;

    iii. The Grant or Contribution was reviewed and approved in accordance with Merit policies and procedures;

    iv. Merit records identify the purpose or use for which the Grant or Contribution was requested; and

    v. Applicable documents or other records verify that the purpose of use for which the Grant or Contribution was requested occurred or was satisfied (e.g., if the Grant or Contribution

was provided to sponsor an event, the IRO shall assess whether the event, in fact, occurred.)

4. *Review of Payments.* For purposes of this Appendix B, the term "Control Documents" shall include all material documents or electronic records associated with each Merit Payment reflected in the Open Payments database for that calendar year. For example, the term "Control Documents" includes, but is not limited to, documents relating to the nature, purpose, and amount of the Payment; contracts relating to the Payment; documents relating to the occurrence of Payment; documents reflecting any work product generated in connection with the Payment; documents submitted by sales representatives or headquarters personnel to request approval for the Payment; and business rationale or justification forms relating to the Payment.

a. For each Reporting Period, the OIG shall have the discretion to identify up to 15 Covered Recipients who received Payments from Merit during the prior calendar year and will be subject to the IRO review described below. If the OIG elects to exercise this discretion, it shall notify the IRO of the Covered Recipients subject to the IRO Review. If the OIG elects not to exercise its discretion, the IRO shall randomly select 15 Covered Recipients to be included in the review.

b. For each selected Covered Recipient, the IRO shall review the Control Documents associated with the Payments to the Covered Recipient for all categories reflected in the Open Payments Data website except for the Food/Beverage and Travel/Lodging categories of Payments. Specifically, for each Covered Recipient selected as part of the sample, the IRO shall review the Control Documents identified by the IRO as necessary and sufficient to validate each Payment reported to CMS to evaluate the following:

i. whether Control Documents are available relating to each Payment;

ii. whether the Control Documents were completed and archived in accordance with the requirements set forth in Merit's policies;

iii. whether the aggregate value of the Payment as reflected in the Open Payments Database is consistent with the value of the Payment reflected in the Control Documents; and

iv. whether the Control Documents reflect that Merit's policies were followed in connection with the Payment (e.g., all

required written approvals for the activity were obtained in accordance with Merit's policies.)

E. Transactions Review Report

A. General Elements to be Included in the Report. For each Reporting Period, the IRO shall prepare a report based on its Transactions Review. The report shall include the following:

1. Review Objectives: A clear statement of the objectives intended to be achieved by each part of the review;

2. 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

3. Sources of Data: A full description of documentation and other information, if applicable, relied upon by the IRO in performing the Transactions Review.

B. Results to be Included in Report. The following results shall be included in each Transactions Review Report:

1. Relating to the Review of Consulting Activities

a. a description of each type of Consulting Activity reviewed, including the number of each type of Consulting Activity reviewed and an identification of the types of documents and information reviewed for each Consulting Activity;

b. for each Consulting Activity reviewed, the IRO's findings and supporting rationale as to whether:

i. a written agreement was in place for each Consulting Activity that describes the scope of work to be performed, the fees and expenses to be paid for each Consulting Activity, and the compliance obligations for the Consultant;

ii. the compensation to be paid for the Consulting Activity was determined in accordance with a centrally managed, pre-set rate structure set by Merit;

iii. the rate structure was established based on an independent FMV analysis;

iv. the Consulting Activity was identified in the annual Consulting budgeting plan developed by Merit;

v. a needs assessment that identifies the business need for the Consulting Activity and provides detail about the activity was prepared prior to the initiation of the Consulting Activity;

vi. the Consulting Activity was reviewed and approved in accordance with Merit Policies and Procedures,

vii. Merit collected and retained a record of the specific activity performed by the HCP and, if applicable, a copy of the work product generated in connection with the Consulting Activity; and

viii. the activity undertaken by the Consultant and/or the work product generated was used by Merit in a manner consistent with the needs assessment that was completed prior to the initiation of the Consulting Activity;

c. any weaknesses in Merit's systems, processes, policies, procedures and/or practices relating to Consulting Activities identified by the IRO; and

d. any recommendations for improvements to Merit's systems, processes, policies, procedures and/or practices relating to Consulting Activities.

2. Relating to the Review of Co-Marketing Activities

a. a description of each type of Consulting Activity reviewed, including the number of each type of Consulting Activity reviewed and an identification of the types of documents and information reviewed for each Consulting Activity

b. For each Co-Marketing Activity reviewed, the IRO’s findings and supporting rationale as to:

i. whether and how Merit determined a business need for performing the Co-Marketing Activities with the HCP(s) and the HCI(s);

ii. whether and how the targets or audience of each Co-Marketing Activity were selected, and by whom;

iii. the contributions of each party to each Co-Marketing Activity, and the financial value of those contributions;

iv. whether and how Merit determined that each party was contributing to and receiving fair market value from the Co-Marketing Activities;

v. whether the Co-Marketing Activity was reviewed and approved in accordance with Merit's Policies and Procedures;

vi. whether Merit collected and retained records of the activities of each party to the Co-Marketing Activities;

vii. any weaknesses in Merit's systems, processes, policies, procedures and/or practices relating to Co-Marketing Activities; and

viii. any recommendations for improvements to Merit's systems, processes, policies, procedures and/or practices relating to Co-Marketing Activities.

3. Relating to the Review of Grants and Charitable Contributions involving HCPs and HCIs

a. a description of each type of Grant or Contribution reviewed, including the number of each type of Grant or Contribution reviewed and an identification of the types of documents and information reviewed for each Grant or Contribution reviewed;

b. for each Grant or Contribution reviewed, the IRO's findings and supporting rationale as to whether:

i. the request for the Grant or Contribution was submitted through the Merit centralized system and processed in accordance with standardized objective criteria;

ii. the terms of the Grant or Contribution are reflected in a written agreement between Merit and the recipient of the Grant or Contribution;

iii. the Grant or Contribution was reviewed and approved in accordance with Merit policies and procedures;

iv. the purpose or use for which the Grant or Contribution was requested is identified in Merit records;

v. records verify that the purpose of use for which the Grant or Contribution was requested occurred or was satisfied;

vi. the IRO identified any weaknesses in Merit's systems, processes, policies, procedures, and/or practices relating to Grants or Contributions; and

vii. the IRO has recommendations for improvements to Merit's systems, processes, policies, procedures and/or practices relating to Grants or Contributions.

4. Relating to the Review of Payments

a. a description of the entry in the Open Payments Database for each Payment sampled and a description of Control Documents reviewed in connection with each sampled Payment; and

b. for each sampled Payment, findings and supporting rationale as to whether:

i. all required Control Documents exist;

ii. each Control Document was completed in accordance with all of the requirements set forth in the applicable Merit policy;

iii. the aggregate value of the Payment as reflected in the Open Payments Database is consistent with the value of the Payment reflected in the Control Documents;

iv. each Control Document reflects that Merit's policies were followed in connection with the underlying activity reflected in the document (all required approvals were obtained); and

v. any corrective action or disciplinary action was undertaken in those instances in which Merit policies were not followed.

FOR IMMEDIATE RELEASE

MERIT MEDICAL SYSTEMS FINALIZES RESOLUTION WITH THE GOVERNMENT

SOUTH JORDAN, Utah, October 13, 2020 -- Merit Medical Systems, Inc. (NASDAQ: MMSI), a leading manufacturer and marketer of proprietary disposable devices used in interventional, diagnostic and therapeutic procedures, particularly in cardiology, radiology, oncology, critical care and endoscopy, announced today that it has finalized its settlement with the U.S. Department of Justice and the U.S. Department of Health and Human Services. In order to avoid distraction from its core mission, and the cost of litigating the matter to success, Merit agreed to pay $18 million to the federal government and certain states. The settlement agreement does not constitute a finding of wrongdoing by Merit or its management, and it expressly recognizes that Merit denies the allegations.

Merit looks forward to continuing to focus each day on its mission: To be the most customer-focused company in healthcare.

ABOUT MERIT

Founded in 1987, Merit Medical Systems, Inc. is engaged in the development, manufacture and distribution of proprietary disposable medical devices used in interventional, diagnostic and therapeutic procedures, particularly in cardiology, radiology, oncology, critical care and endoscopy. Merit serves client hospitals worldwide with a domestic and international sales force and clinical support team totaling in excess of 500 individuals. Merit employs approximately 6,000 people worldwide with facilities in South Jordan, Utah; Pearland, Texas; Richmond, Virginia; Malvern, Pennsylvania; Rockland, Massachusetts; Aliso Viejo, California; Maastricht and Venlo, The Netherlands; Paris, France; Galway, Ireland; Beijing, China; Tijuana, Mexico; Joinville, Brazil; Markham, Ontario, Canada; Melbourne, Australia; Tokyo, Japan; Reading, United Kingdom; Johannesburg, South Africa; and Singapore.

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FORWARD-LOOKING STATEMENTS

Statements contained in this release which are not purely historical, including, without limitation, statements regarding the anticipated resolution of an ongoing investigation being conducted by the DOJ, are forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 and are subject to risks and uncertainties such as those described in Merit's Annual Report on Form 10-K for the year ended December 31, 2019 (as amended by an Amendment No. 1 to Annual Report on Form 10-K/A, the "Annual Report on Form 10-K") and subsequent filings with the Securities and Exchange Commission. Such risks and uncertainties include inherent risks and uncertainties relating to risks and uncertainties associated with the COVID-19 pandemic; risks relating to Merit's potential inability to successfully manage growth through acquisitions generally, including the inability to effectively integrate acquired operations or products or commercialize technology developed internally or acquired through completed, proposed or future transactions; negative changes in economic and industry conditions in the United States or other countries; expenditures relating to research, development, testing and regulatory approval or clearance of Merit's products and risks that such products may not be developed successfully or approved for commercial use; governmental scrutiny and regulation of the medical device industry, including governmental inquiries, investigations and proceedings involving Merit; litigation and other judicial proceedings affecting Merit; restrictions on Merit's liquidity or business operations resulting from its debt agreements; infringement of Merit's technology or the assertion that Merit's technology infringes the rights of other parties; actions of activist shareholders; product recalls and product liability claims; changes in customer purchasing patterns or the mix of products Merit sells; risks and uncertainties associated with Merit's information technology systems, including the potential for breaches of security and evolving regulations regarding privacy and data protection; increases in the prices of commodity components; the potential of fines, penalties or other adverse consequences if Merit's employees or agents violate the U.S. Foreign Corrupt Practices Act or other laws or regulations; laws and regulations targeting fraud and abuse in the healthcare industry; potential for significant adverse changes in governing regulations, including reforms to the procedures for approval or clearance of Merit's products by the U.S. Food & Drug Administration or comparable regulatory authorities in other jurisdictions; changes in tax laws and regulations in the United States or other countries; termination or interruption of relationships with Merit's suppliers, or failure of such suppliers to perform; fluctuations in exchange rates; uncertainties relating to the LIBOR calculation method and the expected discontinuation of LIBOR; concentration of a substantial portion of Merit's revenues among a few products and procedures; development of new products and technology that could render Merit's existing or future products obsolete; market acceptance of new products; volatility in the market price of Merit's common stock; modification or limitation of governmental or private insurance reimbursement policies; changes in healthcare policies or markets related to healthcare reform initiatives; failure to comply with applicable environmental laws; changes in key personnel; work stoppage or transportation risks; introduction of products in a timely fashion; price and product competition; availability of labor and materials; fluctuations in and obsolescence of inventory; and other factors referenced in the Annual Report on Form 10-K and other materials filed with the Securities and Exchange Commission. All subsequent forward-looking statements attributable to Merit or persons acting on its behalf are expressly qualified in their entirety by these cautionary statements. Actual results will likely differ, and may differ materially, from anticipated results. Financial estimates are subject to change and are not intended to be relied upon as predictions of future operating results, and Merit assumes no obligation to update or disclose revisions to those estimates.