Business Associate Agreement

This Business Associate Agreement (the "Agreement") is made and entered into as of [<<<Insert Date>>>] and between Mangum Regional Medical Center, (the "Covered Entity") and Convatec, Inc., (the "Business Associate"), in accordance with the meaning given to those terms at 45 CFR §160.103. In this Agreement, Covered Entity and Business Associate are each a "Party" and, collectively, are the "Parties".

WHEREAS, The Parties have entered into or will enter into one or more agreements under which the Business Associate provides or will provide certain specified services to Covered Entity (collectively, the "Services Agreement");

WHEREAS, the nature of the contractual relationship between the Covered Entity and Business Associate may involve the exchange of Protected Health Information ("PHI") as that term is defined under the Health Insurance Portability and Accountability Act of 1996 (HIPAA), Public Law 104-191, as amended and extended by the Health Information Technology for Economic and Clinical Health Act, Public Law 111-005, the implementing regulations at 45 C.F.R. Parts 160, 162, and 164 promulgated by the United States Department of Health and Human Services ("DHHS"), along with any guidance or regulations issued by DHHS, and other applicable laws (collectively, "HIPAA Rules").

WHEREAS, by providing the services pursuant to the Service Agreement, the Business Associate will become a "business associate" of the Covered Entity as such term is defined under the HIPAA Rules.

WHEREAS, the parties wish to enter into this Agreement to set forth their understanding with regard to Business Associate's Use and Disclosure of Protected Health Information (defined below) in accordance with the business associate agreement requirements of the HIPAA Rules.

NOW, THEREFORE, in consideration of the mutual promises and covenants contained herein, the receipt and sufficiency of which is hereby acknowledged, the Parties agree as follows:

1. **Definitions**

As used in this Agreement, the following terms shall have the indicated meaning. Capitalized terms used, but not otherwise defined, in this Agreement shall have the same meaning as those terms in the HIPAA Rules. The definitions below which set forth a reference to the Code of Federal Regulations are defined HIPAA terms, and such definitions are incorporated herein as though set forth in full. A change to the HIPAA Rules that modifies any defined term, or that alters the regulatory citation for the definition, shall be deemed incorporated into this Agreement.

1.1. "Services Agreement" means the written agreement(s) between Covered Entity and Business Associate, whereby Business Associate provides or will provide certain services to Covered Entity and, in providing those services, may have access to PHI.

1.2. "Authorization" shall have the meaning given to the term under the HIPAA Rules, including, but not limited to, 45 C.F.R. Section 164.508.

1.3. "Breach" shall have the same meaning as the term "breach" in 45 C.F.R. Section 164.402 and shall include the unauthorized acquisition, access, use or disclosure of PHI that compromises the security or privacy of such information.

1.4. "Business Associate" shall mean Convatec, Inc., as defined. Where the term "business associate" appears without initial capital letters, it shall have the meaning given to such term under the HIPAA Rules, including, but not limited to, 45 C.F.R. Section 160.103.

1.5. "Covered Entity" shall mean the Distributor, as defined. It shall also have the meaning given to the term under the HIPAA Rules, including, but not limited to, 45 C.F.R. Section 160.103.

1.6. "Data Aggregation" shall have the meaning, with respect to PHI created or received by Business Associate in its capacity as the "business associate" under HIPAA of Covered Entity, the combining of such PHI by Business Associate with the PHI received by Business Associate in its capacity as a business associate of one or more other "covered entity(ies)" under HIPAA, to permit data analyses that relate to the Health Care Operations (defined below) of the respective covered entities. The meaning of "data aggregation" in this Agreement shall be consistent with the meaning given to that term under the HIPAA Rules, including, but not limited to, 45 C.F.R. Section 164.501.

1.7. "Designated Record Set" shall have the meaning given to the term under the HIPAA Rules, including, but not limited to, 45 C.F.R. Section 164.501.

1.8. "Electronic Protected Health Information" ("EPHI") shall have the meaning given to the term Electronic Protected Health Care Information under the HIPAA Rules, including, but not limited to, 45 C.F.R. Section 160.103, that is created, received, maintained or transmitted from or on behalf of Covered Entity.

1.9. "Health Care Operations" shall have the meaning given to the term under the HIPAA Rules, including, but not limited to, 45 C.F.R. Section 164.501.

1.10. "HIPAA Rules" shall mean the Health Insurance Portability and Accountability Act of 1996, Public Law 104-191, as amended and extended by the Health Information Technology for Economic and Clinical Health Act, Public Law 111-005, the implementing regulations at 45 C.F.R. Parts 160, 162, and 164 promulgated by the United States Department of Health and Human Services ("DHHS"), along with any guidance or regulations issued by DHHS, and other applicable laws.

1.11. "HHS" shall mean the U.S. Department of Health and Human Services.

1.12. "HITECH ACT" shall mean the Health Information Technology for Economic and Clinical Health Act, enacted as part of the American Recovery and Reinvestment Act of 2009, Public Law 111-005.

1.13. "Individual" shall have the meaning given to the term under the HIPAA Rules, including, but not limited to, 45 C.F.R. Section 160.103. It shall also include a person who qualifies as a personal representative in accordance with 45 C.F.R. Section 164.502(g).

1.14. "Privacy Rule" shall mean that part of the HIPAA Rules set forth in 45 CFR Part 160 and Part 164, Subparts A and E.

1.15. "Protected Health Information" ("PHI") means any information, whether oral or recorded in any form or medium: (i) that relates to the past, present or future physical or mental condition of an individual; the provision of health care to an individual; or the past, present or future payment for the provision of health care to an individual; and (ii) that identifies the individual or with respect to which there is a reasonable basis to believe that the information can be used to identify the individual, and shall have the meaning given to the term under the HIPAA Rules, including, but not limited to, 45 C.F.R. Section 160.103, that is created, received, maintained or transmitted from or on behalf of Covered Entity.

1.16. "Required by Law" shall have the meaning given to the term under the HIPAA Rules, including, but not limited to, 45 C.F.R. Section 164.103.

1.17. "Security Incident" shall mean the attempted or successful unauthorized access, use, disclosure, modification or destruction of EPHI, or interference with system operations in an information system pursuant to 45 CFR Section 164.304. For purposes of this Agreement, a Security Incident does not include inconsequential incidents that occur on a daily basis, such as scans, "pings", or unsuccessful attempts to penetrate computer networks or servers maintained by Business Associate.

1.18. Security Standards shall mean those security standards promulgated or to be promulgated pursuant to HIPAA and other applicable federal or state regulations or statutes.

1.19. "Unsecured Protected Health Information" or "Unsecured PHI" shall mean PHI that is not secured through the use of a technology or methodology specified by the Secretary of DHHS in guidance or as otherwise defined in 45 C.F.R. Section 164.402.

2. **Obligations and Activities of Business Associate**

2.1. Permitted Use and Disclosure of Protected Health Information. Except as otherwise provided in this Agreement, Business Associate agrees to only use, access, and/or disclose PHI as reasonably necessary to satisfy its obligations under the Services Agreement or this Agreement, or as Required by Law. Business Associate may not use or disclose PHI in a manner that would violate Subpart E of 45 C.F.R. Part 164 if done by Covered Entity.

a. Permitted Use. Covered Entity authorizes Business Associate to use the PHI in its possession for the proper management and administration of Business Associate's business and to carry out its legal responsibilities. Business Associate may not use PHI

in any manner that would constitute a violation of the HIPAA Rules if done by Covered Entity, except that Business Associate may use PHI if necessary: (i) for the proper management and administration of Business Associate; (ii) to carry out the legal responsibilities of Business Associate; or (iii) to provide Data Aggregation services relating to the Health Care Operations of Covered Entity. Business Associate may de-identify the PHI in accordance with 45 CFR 164.514(a)-(c).

b. Permitted Disclosure. Business Associate may disclose PHI for its proper management and administration, or to carry out its legal responsibilities, provided the disclosures are (i) required by law, or (ii) Business Associate obtains reasonable assurances from the person to whom the information is disclosed that the information will remain confidential and be used or further disclosed only as required by law or for the purposes for which it was disclosed to the person, and the person notifies business associate of any instances of which it is aware in which the confidentiality of the information has been breached.

c. Minimum Necessary. Any permitted Use or Disclosure shall be consistent with the minimum necessary requirements set forth in the HIPAA Rules. Business Associate further represents that, to the extent it requests Covered Entity to disclose PHI to Business Associate, such request will only be for the minimum PHI necessary for the accomplishment of Business Associate's purpose.

2.2. Safeguarding PHI and Personal Information. Business Associate shall use appropriate safeguards to prevent use or disclosure of PHI other than as permitted by this Agreement. Business Associate further agrees to use appropriate administrative, physical and technical safeguards to protect the confidentiality, integrity and availability of any PHI that Business Associate creates, receives, maintains or transmits on behalf of Covered Entity, in accordance with the HIPAA Rules. Business Associate agrees to take reasonable steps, including providing adequate training to its employees to ensure compliance with this Agreement and to ensure that the actions or omissions of its employee or agents do not cause Business Associate to breach the terms of this Agreement.

2.3. Mitigation of Harmful Effects. Business Associate agrees to mitigate, to the extent practicable, any harmful effect that is known to Business Associate of a use or disclosure of PHI by Business Associate in violation of the requirements of this Agreement.

2.4. To the extent that Business Associate is to carry out one or more of Covered Entity's obligation(s) under Subpart E of 45 C.F.R. Part 164, Business Associate agrees to comply with the requirements of Subpart E that apply to Covered Entity in the performance of such obligation(s).

3. **Breach of Privacy or Security Obligations.**

3.1. Reporting Disclosures of PHI and Security Incidents. Business Associate will report to Covered Entity in writing any use or disclosure of PHI not provided for by this Agreement of which it

becomes aware and Business Associate agrees to report to Covered Entity any Security Incident affecting Electronic PHI of Covered Entity of which it becomes aware. Business Associate agrees to report any such event within thirty (30) business days of becoming aware of the event.

3.2. Reporting Breaches of Unsecured PHI. Business Associate will notify Covered Entity in writing promptly upon the discovery of any Breach of Unsecured PHI in accordance with the requirements set forth in 45 CFR §164.410, but in no case later than thirty (30) calendar days after discovery of a Breach.

3.3. Mitigation of Disclosures of PHI. Business Associate will take reasonable measures to mitigate, to the extent practicable, any harmful effect that is known to Business Associate of any use or disclosure of PHI by Business Associate or its agents or subcontractors in violation of the requirements of this Agreement.

3.4. Agreements with Agents or Subcontractors. Business Associate agrees to ensure that any agent, including a subcontractor, to whom it provides or transmits PHI received from, or created or received by Business Associate on behalf of Covered Entity, agrees to provide in writing the same restrictions and conditions concerning uses and disclosures of PHI contained in this Agreement and agrees to implement reasonable and appropriate safeguards to protect any Electronic PHI that it creates, receives, maintains or transmits on behalf of Business Associate or, through the Business Associate, Covered Entity.

3.5. Access to Information. Business Associate agrees, at the request of Covered Entity, to provide Covered Entity access to PHI about an Individual contained in a Designated Record Set (if any) in a prompt commercially reasonable manner in order to enable Covered Entity to meet the requirements of 45 C.F.R. Section 164.524. In the event any Individual or personal representative requests access to the Individual's PHI directly from Business Associate, Business Associate, within ten (10) business days, will forward that request to Covered Entity. Any disclosure of, or decision not to disclose, the PHI requested by an Individual or a personal representative and compliance with the requirements applicable to an Individual's right to obtain access to PHI shall be the sole responsibility of Covered Entity.

3.6. Amendment of Protected Health Information. Business Associate agrees to make any amendment of an Individual's PHI or a record regarding an Individual contained in a Designated Record Set (if any) that Covered Entity directs or agrees to pursuant to 45 C.F.R. Section 164.526 at the request of Covered Entity or an Individual, within fifteen (15) business days of Covered Entity's request. In the event that any Individual requests that Business Associate amend such Individual's PHI or record in a Designated Record Set, Business Associate, within ten (10) business days, will forward this request to Covered Entity. Any amendment of, or decision not to amend, the PHI or record as requested by an Individual and compliance with the requirements applicable to an Individual's right to request an amendment of PHI will be the sole responsibility of Covered Entity.

3.7. Accounting of Disclosures. Business Associate agrees to document any disclosures of PHI made by it to account for such disclosures as required by 45 CFR §164.528(a). Business Associate also will make available information related to such disclosures as would be required for Covered Entity to respond to a request for an accounting of disclosures in accordance with 45 CFR §164.528. At a minimum, Business Associate will furnish Covered Entity the following with respect to any covered disclosures by Business Associate: (i) the date of disclosure of PHI; (ii) the name of the entity or person who received PHI, and, if known, the address of such entity or person; (iii) a brief description of the PHI disclosed; and (iv) a brief statement of the purpose of the disclosure which includes the basis for such disclosure. Business Associate will furnish to Covered Entity information collected in this Section, within ten (10) business days after written request by Covered Entity, to permit Covered Entity to respond to an accounting of disclosure request as required by 45 CFR §164.528.

3.8. Responding to Requests by Individuals. With respect to the forgoing Sections 3.5, 3.6 and 3.7, in no case shall Business Associate be responsible for responding directly to any Individual who submits a request to Business Associate, provided that Business Associate shall promptly forward such request to Covered Entity in accordance with Sections 3.5, 3.6 or 3.7.

3.9. Auditing, Inspections and Enforcement. Upon reasonable notice, Business Associate agrees to make its internal practices, books and records relating to the use or disclosure of PHI available to the Secretary of DHHS, or the Secretary's designee, in a prompt commercially reasonable manner for purposes of determining Covered Entity's compliance with the HIPAA Rules.

4. **Covered Entity's Obligations**

4.1. Notice of Limitations and Restrictions. Covered Entity shall notify Business Associate of any limitations or restrictions in Business Associate's ability to use or disclose Covered Entity's PHI to the extent that such limitations or restrictions may affect Business Associate's use or disclosure of PHI, within a reasonable period of time after Covered Entity becomes aware of or agrees to such limitations or restrictions.

4.2. Revocation of Authorization by Individual. Covered Entity agrees to inform Business Associate of any change to, or revocation of, an Individual's Authorization to use or disclose PHI to the extent that such change may affect Business Associate's use or disclosure of PHI, within a reasonable period of time after Covered Entity becomes aware of such change.

4.3. Restrictions on Use and Disclosure. Covered Entity agrees to notify Business Associate of any restrictions to the use or disclosure of PHI agreed to by Covered Entity in accordance with 45 C.F.R. Section 164.522, to the extent that such restriction may affect Business Associate's use or disclosure of PHI.

4.4. Permissible Requests. Covered Entity shall not request Business Associate to use or disclose PHI in any manner that would not be permissible under the HIPAA Rules if done by Covered

Entity. Requests by Covered Entity for Business Associate to disclose PHI to a third party will be in writing and will specify whether or not the third party is also a business associate of Covered Entity.

4.5. Safeguards. Covered Entity shall use appropriate safeguards in accordance with 45 C.F.R. §164.306 and any related implementing regulations, to ensure the security of PHI provided to Business Associate pursuant to the Services Agreement and this Agreement, until such PHI is received by Business Associate.

4.6. Compliance. Covered Entity shall comply with all HIPAA Rules applicable to Covered Entity.

5. **Termination of Agreement**

5.1. Term. The term of this Agreement shall end upon termination of the Services Agreement, subject, however, to the requirements of Section 5.3 for return or destruction of all PHI.

5.2. Termination Upon Breach of Provisions Applicable to Protected Health Information or Personal Information. Any other provision of this Agreement notwithstanding, this Agreement may be terminated by either Party upon thirty (30) days' prior written notice to the other Party in the event that the other Party materially breaches any obligation of this Agreement and fails to cure the breach within such thirty (30) day period.

5.3. Return or Destruction of Protected Health Information and Personal Information Upon Termination. Upon termination of this Agreement and the Services Agreement, Business Associate shall either return to Covered Entity or destroy all PHI in Business Associate's possession and in the possession of its agents or subcontractors. Business Associate shall not retain any copies of PHI. Notwithstanding the foregoing, if Business Associate determines that returning or destroying PHI is infeasible, Business Associate shall extend the protections of this Agreement to such PHI and limit further uses and disclosures of such PHI to those purposes that make return or destruction infeasible, for so long as Business Associate maintains such PHI.

6. **Miscellaneous**

6.1. Ownership of Protected Health Information and Personal Information. As between Business Associate and Covered Entity, the PHI and any related information created for or received from or on behalf of Covered Entity is, and will remain, the property of Covered Entity, including any and all forms thereof developed by Business Associate in the course of fulfilling its obligations pursuant to the Services Agreement. Business Associate agrees that it acquires no ownership rights in or title to PHI or any related information.

6.2. Notices. All notices, requests and demands or other communications to be given under this Agreement to a Party will be made via either first class mail, registered or certified or express courier, or electronic mail to the Party's address given below:

If to Covered Entity, to:

If to Business Associate, to:

Data Protection Officer

6.3. Remedies. Notwithstanding any rights or remedies set forth in this Agreement or provided by law, each Party retains all rights to seek injunctive relief to prevent or stop the unauthorized use or disclosure of PHI by the other Party, the other Party's agents or subcontractors, or any third party who has received PHI from either Party.

6.4. Amendment to Comply With Law. Business Associate and Covered Entity agree to amend this Agreement to the extent necessary to allow either Party to comply with the standards and requirements of the HIPAA Rules and other applicable state and federal laws relating to the security or confidentiality of PHI. Business Associate and Covered Entity will comply fully with all applicable standards and requirements of such federal or state regulations or statutes. To the extent that any amendment of such laws requires changes to this Agreement, Business Associate shall provide written notice to Covered Entity of such changes and this Agreement shall be automatically amended to incorporate the changes set forth in the written notice provided by Business Associate to Covered Entity unless the Covered Entity objects to such changes in writing within fifteen (15) days of receipt of such notice. If Covered Entity objects in a timely manner to such amendment, the Parties shall work in good faith to reach agreement on a change to this Agreement that complies with the amendment of such laws. If the Parties are unable to reach agreement on a change to this Agreement within forty-five (45) days of the date that Business Associate receives written objection from Covered Entity, then either Party may terminate this Agreement upon written notice of such termination.

6.5. Other Amendments**.** Any other amendment to this Agreement unrelated to compliance with applicable law and regulations shall be effective only upon execution of a written agreement between the Parties.

6.6. Survival. The respective rights and obligations of Business Associate under Section 5.3 of this Agreement shall survive the termination of this Agreement and the Services Agreement.

6.7. Effect on Services Agreement. The provisions of this Agreement shall prevail over any provisions of the Services Agreement that conflict with or are inconsistent with any provision of this Agreement. All other terms of the Services Agreement shall remain in full force and effect.

6.8. Prior Business Associate Agreements. This Agreement shall supersede and prevail over any prior business associate agreements between the Parties.

6.9. Interpretation. This Agreement and the Services Agreement shall be interpreted as broadly as necessary to implement and comply with the HIPAA Rules. The Parties agree that any ambiguity in this Agreement or the Services Agreement shall be resolved in favor of a meaning that complies with and is consistent with the HIPAA Rules.

In light of the mutual agreement and understanding described above, the Parties execute this Agreement as of the date first written above.

By: _____

Name:

Title:

By: _____

Name:

Title: