

NightWare Incorporated Terms of Use and NightWare System Services Agreement

Last Revised April 9 2023

Thank you for visiting the NightWare, which is owned and operated by NightWare, Inc., a Delaware corporation with a place of business at 8900 Excelsior Boulevard, Hopkins, MN 55343 ("NightWare"). Please read these Terms of Use ("Terms") carefully before using the Services described herein. This agreement sets forth the legally binding Terms for your use of the NightWare Digital Therapeutic and related Nightware Services, which include the following:

- The NightWare Website and related sub-domains and subsites ("NightWare Website");
- The "NightWare Software and the NightWare Portal" as defined below;
- The NightWare Device, which includes an Apple Watch and an Apple iPhone SE®, which, together with the NightWare Software and the NightWare Portal, comprise the NightWare Digital Therapeutic ("NightWare Products");
- Any offering combining NightWare Website, NightWare Products, the NightWare Software, and NW Portal ("NightWare Services").

These Terms of Use are entered into by and between NightWare and any individual or entity, including each NightWare prescribing Provider (collectively referred to as "Provider," "You," and "Your"). If you use the Services on behalf of a company or other entity, the "you" includes you and that entity. You represent and warrant that (a) you are an authorized representative of the entity with the authority to bind the entity to these Terms of Use, and (b) you agree to these Terms of Use on the entity's behalf. All users of the Services must accept and comply with the terms and conditions set forth herein. In addition, certain portions of the Services may be subject to additional terms and conditions specified by us from time to time (the "Additional Terms"); your use of the Services is subject to those Additional Terms. If you have any questions regarding these Terms of Use, please get in touch with us via email at support@nightware.com. If you do not accept these Terms of Use, you are not authorized to use the Services.

BY USING THE SERVICES, YOU ACCEPT ALL OF THE PROVISIONS OF THESE TERMS OF USE AND REPRESENT TO US THAT YOU ARE LEGALLY COMPETENT TO ENTER INTO AND AGREE TO THESE TERMS OF USE.

Please read these Terms of Use carefully. You and any individual authorized to act on your behalf or for an entity with which you are affiliated acknowledge that each time you use any of the NightWare Services or this NightWare Portal or its content that:

- You have read and understand all of these Terms and Conditions;
- You agree to be bound by the Terms of Use;
- You understand that these Terms of Use are the legal equivalent of a signed, written contract between you and NightWare; and
- You have full authority to bind your entity to all of these Terms of Use.

1.0 Definitions.

- 1.1. "Authorized User" means a Provider or Provider employee authorized to access, prescribe, and use the NightWare device through Provider's Account in the NightWare Portal.
- 1.2. "Device" means the NightWare Product that monitors and records sleep-related data and issues alerts to the Patient as detailed in the Provider Instructions for Use and the related NightWare System Patient Instructions for Use. When worn as directed and connected to the internet via Wi-Fi, the Apple Watch monitors the patient's heart rate and movement throughout the night and occasionally provides interventions. This information is recorded by the Apple Watch and automatically uploads to the NightWare Software to establish the patient's unique stress index thresholds.
- 1.3. "Patient" means a patient who (i) is enrolled by a Provider to receive and use the Device and (ii) has granted all necessary consents and authorizations required for the supply of the Device and the provision of the Services.
- 1.4. "NightWare Digital Therapeutic" means NW's proprietary sleep monitoring system comprised of (i) the Device, (ii) the NightWare Software, an Apple Watch and an Apple iPhone SE pre-provisioned by NightWare, Inc., and (iii) the NightWare Report.
- 1.5. "NightWare Portal" means NW's web-based platform through which NightWare Reports may be viewed and through which the NightWare Reports are made available to Authorized Users.
- 1.6. "NightWare Reports" are the Data gathered via the Apple Watch SE when in use by a Patient and transmitted to NightWare via the NightWare Software, is aggregated and made available to Authorized Users in report form. NightWare Reports may be reviewed by Provider within the NightWare Portal and downloaded as a PDF.

2. Using the Services

- 2.1. You acknowledge and agree that you will use the NightWare Services only for the purposes expressly permitted by these Terms of Use as described in this Section and that all other purposes are expressly prohibited. The purposes expressly permitted for accessing, visiting, and/or using the Services are:
 - 2.1.1. To Register and create a NightWare account as an Authorized User;
 - 2.1.2. To obtain information about NightWare Services or to place an order for NightWare Services; and
 - 2.1.3. To review the information contained in the NightWare Portal for legitimate business purposes or Patient care.
- 2.2. You further acknowledge and agree that other than the above-permitted purposes, your use of the Services for any other purpose is strictly prohibited and constitutes a material breach of these Terms on the part of you and any person or entity for whom you are acting.

3. Ordering and Supply of the NightWare System.

NOTICE: FEDERAL LAW RESTRICTS THE NIGHTWARE DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN OR OTHER QUALIFIED LICENSED HEALTHCARE PROFESSIONAL.

- 3.1. Provider Registration and Authorization. To Use This NightWare Portal and the NightWare Services, Provider:
 - 3.1.1. must request that its designated NightWare account representative create a NightWare Portal account on its behalf (an "Account");
 - 3.1.2. represents and warrants that all information provided to NightWare is current, complete, and accurate;
 - 3.1.3. is solely responsible for:
 - 3.1.3.1. ensuring that all Authorized Users are bound by and comply with all relevant provisions of the Terms of Use and will be responsible for any of its Authorized Users failures to comply; and
 - 3.1.3.2. maintaining and ensuring that its Authorized Users maintain the confidentiality of all Account credentials;
 - 3.1.4. shall notify NightWare immediately in the event of any suspected unauthorized use of an Account and will cease all use of such Account;
 - 3.1.5. agrees that its Account is self-directed and that Provider is solely responsible for all activities undertaken; and
 - 3.1.6. agrees that any provider Personal Identifying Information (PII) provided to NightWare in connection with the Services is subject to the NightWare Privacy Policy (<https://nightware.com/healthcare-professionals/privacy-policy/>) and Provider consents to all actions NightWare takes concerning such information consistent with the Privacy Policy.
 - 3.2. Ordering Requirements. Provider agrees he / she will:
 - 3.2.1. obtain necessary Patient consents and authorizations for:
 - 3.2.1.1. Provider to submit an order for the NightWare Services based on a valid prescription, and provider to activate NightWare Services for the Patient for whom the prescription was written.
 - 3.2.1.2. To maintain a record of the serial code of the NightWare Device dispensed to each Patient and will ensure NightWare Reports match the NightWare Device assigned to that Patient;
 - 3.2.1.3. NightWare to collect and hold Patient data, including PII and Protected Health Information (PHI);
 - 3.2.1.4. NightWare to contact the Patient by telephone or text message for purposes of Technical Support and to follow-up on Patient questions or replace the NightWare Device as needed.
 - 3.3. Returns; Defects.
 - 3.3.1. *Defective Device.* If a Patient's NightWare Device has a defect, Provider will inform the Patient to notify NightWare by email at support@nightware.com or by phone at **833-44-NIGHT, 883-446-4448** and, if applicable, return any defective Device directly to NightWare as soon as possible following receipt of instructions and a pre-paid return label from NightWare. NIGHTWARE'S SOLE LIABILITY FOR ANY DEFECTIVE DEVICE SHALL BE TO REPAIR OR REPLACE THE APPLICABLE DEVICE AS SPECIFIED IN THIS SECTION
 - 3.4. Provider and Patient Notifications; Recalls and Suspension; Investigations. If required, the Provider will reasonably cooperate with NightWare and comply with NightWare's written instructions concerning any:
 - 3.4.1. NightWare System provider and Patient notifications;
 - 3.4.2. Device recalls, market withdrawals, or corrections; and/or
 - 3.4.3. action, warning, inspection, or other notice or communication from any regulatory or governmental authority relating to the NightWare Services and will promptly notify NightWare if it receives notice of a regulatory inquiry relating to the NightWare System.
 - 3.5. Complaint, Adverse Reaction and Adverse Event Reporting. Provider shall (i) notify NightWare within 24 hours of learning of any NightWare System complaint, unintended response, or adverse reaction relating or possibly relating to the NightWare Services by email at support@nightware.com and (ii) promptly provide such assistance and information as NightWare reasonably requests to fulfill its adverse reaction reporting obligations for the NightWare Services.
 - 3.6. Claims to Third-Party Payers. Provider is solely responsible for submitting claims to payers and for the NightWare Services. NightWare does not make any representations concerning Provider's ability to submit claims or receive reimbursement for the NightWare Services provided to Patients based on data obtained via the NightWare Portal or Services.
 - 3.7. Disclaimer of Product Warranty. NIGHTWARE'S SOLE LIABILITY FOR BREACH OF ANY WARRANTY RELATING TO THE NIGHTWARE DEVICE SHALL BE, AT NIGHTWARE'S SOLE DISCRETION, CREDIT FOR, REPAIR, OR REPLACEMENT OF THE NONCONFORMING DEVICE. EXCEPT FOR THE NIGHTWARE DEVICE WARRANTY, NIGHTWARE DOES NOT PROVIDE ANY REPRESENTATIONS OR WARRANTIES WHATSOEVER CONCERNING THE NIGHTWARE DEVICE, THE NIGHTWARE SERVICES OR THE USE THEREOF, AND NIGHTWARE EXPRESSLY DISCLAIMS ALL OTHER REPRESENTATIONS AND WARRANTIES, WHETHER EXPRESS, IMPLIED, OR STATUTORY, INCLUDING WITHOUT LIMITATION WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE; WARRANTIES OF SAFETY, ACCURACY, OR NON-INFRINGEMENT; AND WARRANTIES ARISING FROM COURSE OF DEALING OR USAGE OF TRADE.
4. **Services.** NightWare shall provide the following additional "Services."
 - 4.1. NightWare Reports. Data gathered via the Apple Watch SE and transmitted to NightWare is aggregated and made available in report form via the NightWare Report. NightWare Reports may be reviewed by Provider within the NightWare Portal and downloaded as a PDF.
 - 4.2. Access to NightWare Reports. Subject to Provider's and its Authorized Users' compliance with the terms of this Agreement, NightWare grants to Provider a limited, non-exclusive, non-transferable, non-sublicensable, and revocable right to access and to allow Authorized Users to access the NightWare Portal during the Term.
 - 4.3. Patient Support. A helpline is available for Patients to submit questions between 8:30 am and 5:00 pm CT on business days to **833-44-NIGHT, 883-446-4448, or support@nightware.com**. NW shall be limited to addressing Patient inquiries regarding the NightWare Services, and Provider shall be responsible for addressing Patient inquiries regarding their treatment program and specific treatment instructions.
 - 4.4. Limitations on Provision of the Services. It is recommended that Patients wear the Apple Watch provided with the NightWare Services consistently, preferably nightly, for the best results. The Apple Watch and the Apple iPhone SE must be fully charged at the beginning of the night and must be connected to wireless internet via WiFi. NightWare's ability to provide the Services, and the specific protocols used to deliver the Services, may be impacted by circumstances outside of NightWare's control, such as Patient compliance or noncompliance factors. Without limiting the foregoing, NightWare shall not be responsible for and disclaims all liability for:
 - 4.4.1. any failure or delay in providing the Services (including any NightWare Reports) to the extent resulting from Provider's (or its Authorized User's) failure to appropriately record the serial number of an assigned NightWare Device for any Patient or Patient failure to activate, charge, use, or wear the NightWare Device or otherwise comply with treatment recommendations; or

4.4.2. any decisions that Provider, or any other Authorized User accessing the Services under Provider's Account, makes based on NightWare Reports.

4.5. **DISCLAIMER.** THE SERVICES AND NIGHTWARE REPORTS ARE NOT INTENDED TO ACT AS A SUBSTITUTE FOR THE SKILL AND JUDGMENT OF A QUALIFIED MEDICAL PRACTITIONER. TO THE MAXIMUM EXTENT PERMITTED BY APPLICABLE LAW, THE NIGHTWARE SERVICES AND NIGHTWARE REPORTS ARE PROVIDED OR MADE ACCESSIBLE SOLELY ON AN "AS IS" AND "AS AVAILABLE" BASIS, WITHOUT WARRANTY OF ANY KIND, AND NW HEREBY DISCLAIMS ALL WARRANTIES, WHETHER EXPRESS OR IMPLIED, INCLUDING WITHOUT LIMITATION ANY IMPLIED WARRANTIES OF QUALITY, COURSE OF DEALING, TRADE USAGE OR PRACTICE, MERCHANTABILITY, TITLE, NON-INFRINGEMENT, OR FITNESS FOR A PARTICULAR PURPOSE, ARISING OUT OF OR IN CONNECTION WITH THIS AGREEMENT, NIGHTWARE'S PERFORMANCE OF THE SERVICES, PROVISION OF THE NIGHTWARE REPORTS, OR THE USE, MISUSE, OR INABILITY TO USE THE SERVICES, OR NIGHTWARE REPORTS. WITHOUT LIMITING THE FOREGOING, NIGHTWARE DOES NOT WARRANT THAT THE SERVICES OR NIGHTWARE REPORTS ARE OR SHALL BE AVAILABLE ON AN UNINTERRUPTED OR ERROR-FREE BASIS.

5. **Reservation of Rights.** All intellectual property rights, including copyrights, patents, patent disclosures, and inventions (whether patentable or not), trademarks, service marks, trade secrets, know-how and other confidential information, trade dress, trade names, logos, corporate names, and domain names, together with all of the goodwill associated therewith, derivative works and all other rights (collectively, "Intellectual Property Rights") in and to the NightWare Device, the NightWare Services, the NightWare Reports, and other materials that are delivered to Provider under this Agreement or prepared by or on behalf of NightWare in the course of performing the Services (collectively, the "Deliverables"), expressly excluding any confidential information of Provider furnished to NightWare by Provider, are and shall be owned by NightWare. NightWare hereby grants Provider a license to use all Deliverables on a non-exclusive, non-transferable, non-sublicensable, fully paid-up, royalty-free basis, during the Term, solely for purposes of facilitating NightWare's provision of the Services as provided by these Terms of Use, and fulfilling Provider's obligations under this Agreement. This license is revocable at any time without notice for any reason, with or without cause, at NightWare's sole discretion.

6. **Business Associate Agreement.**

6.1. **Patient Privacy and Provider Authorizations.** Any matter related to the Patient's Protected Health Information (PHI) will be governed by the Business Associate Agreement ("BAA"). NightWare shall not be a Business Associate of Provider, and the Parties shall not be obligated to comply with the BAA when and if NightWare is acting as a health care provider rather than a Business Associate of Provider, as described in the U.S. Department of Health and Human Services FAQ #490, currently available at <https://www.hhs.gov/hipaa/for-professionals/faq/490/when-may-a-covered-health-care-provider-disclose-protected-health-information-without-authorization/index.html>.

7. **Term; Termination.**

7.1. **Term.** This Agreement shall commence on the Effective Date and shall continue for one (1) year unless terminated earlier in accordance with this Agreement (the "Initial Term"). At the expiry of the Initial Term, this Agreement shall automatically renew for successive one (1) year terms unless either Party provides written notice of non-renewal at least thirty (30) days before such expiration (all such renewal terms, together with the Initial Term, the "Term").

7.2. **Suspension.** Notwithstanding anything to the contrary in this Agreement, NightWare may suspend or terminate Provider's access to any portion or all of the Services if NightWare reasonably determines that (i) there is a threat or attack on any of the Services or systems, or any data stored thereon; (ii) Provider's use of the Services, or use under Provider's Account, disrupts or poses a security risk to NightWare or any of NightWare's customers or vendors; (iii) Provider is using the Services for purposes of engaging in, or Provider's Account is being used to engage in, fraudulent or illegal activities; or (iv) our provision of the Services to you is prohibited by applicable law or regulation. NightWare will use commercially reasonable efforts to provide notice of any suspension and resumption of Services access. NightWare will have no liability for any damage, liabilities, losses (including any loss of data or profits), or any other consequences resulting from a Service suspension.

7.3. **Termination.** Either Party may terminate this Agreement at any time upon written notice to the other Party. Upon termination of (i) your access to the Services and/or (ii) your User Account and/or relationship with NightWare, you shall immediately cease accessing and using the Services. Upon such termination, all provisions of these Terms of Use shall remain in full force and effect, excluding the provisions in which NightWare has granted you any licenses or access to the Services, which shall thereafter be terminated, and you will no longer be permitted to access and use the Services.

7.4. **Consequences of Expiration or Termination.**

7.4.1. Effective as of the date of expiration or termination of this Agreement:

7.4.1.1. Provider shall pay to NightWare all outstanding fees and amounts due and payable to NightWare, if any, that accrued before the date of termination or expiration;

7.4.1.2. if agreed by NightWare, Provider may request continued use of the Services and NightWare Devices that are in use until the end of the calendar month in which such termination or expiration occurs, subject to the terms and conditions of this Agreement and provided that Provider must pay all applicable Service Fees for any such continued access or use.

8. **Mutual Representations and Warranties.**

8.1. **Federal Programs.** Each Party represents, warrants, and certifies that neither it nor any of its principals were or are (i) debarred, suspended, proposed for debarment, or otherwise determined to be ineligible to participate in Federal health care programs (as that term is defined in 42 U.S.C. § 1320a-7b(f)), including without limitation pursuant to Section 335(a) of the FDCA, (ii) convicted of a criminal offense related to the provision of health care items or services, including without limitation any offense that could result in debarment under 21 U.S.C. § 335(a), or (iii) the subject of any Department of Health and Human Services Office of Inspector General investigation or enforcement action related to their exclusion from Federal health care programs ((i), (ii) and (iii) collectively, "Adverse Enforcement Actions"). Each Party shall notify the other Party immediately if such Party or any of its principals becomes the subject of an Adverse Enforcement Action.

9. **Limitation of Liability and Indemnification.**

9.1. TO THE MAXIMUM EXTENT PERMITTED UNDER APPLICABLE LAW, EACH PARTY AND ITS PERSONNEL EXCLUDES ANY LIABILITY TO THE OTHER FOR ANY LOSS OF USE, REVENUE, OR PROFIT OR LOSS OF DATA OR DIMINUTION IN VALUE OR FOR ANY CONSEQUENTIAL, INCIDENTAL, INDIRECT, EXEMPLARY, SPECIAL, OR PUNITIVE DAMAGES, WHETHER ARISING OUT OF BREACH OF CONTRACT, TORT (INCLUDING NEGLIGENCE), OR OTHERWISE.

9.2. IN NO EVENT SHALL THE NW'S AGGREGATE LIABILITY FOR ANY LOSS, COST, DAMAGE, OR EXPENSE ARISING OUT OF OR RELATED TO THIS AGREEMENT (WHETHER IN CONTRACT, TORT (INCLUDING NEGLIGENCE), UNDER STATUTE OR OTHERWISE) EXCEED THE AGGREGATE AMOUNTS PAID OR PAYABLE TO NW PURSUANT TO THIS AGREEMENT IN THE TWELVE (12) MONTH PERIOD PRECEDING THE EVENT GIVING RISE TO THE CLAIM.

10. **Miscellaneous.**

- 10.1. **Feedback.** If Provider provides NightWare with any comments, suggestions, or any other feedback regarding the Services or Deliverables ("Feedback"), NightWare may use such Feedback into its products and services and distribute such products and services without any obligation or recourse to Provider. All Feedback shall become the sole property of NightWare.
- 10.2. **Entire Agreement.** These Terms of Use, together with any Additional Terms, constitute the complete agreement between you and NightWare and supersede all prior or contemporaneous discussions, representations, and proposals, written and oral, concerning the subject matter discussed herein.
- 10.3. **Force Majeure.** Neither party will be liable for any failure to perform this Agreement (except Provider's payment obligations) if that failure is caused by an event beyond the impacted Party's reasonable control.
- 10.4. **U.S. Government Rights.** The NightWare Services and the NightWare Report and all related Deliverables and Services are classified as a "commercial item" as that term is defined at 48 C.F.R. § 2.101, consisting of "commercial computer software" and "commercial computer software documentation" as such terms are used in 48 C.F.R. § 12.212. Accordingly, if Provider is an agency of the U.S. Government or any contractor therefore, Provider only receives those rights concerning the NightWare Services and such related Deliverables and Services as are granted to all other end users, in accordance with (a) 48 C.F.R. § 227.7201 through 48 C.F.R. § 227.7204, with respect to the Department of Defense and their contractors, or (b) 48 C.F.R. § 12.212, with respect to all other US Government users and their contractors.
- 10.5. **Modifications.** NightWare may modify these Terms of Use at any time. Modifications become effective with respect to you immediately upon your first interaction with or use of the Services after the "Last Revised" date at the top of these Terms of Use. **YOU ARE RESPONSIBLE FOR REVIEWING** the Terms of Use from time to time to view any such changes. Your continued access or use of the Services after the modifications have become effective will be deemed your conclusive acceptance of the modified Terms of Use. If you disagree with the modifications to the Terms of Use, then please do not continue to access or use the Services.
- 10.6. **Contact Us:** You may contact us regarding the Services of these Terms of Use, including if you require information that is not available on the NightWare website at www.nightware.com, or by emailing NightWare at support@nightware.com.

EXHIBIT B

**NIGHTWARE BUSINESS
ASSOCIATE AGREEMENT**

This Business Associate Agreement ("Agreement") is made by and between _____
(Business Associate") and NightWare ("Covered Entity") and is effective as of the date last signed below.

RECITALS

WHEREAS Business Associate provides consulting services to Covered Entity and, in connection with those services, Covered Entity may disclose Protected Health Information ("PHI") to Business Associate, and Business Associate may create or receive PHI on behalf of Covered Entity; and

WHEREAS, the Health Insurance Portability and Accountability Act of 1996, Public Law 104-191, and the Standards for Privacy of Individually Identifiable Health Information at 45 C.F.R. Part 160 and Part 164 require Covered Entity to enter into a contract with Business Associate containing specific requirements pertaining to Business Associate's Use and Disclosure of PHI received from, or created or received on behalf of, Covered Entity.

NOW THEREFORE, in consideration of the recitals above and mutual covenants and conditions below, Covered Entity and Business Associate enter into this Agreement, and agree as follows:

SECTION 1- DEFINITIONS

Terms used in this Agreement but not otherwise defined, including the following terms, shall have the same meaning as those terms in the HIPAA Rules: Breach, Data Aggregation, Designated Record Set, Disclosure, Health Care Operations, Individual, Minimum Necessary, Notice of Privacy Practices, Protected Health Information (or PHI), Required by Law, Secretary, Security Incident, Subcontractor, Unsecured Protected Health Information (or Unsecured PHI), and Use.

Specific definitions:

1.1 **Business Associate.** "Business Associate" shall generally have the same meaning as the term "business associate" at 45 CFR 160.103, and in reference to the party to this Agreement, shall mean Clary Document Management, Inc.

1.2 **Covered Entity.** "Covered Entity" shall generally have the same meaning as the term "covered entity" at 45 CFR 160.103, and in reference to the party to this Agreement, shall mean NightWare.

1.3 **HIPAA Rules.** "HIPAA Rules" shall mean the Privacy, Security, Breach Notification, and Enforcement Rules at 45 CFR Part 160 and Part 164.

SECTION 2- OBLIGATIONS OF BUSINESS ASSOCIATE

2.1 Prohibition on Unauthorized Use or Disclosure. Business Associate shall not Use or Disclose PHI other than as permitted or required by the HIPAA Rules, this Agreement, or as Required By Law.

2.2 Safeguards. Business Associate shall use appropriate safeguards and comply with Subpart C of 45 CFR Part 164 with respect to electronic PHI, to prevent the Use or Disclosure of PHI other than as provided by this Agreement.

2.3 Duty to Report Violations. Business Associate shall report to Covered Entity any Use or Disclosure of PHI not provided for by the HIPAA Rules or this Agreement of which it becomes aware, including breaches of Unsecured PHI as required at 45 CFR 164.410, and any Security Incident of which it becomes aware.

2.4 Subcontractors. Business Associate shall, in accordance with 45 CFR 164.502(e)(1)(ii) and 164.308(b)(2), if applicable, ensure that any Subcontractors that create, receive, maintain, or transmit PHI on behalf of Business Associate agree to the same restrictions, conditions, and requirements that apply to Business Associate with respect to such information.

2.5 Access to PHI. Within twenty (20) days of a request by Covered Entity, Business Associate shall make available PHI in a Designated Record Set to the Covered Entity as necessary to satisfy Covered Entity's obligations under 45 CFR 164.524.

2.6 Amendment to PHI. Within twenty (20) days of a request by Covered Entity, Business Associate shall make any amendment(s) to PHI in a Designated Record Set as directed or agreed to by the Covered Entity pursuant to 45 CFR 164.526 or take other measures as necessary to satisfy Covered Entity's obligations under 45 CFR 164.526.

2.7 Accounting of Disclosures. Business Associate shall maintain and make available the information required to provide an accounting of Disclosures to the Covered Entity as necessary to satisfy Covered Entity's obligations under 45 CFR 164.528.

2.8 Compliance with Requirements. To the extent Business Associate is to carry out one or more of Covered Entity's obligation(s) under Subpart E of 45 CFR Part 164, Business Associate shall comply with the requirements of Subpart E that apply to the Covered Entity in the performance of such obligation(s).

2.9 Inspection of Books and Records. Business Associate shall maintain and make its internal practices, books, and records available to the Secretary for purposes of determining compliance with the HIPAA Rules.

SECTION 3 - PERMITTED USES AND DISCLOSURES

3.1 Permitted Use and Disclosure. Business Associate may only Use or Disclose PHI as necessary for the purpose of providing legal services to Covered Entity.

3.2 Required by Law. Business Associate may Use or Disclose PHI as Required By Law.

Minimum Necessary. Business Associate agrees to make Uses, disclosures, and requests for PHI consistent with Covered Entity's Minimum Necessary policies and procedures.

3.3 Other Permitted Uses and Disclosures. Business Associate may not Use or Disclose PHI in a manner that would violate Subpart E of 45 CFR Part 164 if done by Covered Entity except for the specific Uses and Disclosures set forth below:

(a) Business Associate may Use PHI for the proper management and administration of Business Associate or to carry out the legal responsibilities of Business Associate.

(b) Business Associate may Disclose PHI for the proper management and administration of Business Associate or to carry out the legal responsibilities of Business Associate, provided the Disclosures are Required By Law, or Business Associate obtains reasonable assurances from the person to whom the information is Disclosed that the information will remain confidential and 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) Business Associate may provide Data Aggregation services relating to the Health Care Operations of the Covered Entity.

3.4 Pursuant to an Authorization. Business Associate may Use or Disclose PHI pursuant to a valid authorization by an Individual that satisfies the requirements of 45 C.F.R. § 164.508.

SECTION 4- OBLIGATIONS OF COVERED ENTITY

4.1 Notice of Limitation. Covered Entity shall notify Business Associate of any limitation(s) in the Notice of Privacy Practices of Covered Entity under 45 CFR 164.520 to the extent that such limitation may affect Business Associate's Use or Disclosure of PHI.

4.2 Notice of Revocation of Authorization. Covered Entity shall notify Business Associate of any changes in, or revocation of, the permission by an Individual to Use or Disclose his or her PHI to the extent that such changes may affect Business Associate's Use or Disclosure of PHI.

4.3 Notice of Restriction. Covered Entity shall notify Business Associate of any restriction on the Use or Disclosure of PHI that Covered Entity has agreed to or is required to abide by under 45 CFR 164.522, to the extent that such restriction may affect Business Associate's Use or Disclosure of PHI.

4.4 Impermissible Requests. Covered Entity shall not request Business Associate to Use or Disclose PHI in any manner that would not be permissible under Subpart E of 45 CFR Part 164 if done by Covered Entity except for the specific Uses and Disclosures set forth in Section 3.4 above.

SECTION 5 - BREACH NOTIFICATION

5.1 Breach Notification. As soon as reasonably possible, and in all cases within thirty (30) days of the first day on which any employee, partner, or agent of Business Associate either knows or, by exercising reasonable due diligence, would have known that a Breach of Unsecured PHI has occurred, Business Associate shall notify Covered Entity of such Breach.

The notification shall include the identification of each Individual whose Unsecured PHI has been or is reasonably believed by Business Associate to have been accessed, acquired, Used, or Disclosed during such Breach. The notification shall also include: (1) a brief description of

what happened, including the date of the Breach and the date of the discovery of the Breach, if known; (2) a description of the types of Unsecured PHI that were involved in the Breach (such as full name, social security number, date of birth, home address, account number, or disability code); (3) recommended steps that Individuals should take to protect themselves from potential harm resulting from the Breach; and (4) a brief description of what Business Associate is doing to investigate the Breach, to mitigate harm to Individuals, and to protect against any further Breaches. Business Associate shall maintain evidence to demonstrate that any required notification under this paragraph was made unless Business Associate determines that a delayed notification applies.

5.2 Delayed Notification to Covered Entity. If a law enforcement official states in writing to Business Associate that the notification to Covered Entity required under Section 5.1 above would impede a criminal investigation or cause damage to national security, then Business Associate may delay the notification for any period of time set forth in the written statement of the law enforcement official. If the law enforcement official provides an oral statement, then Business Associate shall document the statement in writing, including the name of the law enforcement official making the statement, and may delay the required notification for no longer than thirty (30) days from the date of the oral statement, unless the law enforcement official provides a written statement during that time that specifies a different time period. Business Associate shall be obligated to maintain evidence to demonstrate that the required notification under this paragraph was made.

SECTION 6 - LIMITATION ON OBLIGATIONS

6.1 Enforceability of Privacy Requirements. Any requirement imposed on Business Associate in Section 2 of this Agreement shall not apply in the event a court of competent jurisdiction determines, in response to a challenge raised by a plan sponsor, Covered Entity or Business Associate, that the HIPAA Rules requiring the inclusion of the requirement in this Agreement is unenforceable, invalid, or otherwise inapplicable to the relationship between Business Associate and Covered Entity or to the action that the Secretary may request of Business Associate or Covered Entity.

6.2 Ethical and Professional Responsibilities. This Agreement shall not be construed to require Business Associate to engage in any conduct which would be deemed unprofessional conduct under the laws, or ethical requirements applicable to lawyers in any state in which Business Associate's lawyers providing services under this Agreement are licensed to practice. Business Associate may delay complying with a request of the Secretary under this Agreement while Business Associate makes reasonable efforts to ascertain its professional responsibilities with respect to complying with the directive of Covered Entity to comply with an obligation imposed in the Obligations of Business Associate Section of this Agreement.

6.3 Privilege. To the maximum extent permitted by applicable law, Covered Entity hereby reserves and retains any and all applicable attorney-client or other privileges in which Covered Entity has an interest with respect to Business Associate's performance of its obligations under this Agreement. To the maximum extent permitted by applicable law, Business Associate hereby reserves and retains any and all applicable work product or other privileges or rights in which Business Associate

has an interest with respect to Business Associate's performance of its obligations under this Agreement. Nothing in this Agreement shall be construed to require Business Associate to Disclose or produce to Secretary communications that are subject to attorney-client privilege held by Business Associate with respect to legal advice it seeks from non-Business Associate attorneys.

SECTION 7 - TERM & TERMINATION

7.1 Term. The term of this Agreement shall be effective as of the date the Agreement is signed and shall terminate when all PHI is returned to Covered Entity or destroyed, or, if it is infeasible to return or destroy PHI, protections are extended to such PHI, in accordance with the termination provisions of this Section 7.

7.2 Termination for Cause. Upon Covered Entity's knowledge of a material breach of this Agreement by Business Associate, Covered Entity shall provide written notice of the breach and provide an opportunity for Business Associate to cure the breach or end the violation within thirty (30) business days of such written notice unless a cure is not possible. If Business Associate fails to cure the breach or end the violation within the specified time period or cure is not possible, Covered Entity may terminate this Agreement immediately upon written notice, unless termination is infeasible.

7.3 Effect of Termination. Except as provided in this Section 7.3, upon termination of this Agreement for any reason, Business Associate, with respect to PHI received from Covered Entity, or created, maintained, or received by Business Associate on behalf of Covered Entity, shall:

- (a) Retain only that PHI which is necessary for Business Associate to continue its proper management and administration or to carry out its legal responsibilities;
- (b) Return to Covered Entity or, if agreed to by Covered Entity, destroy the remaining PHI that Business Associate still maintains in any form;
- (c) Continue to use appropriate safeguards and comply with Subpart C of 45CFR Part 164 with respect to electronic PHI to prevent Use or Disclosure of the PHI, other than as provided for in this Section 7.3, for as long as Business Associate retains the PHI;
- (d) Not Use or Disclose the PHI retained by Business Associate other than for the purposes for which such PHI was retained and subject to the same conditions set forth in Section 3 above, which applied before termination; and
- (e) Return to Covered Entity or, if agreed to by Covered Entity, destroy the PHI retained by Business Associate when Business Associate no longer needs it for its proper management and administration or to carry out its legal responsibilities.

SECTION 8 - MISCELLANEOUS

8.1 Regulatory References. A reference in this Agreement to a section in the HIPAA Rules means the section as in effect or as amended.

8.2 Amendment. Business Associate and Covered Entity agree to take such action as is necessary to amend this Agreement from time to time as is necessary for compliance with the requirements of the HIPAA Rules and any other applicable law.

8.3 Survival. The respective rights and obligations of Business Associate under Sections 6, 7, and 8 shall survive the termination of this Agreement.

8.4 Interpretation. Any ambiguity in this Agreement shall be interpreted to permit compliance with the HIPAA Rules.

8.5 Third-Party Beneficiaries. Nothing in this Agreement, whether express or implied, is intended to confer or create, nor be interpreted to confer or create, any rights, remedies, obligations, or liabilities to or for any third party.

IN WITNESS WHEREOF, the parties have each caused this Business Associate Agreement to be executed by an authorized officer.

APPROVED AND ACCEPTED BY:

Business Associate Print Name & Title	Signature	Date
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NightWare Print Name	Signature	Date
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