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Dear Valued Customer:

HIPAA compliance is at or near the top of the to-do list of most healthcare providers. As a health care provider, you have the responsibility to ensure that individually identifiable health information is not released in unauthorized ways.

Cadwell has received many requests to enter Business Associate contracts to protect this information. While Cadwell fully supports the Health Information Privacy Act and has the desire to meet our customer's needs and expectations, the additional administrative burden arising from the review of these contractual requirements has become excessive. The tremendously varied form of these correspondences requires Cadwell to review each request/contract individually prior to providing the requested information or signing the agreements.

Furthermore, most of the requests have little or no bearing on the business relationship between Cadwell and the Health Care Provider. In order to provide a timely and consistent response to these requests we have reviewed HIPAA requirements as they relate to Cadwell as a medical device manufacturer and provide this response and the attachment. These materials serve as our binding commitment to meet the requirements of HIPAA as they pertain to the protection of your patients' health records.

Cadwell has implemented strict procedures to prevent disclosure of patient data that may enter our hands. Additionally, we note that under the HIPAA regulations, Cadwell's activities, such as repairing its medical devices, are covered as Public Health Activities under Section 164.512(b)(iii)(C) and are thus "uses and disclosures for which consent, an authorization, or opportunity to agree or object is not required[.]" The attached text taken from the rule confirms that medical device manufacturers are not considered Business Associates under HIPAA when selling medical devices to a covered provider or when repairing medical devices. While a medical device manufacturer could be considered a Business Associate when providing "health care" or when using protected health information for marketing purposes, Cadwell does not participate in either of these activities and is thus not a Business Associate for those purposes.

Please accept this statement and the attachment in lieu of the contractual agreement you have requested.

Thank you for your understanding in this matter.

Chris Bolkan
Quality Assurance / Regulatory Affairs

Attachment: Excerpt from "Standards for Privacy of Individually Identifiable Health Information; Final Rule"



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Excerpt from:

Department of Health and Human Services
45 CFR Parts 160 and 164
Standards for Privacy of Individually Identifiable Health Information; Final Rule

PART 164—SECURITY AND PRIVACY

§ 164.512 Uses and disclosures for which consent, an authorization, or opportunity to agree or object is not required.

A covered entity may use or disclose protected health information without the written consent or authorization in the situations covered by this section...

- (b) A covered entity may disclose protected health information for the public health activities and purposes described in this paragraph to: ...
 - (iii) A person subject to the jurisdiction of the Food and Drug Administration:
 - (A) To report adverse events ... product defects or problems (including problems with the use or labeling of a product), ... if the disclosure is made to the person required or directed to report such information to the Food and Drug Administration;
 - (B) To track products if the disclosure is made to a person required or directed by the Food and Drug Administration to track the product;
 - (C) To enable product recalls, repairs, or replacement (including locating and notifying individuals who have received products of product recalls, withdrawals, or other problems); or
 - (D) To conduct post marketing surveillance to comply with requirements or at the direction of the Food and Drug Administration;