

HIPAA COMPLIANCE POLICY

ConforMIS is a “Covered Entity” under the current HIPAA regulation: A covered entity may use and disclose an individual’s protected health information for its own treatment, payment, or health care operations without obtaining the individual’s permission (e.g. authorization or consent). In addition, a covered entity may disclose, without the individual’s specific permission, protected health care information for: treatment or payment activities of a health care provider; the payment activities of another covered entity; and for certain health care operations of another covered entity, if each entity has or had a relationship with the individual who is the subject of the protected health care information and the requested information pertains to that relationship.¹

Based on the above, ConforMIS may receive from other health care providers personal, identifiable information regarding patients for whom a patient-specific, unique medical device is to be designed. Such information must, of course, be adequately safe guarded from inappropriate or inadvertent release.

SPECIFIC COMPLIANCE POLICIES:

ConforMIS conducts all aspects of its business which may be subject to the provisions of HIPAA in substantial compliance with those regulations;

ConforMIS has a proactive program to assure compliance with current HIPAA regulations and this program includes the following activities:

- A designated HIPAA Compliance Officer who is certified in HIPAA Compliance;
- Ongoing analysis of HIPAA regulations with regard to all aspects of ConforMIS’ business practice;
- Formulation and implementation of appropriate policies for HIPAA compliance;
- Periodic training of employees, as appropriate, in HIPAA compliance, including orientation of sales personnel and newly hired employees;
- Monitoring of HIPAA regulations to remain aware of changes in either regulations or interpretations;
- Use of secure file-transfer and storage to protect electronic data;
- Periodic reports to senior management regarding the status of HIPAA compliance by the company

S. Michael Sharp, PhD
HIPAA Compliance Officer
Sr. Vice President, Regulatory Affairs

¹(Summary of the HIPAA Regulations provided by the Health Privacy Project, Institute for Health Care Research and Policy, Georgetown Univ.)