Department of Health and Human Services

Standards	Sections	Implementation Specifications (R)=Required, (A)=Addressable
Security Awareness and Training	164.308(a)(5)	Access Authorization (A) Access Establishment and Modification (A) Security Reminders (A) Protection from Malicious Software (A) Log-in Monitoring (A)
Security Incident Procedures	164.308(a)(6) 164.308(a)(7)	Password Management (A) Response and Reporting (R) Data Backup Plan (R) Disaster Recovery Plan (R) Emergency Mode Operation Plan (R) Testing and Revision Procedure (A)
Evaluation	164.308(a)(8) 164.308(b)(1)	Applications and Data Criticality Analysis (A) (R) Written Contract or Other Arrangement (R)
	Physical Safe	guards
Facility Access Controls	164.310(a)(1)	Contingency Operations (A) Facility Security Plan (A) Access Control and Validation Procedures (A) Maintenance Records (A)
Workstation Use	164.310(b) 164.310(c) 164.310(d)(1)	(R) (R) Disposal (R) Media Re-use (R) Accountability (A) Data Backup and Storage (A)
	Technical Safeguards	(see § 164.312)
Access Control	164.312(a)(1)	Unique User Identification (R) Emergency Access Procedure (R) Automatic Logoff (A) Encryption and Decryption (A)
Audit Controls	164.312(b) 164.312(c)(1) 164.312(d) 164.312(e)(1)	(R) Mechanism to Authenticate Electronic Protected Health Information (A) (R) Integrity Controls (A) Encryption (A)

Subpart D—Notification in the Case of Breach of Unsecured Protected Health Information

SOURCE: 74 FR 42767, Aug. 24, 2009, unless otherwise noted.

§ 164.400 Applicability.

The requirements of this subpart shall apply with respect to breaches of protected health information occurring on or after September 23, 2009.

§ 164.402 Definitions.

As used in this subpart, the following terms have the following meanings:

Breach means the acquisition, access, use, or disclosure of protected health information in a manner not permitted under subpart E of this part which

compromises the security or privacy of the protected health information.

- (1)(i) For purposes of this definition, compromises the security or privacy of the protected health information means poses a significant risk of financial, reputational, or other harm to the individual.
- (ii) A use or disclosure of protected health information that does not include the identifiers listed at §164.514(e)(2), date of birth, and zip code does not compromise the security or privacy of the protected health information.
 - (2) Breach excludes:
- (i) Any unintentional acquisition, access, or use of protected health information by a workforce member or person acting under the authority of a covered entity or a business associate, if such acquisition, access, or use was