

## 5.) General Administrative Requirements Applicable to Subchapter C – All HIPAA Rules (Part 160, Subpart A)

- § 160.101 – Statutory basis and purpose
- § 160.102 – Applicability
- § 160.103 – Definitions (business associate, subcontractor, protected health information, State, electronic media, health information, genetic information, genetic test, genetic services, family member, manifestation or manifested)
- § 160.105 – Compliance dates for implementation of new or modified standards and implementation specifications

Provision	HIPAA Requirements	Proposed/Interim Final Rules	Final Rule
§ 160.101 – Statutory basis and purpose	The requirements in the HIPAA regulations are based on the regulations in §§ 1171 – 1179 of the Social Security Act (as added by HIPAA § 262), and on § 264 of HIPAA. <sup>1</sup>	The Proposed Rule added a reference to §§ 13400 – 13424 of HITECH, <sup>2</sup> and the Proposed GINA Rule added references to § 105 of GINA and § 1180 of the Social Security Act <sup>3</sup> as bases for the proposed requirements.	Adopts as proposed. <sup>4</sup>

<sup>1</sup> 45 C.F.R. § 160.101 (2007) (Note that the July 2011 IFR proposing operating rules for eligibility for a health plan and health care claims status added a reference to § 1104 of the Affordable Care Act, which was included in 45 C.F.R. § 160.101 as of 2011).

<sup>2</sup> Modifications to the HIPAA Privacy, Security, and Enforcement Rules Under the Health Information Technology for Economic and Clinical Health Act; Notice of Proposed Rulemaking, 75 Fed. Reg. 40868, 40872 (July 14, 2010) (Note that the Breach Notification IFR added a reference to HITECH Act § 13402, which was included in the CFR as of 2009, and the Enforcement IFR added a reference to HITECH Act § 13410(d), which was included in the CFR as of 2010).

<sup>3</sup> HIPAA Administrative Simplification: Standards for Privacy of Individually Identifiable Health Information; Notice of Proposed Rulemaking, 74 Fed. Reg. 51698, 51708 (October 7, 2009).

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§ 160.102 – Applicability	The HIPAA rules apply to <i>covered entities</i> , which include health plans, health care clearinghouses, and health care providers who transmit any health information in electronic form in connection with a transaction covered by the HIPAA rules. <sup>5</sup>	The Proposed Rule added a provision stating that the HIPAA rules apply to business associates where specified. <sup>6</sup>	Adopts as proposed. <sup>7</sup>
§ 160.103 – Definitions, <i>business associate</i>	<p>A <i>business associate</i> is a person who, on behalf of a covered entity (or on behalf of an organized health care arrangement in which the covered entity participates), performs or helps perform any function or activity that involves the use or disclosure of individually identifiable health information, or that is otherwise regulated by the HIPAA rules.<sup>8</sup></p> <p>A person who provides certain services to or for a covered entity (or to or for an organized health care arrangement in which the covered entity participates) is a <i>business associate</i> when provision of the service involves the disclosure of individually identifiable health</p>	<p>The Proposed Rule added “patient safety activities” to the list of activities that create a business associate relationship when performed on behalf of a covered entity or arrangement.<sup>10</sup></p> <p>The Proposed Rule changed the term “individually identifiable health information” to “protected health information.”<sup>11</sup></p> <p>The Proposed Rule specifically identified three types of entities as <i>business associates</i>: (i) Health Information Organizations, E-prescribing Gateways, or other persons that provide data transmission services of protected health</p>	<p>Adopts as proposed.<sup>14</sup></p> <p>The Final Rule further modifies <i>business associate</i> such that a business associate is a person who, on behalf of a covered entity (or on behalf of an organized health care arrangement in which the covered entity participates), creates, receives, maintains, or transmits protected health information for a function or activity that is regulated by the HIPAA rules.<sup>15</sup></p>

<sup>4</sup> Modifications to the HIPAA Privacy, Security, Enforcement, and Breach Notification Rules Under the Health Information Technology for Economic and Clinical Health Act and the Genetic Information Nondiscrimination Act; Other Modifications to the HIPAA Rules; Final Rule 78 Fed. Reg. 5566, 5570 and 5661 (January 25, 2013) (to be codified at 45 C.F.R. § 160.101).

<sup>5</sup> 45 C.F.R. § 160.102(a) (2007).

<sup>6</sup> 75 Fed. Reg. at 40872.

<sup>7</sup> 78 Fed. Reg. at 5570; 45 C.F.R. § 160.102(b).

<sup>8</sup> 45 C.F.R. § 160.103, at ¶ (1)(i) of “Business associate” (2007).

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	information from the covered entity or arrangement to the person. <sup>9</sup> A member of the covered entity or organized health care arrangement’s workforce is not considered a business associate in either situation.	information to a covered entity and who require access on a routine basis to such information; (ii) a person that offers personal health records to individuals on behalf of a covered entity; and (iii) a subcontractor that creates, receives, maintains, or transmits protected health information on behalf of a business associate. <sup>12</sup> The Proposed Rule moved provisions from §§ 164.308 and 164.502 excluding certain recipients of protected health information to the definition of <i>business associate</i> . <sup>13</sup>	
§ 160.103 – Definitions, <i>subcontractor</i>	The HIPAA Rules do not define <i>subcontractor</i> .	The Proposed Rule defined <i>subcontractor</i> as “a person who acts on behalf of a business associate, other than in the capacity of a member of the workforce of such business associate.” <sup>16</sup>	The Final Rule defines <i>subcontractor</i> as a person to whom a business associate delegates a function, activity, or service, other than in the capacity of a member of the workforce of such business associate. <sup>17</sup>
§ 160.103 – Definitions, <i>protected health</i>	<i>Protected health information</i> is individually identifiable health	The Proposed Rule also excluded individually identifiable health	Adopts as proposed. <sup>21</sup>

<sup>10</sup> 75 Fed. Reg. at 40872.

<sup>11</sup> 75 Fed. Reg. at 40874.

<sup>14</sup> 78 Fed. Reg. at 5571-73; 45 C.F.R. § 160.103, at “Business associate.”

<sup>15</sup> 78 Fed. Reg. at 5572, 74; 45 C.F.R. § 160.103, at ¶ (1)(i) of “Business Associate.”

<sup>9</sup> 45 C.F.R. § 160.103, at ¶ (1)(ii) of “Business associate” (2007).

<sup>12</sup> 75 Fed. Reg. at 40872-74.

<sup>13</sup> 75 Fed. Reg. at 40873 – 74 (referencing the provisions at § 164.308(b)(2) and § 164.502(e)(1)(ii)).

<sup>16</sup> 75 Fed. Reg. at 40873.

<sup>17</sup> 78 Fed. Reg. at 5689; 45 C.F.R. § 160.103, at “Subcontractor.”

Provision	HIPAA Requirements	Proposed/Interim Final Rules	Final Rule
<i>information</i>	information that is transmitted or maintained in any form or medium. <sup>18</sup> The definition excludes individually identifiable health information in certain education records and in employment records held by a covered entity in its role as employer. <sup>19</sup>	information regarding persons who have been deceased for over 50 years from <i>protected health information</i> . <sup>20</sup>	
§ 160.103 – Definitions, <i>State</i>	<i>State</i> includes any of the several States, D.C., Puerto Rico, the Virgin Islands, and Guam. <sup>22</sup>	The Proposed Rule included American Samoa and the Northern Mariana Islands in <i>State</i> . <sup>23</sup>	Adopts as proposed. <sup>24</sup>
§ 160.103 – Definitions, <i>electronic media</i>	<i>Electronic media</i> is electronic storage media <sup>25</sup> or transmission media used to exchange information already in electronic storage media. <sup>26</sup>  Transmission media includes the internet (wide-open), extranet (using internet technology to link a business with information accessible only to collaborating parties), leased lines, dial-up lines, private networks, and	The Proposed Rule replaced “electronic storage media” with “electronic storage material on which data is or may be recorded electronically.” <sup>27</sup>  The Proposed Rule expanded the list of examples of transmission media to include “extranet <b>or intranet</b> .”	Adopts as proposed. <sup>28</sup>  The Final Rule further amends the list of transmission media examples by removing the phrase “wide open” after Internet and removing the language following “extranet or intranet.” <sup>29</sup>  The Final Rule also clarifies that transmissions via electronic media exclude transmissions only where the

<sup>21</sup> 78 Fed. Reg. at 5576; 45 C.F.R. § 160.103, at ¶ (2)(iv) of “Protected health information.”

<sup>18</sup> 45 C.F.R. § 160.103, at ¶ (1) of “Protected health information” (2007).

<sup>19</sup> 45 C.F.R. § 160.103, at ¶ (2) of “Protected health information” (2007).

<sup>20</sup> 75 Fed. Reg. at 40874.

<sup>22</sup> 45 C.F.R. § 160.103, at ¶ (2) of “State” (2007).

<sup>23</sup> 75 Fed. Reg. at 40874.

<sup>24</sup> 78 Fed. Reg. at 5576; 45 C.F.R. § 160.103, at ¶ (2) of “State.”

<sup>25</sup> 45 C.F.R. § 160.103, at ¶ (1) of “Electronic media” (2007).

<sup>26</sup> 45 C.F.R. § 160.103, at ¶ (2) of “Electronic media” (2007).

<sup>27</sup> 75 Fed. Reg. at 40874.

<sup>28</sup> 78 Fed. Reg. at 5576; 45 C.F.R. § 160.103, at “Electronic media.”

<sup>29</sup> 78 Fed. Reg. at 5576; 45 C.F.R. § 160.103, at ¶ (2) of “Electronic media.”

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	the physical movement of removable/transportable electronic storage media. Transmissions via electronic media exclude transmissions where the information being exchanged did not exist in electronic form before the transmission.		information being exchanged did not exist in electronic form <b>immediately</b> before the transmission.
§ 160.103 – Definitions, <i>health information</i>	<i>Health information</i> is any information that is created or received by a specified entity and that relates to an individual’s health or condition, provision of health care to an individual, or payment for such care. <sup>30</sup>	The Proposed GINA Rule amended the definition so that <i>health information</i> expressly includes genetic information. <sup>31</sup>	Adopts as proposed. <sup>32</sup>
§ 160.103 – Definitions, <i>genetic information</i>	The HIPAA rules do not define <i>genetic information</i> .	The Proposed GINA Rule defined <i>genetic information</i> as information about: (i) an individual’s genetic tests; (ii) an individual’s family members’ genetic tests; (iii) the manifestation of a disease or disorder in an individual’s family member; or (iv) an individual or his or her family member’s request for or receipt of genetic services, or participation in clinical research that includes genetic services. Genetic information about an individual or his or her family member includes the genetic information of a fetus carried, or an embryo held using assisted reproductive technology, by the	Adopts as proposed. <sup>34</sup>

<sup>30</sup> 45 C.F.R. § 160.103, at “Health information” (2007).

<sup>31</sup> 74 Fed Reg. at 51700.

<sup>32</sup> 78 Fed. Reg. at 5661; 45 C.F.R. § 160.103.

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		individual or family member. An individual’s age and sex are not genetic information. <sup>33</sup>	
§ 160.103 – Definitions, <i>genetic test</i>	The HIPAA rules do not define <i>genetic test</i> .	The Proposed GINA Rule defined <i>genetic test</i> as “an analysis of human DNA, RNA, chromosomes, proteins, or metabolites, if the analysis detects genotypes, mutations, or chromosomal changes.” This definition does not include an analysis of proteins or metabolites that is directly related to “a manifested disease, disorder, or pathological condition.” <sup>35</sup>	Adopts as proposed. <sup>36</sup>
§ 160.103 – Definitions, <i>genetic services</i>	The HIPAA rules do not define <i>genetic services</i> .	The Proposed GINA Rule defined <i>genetic services</i> as: (1) a genetic test; (2) genetic counseling; or (3) genetic education. <sup>37</sup>	Adopts as proposed. <sup>38</sup>
§ 160.103 – Definitions, <i>family member</i>	The HIPAA rules do not define <i>family member</i> .	The Proposed GINA Rule defined <i>family member</i> as: (1) an individual’s dependent; or (2) a first, second, third, or fourth degree relative of the individual or his or her dependent. The rule treats relatives by law (e.g., marriage or adoption), as well as less than full-blood relatives (e.g., half-	Adopts as proposed. <sup>40</sup>

<sup>34</sup> 78 Fed. Reg. at 5662; 45 C.F.R. § 160.103, at “Genetic information.”

<sup>33</sup> 74 Fed. Reg. at 51700.

<sup>35</sup> 74 Fed. Reg. at 51700-01.

<sup>36</sup> 78 Fed. Reg. at 5662; 45 C.F.R. § 160.103, at “Genetic test.”

<sup>37</sup> 74 Fed. Reg. at 51701.

<sup>38</sup> 78 Fed. Reg. at 5663; 45 C.F.R. § 160.103.

Provision	HIPAA Requirements	Proposed/Interim Final Rules	Final Rule
<p>§ 160.103 – Definitions, <i>manifestation or manifested</i></p>	<p>The HIPAA rules do not define <i>manifestation</i> or <i>manifested</i>.</p>	<p>siblings), in the same manner as full-blood relatives.<sup>39</sup></p> <p>The Proposed GINA Rule defined <i>manifestation</i> or <i>manifested</i> with respect to a disease, disorder, or pathological condition to mean that “an individual has been or could reasonably be diagnosed with the disease, disorder, or pathological condition by a health care professional with appropriate training and expertise in the field of medicine involved.” A disease, disorder, or pathological condition is not manifested if the diagnosis is primarily based on genetic information.<sup>41</sup></p>	<p>Adopts as proposed.<sup>42</sup></p>
<p>§ 160.105 – Compliance dates for implementation of new or modified standards and implementation specifications</p>	<p>The HIPAA rules do not contain § 160.105.</p>	<p>The Proposed Rule added this section to give covered entities and business associates 180 days after the effective date of the Final Rule to comply with the new or amended requirements. Any future changes to the HIPAA rules will also be subject to a 180-day compliance period<sup>43</sup></p>	<p>Adopts as proposed.<sup>44</sup></p> <p>The effective date of the Final Rule will be March 26, 2013. Covered entities and business associates must be in compliance by September 23, 2013.</p>

<sup>40</sup> 78 Fed. Reg. at 5663; 45 C.F.R. § 160.103, at “Family member.”

<sup>39</sup> 74 Fed. Reg. at 51701.

<sup>41</sup> 74 Fed. Reg. at 51701-02.

<sup>42</sup> 78 Fed. Reg. at 5569; 45 C.F.R. § 160.103, at “Manifestation or manifested”.

<sup>43</sup> 75 Fed. Reg. at 40871.

<sup>44</sup> 78 Fed. Reg. at 5569; 45 C.F.R. § 160.105.