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DQA Memo 13-019

<b>To:</b>	Adult Family Homes	AFH	09
	Ambulatory Surgical Centers	ASC	03
	Certified Mental Health and AODA	CMHA	04
	CLIA-Certified Laboratories	CLIA	02
	Community-Based Residential Facilities	CBRF	10
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	End Stage Renal Dialysis	ESRD	02
	Facilities Serving People with Developmental Disabilities	FDD	04
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**From:** Otis Woods, Administrator  
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**HIPAA Final Rule – Recommendations for Facility Compliance**

The final omnibus rule (Omnibus Rule) that modifies the Health Insurance Portability and Accountability Act of 1996 (HIPAA), which was published on January 26, 2013, took effect on March 26, 2013. **HIPAA covered entities and business associates have until September 23, 2013, to become compliant with the Omnibus Rule.**

While some of the rule changes are not surprising, others are significant and will change the obligations imposed on covered entities, business associates, and their subcontractors. Some highlights of the Omnibus Rule include the following:

- **Breach Notification.** Under the HIPAA Omnibus Rule, the harm standard is replaced by more objective guidance on breach notification. As a result of the new guidance, breach incidents must be reported unless the risk of compromise is low.
- **Enforcement and Penalties.** HIPAA enforcement is moving towards a penalty-based system and away from voluntary compliance.

- **Business Associates.** Business associates (BA) are directly liable for HIPAA violations. In addition, business associates are now required to enter into written agreements with subcontractors to ensure that such subcontractors will appropriately safeguard protected health information (PHI). Also, new provisions may need to be added to existing Business Associate Agreements that may have to be renegotiated and signed no later than September 22, 2014.
- **Individual Rights.** Expanded rights for individuals to request electronic copies of their PHI in their designated record set and requests for some restrictions of their PHI must be honored. The Notices of Privacy Practices\* will need to be revised/amended.
- **Sale of PHI and Marketing.** Made changes regarding the sale of PHI and the use of PHI for marketing or fundraising.

### **What actions do you need to consider?**

Covered entities and business associates should take the following actions now, if they haven't already done so:

- Revise business associate contract template and determine whether the existing template is compliant or needs to be signed. If not compliant, the covered entity will need to amend/renegotiate each one. Existing BA agreements must be compliant by September 22, 2014. BA agreements that renew prior to that date must be compliant upon renewal.
- Revise HIPAA Policies and Procedures, including modifications to address response to potential breaches involving unsecured PHI.
- Update and make available Notices of Privacy Practices effective September 23, 2013 to new patients and existing patients upon request.
- Define process for providing electronic copies of PHI for individuals' requests for PHI maintained in a designated record set.
- Analyze current arrangements for compliance with restrictions on the sale of PHI and for marketing and fundraising restrictions.
- Train employees on updated obligations.

### **Where can I get more information?**

- HHS Office of Civil Rights  
<http://www.hhs.gov/ocr/privacy/index.html>
- The complete suite of HIPAA Administrative Simplification Regulations can be found at 45 CFR Parts 160, 162, and 164  
<http://www.hhs.gov/ocr/privacy/hipaa/administrative/combined/index.html>
- HHS Model Business Associate Agreement  
<http://www.hhs.gov/ocr/privacy/hipaa/understanding/coveredentities/contractprov.html>
- HIPAA COW Resources  
<http://hipaacow.org/>

The Health Insurance Portability and Accountability Act Collaborative of Wisconsin (HIPAA COW) was established in 2001 and is a non-profit organization open to entities considered to be Covered Entities, Business Associates, and/or Trading Partners under HIPAA, as well as any other organization impacted by HIPAA regulations. HIPAA COW provides many resources, as well as sample templates for forms and policies for Covered Entities and Business Associates to utilize for their own organization.

#### **Links of Interest from the HIPAA COW Website**

- **Breach Notification**  
<http://hipaacow.org/news/breach-notification-policy-updated-6113/>
- **Notices of Privacy Practices and Business Associate Agreement Templates**  
<http://hipaacow.org/resources/hipaa-cow-documents/privacy-security/>

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