

# Lewis Creek Systems, LLC

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## New Regulation for HIPAA Business Associates Due Soon

December 15, 2009

You may be aware that the changes to HIPAA embodied in the American Recovery and Reinvestment Act (ARRA) include some significant changes to the regulations pertaining to HIPAA Business Associates, including that they are now covered directly under the HIPAA Privacy and Security Regulations. The new extension of HIPAA to Business Associates is set by statute to go into effect by February 17, 2010, and regulations will be issued for implementing the changes.

As of mid-December, the Business Associate regulations had not been issued. Based on comments by Susan McAndrew, Deputy Director, Health Information Privacy Division, at the US Department of Health and Human Services Office for Civil Rights (HHS OCR), speaking at the Workgroup for Electronic Data Interchange Fall Conference on November 19, 2009, HHS OCR is hoping to deliver a regulation implementing the new ARRA Business Associate requirements by the end of the Fall season, which is by December 21, 2009. Unfortunately, predicting an exact date of release is difficult because of uncertainties in the approval process, and OCR may not make the end-of-Fall deadline. McAndrew did say that she expects the regulation to allow a 180-day enforcement delay, which will put effective enforcement of the Business Associate changes off to a date likely in June of 2010.

In addition, though, ARRA also includes a new Breach Notification provision for health information, for which a regulation already has been issued, going into effect September 23, 2009, but with a 180-day delay in enforcement. The Breach Notification rule is enforceable February 22, 2010. The Breach Notification Rule has a significant impact on business associate relationships, because of the significant requirements and costs inherent in providing notification, especially if the number of individuals affected is more than 500. HIPAA covered entities will need to modify their Business Associate Agreements (BAAs) to deal with issues such as indemnification and liquidated damages in order to protect themselves from the costs of breach notification when the breach is caused by the other party.

Unfortunately, even though BAAs may not need to be revised for the Business Associate regulation until June, it will be important to revise the BAAs to provide for Breach Notification by February 22, 2010, so the delay in the Business Associate regulation enforcement is largely illusory. Nonetheless, it does not make sense to forge ahead with revisions to agreements until the regulation has been issued, especially because some of the regulations issued under ARRA have varied from expectations based on the legislation itself. Once the regulation is issued, it will be important for Coalition members (and other HIPAA covered entities) to work quickly on the process of updating their BA agreements.

Therefore, covered entities, such as Coalition members, should begin now to evaluate their Business Associates to determine which ones are at the highest risk for breaches (usually the ones that deal with the most Protected Health Information), and be prepared to deal with those agreements first once the regulation is issued. Prioritization of revisions will be essential to the protection of Coalition members.

As soon as the regulation is issued, Lewis Creek Systems, LLC will be preparing suggested language for Coalition members that may be incorporated into BAAs. Once the suggested language is released to Coalition members, they should work with their legal counsel to develop their precise language using the suggested language as a guide, and/or use the suggested language as a checklist when evaluating BAAs presented to them by their Business Associates. Legal counsel should be involved in developing any new agreements, because of the significant exposures under Breach Notification. The Coalition and Lewis Creek Systems will do their best to provide assistance with the BAA language needed according to the regulation, but, ultimately, BAAs are significant legal contracts that must involve counsel and may require negotiation with the BA. We recommend that preparations begin now.