



LICENSING ALERT

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Deputy Secretary for Quality Assurance

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Division of Drug and Alcohol Program Licensure
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ELECTRONIC CLINICAL RECORDS

Over the last year, the Department has received several inquiries regarding compliance with licensing regulations through the use of electronic clinical records. The Department realizes the efficacy of electronic charting and does not intend to preclude the provider community from this technological advancement. However, there can be no compromise in patient care or regulatory compliance as a result of a conversion to an electronic record keeping system. This Licensing Alert is intended to provide assistance in maintaining compliance with applicable regulations.

Facilities utilizing electronic record keeping systems must develop written procedures addressing how the integrity of the electronic storage system will be maintained, specifically:

- Identify by position the staff that will be able to access the database; the access restrictions assigned to each position, and a listing of staff with administrative privileges.
- Describe the security system protecting the database including how access restrictions will be implemented, firewall protections, password protocols, and how and to whom temporary access would be afforded for audit and evaluation purposes.
- Describe the maintenance procedures addressing the location of the server, schedule for backing up the data, staff responsible for maintenance, location of back-up storage mediums, and timeframes for deletion.

There has been discussion in the past regarding the validity of an electronic signature in relation to patient consent for treatment and disclosure of information. The signing of the Electronic Transaction Act (Act 69 of 1999) established a protocol which allows for the electronic signing of the consent to treatment and consent to release information. The validity of the electronic signature is contingent upon the signer's - in this case, the patient's - agreement to utilize electronic signatures. If a patient refuses to sign electronically, the facility must afford the patient the opportunity to sign the document manually.

With the validity of the electronic signature established, the Department must also ensure that the consent is informed and voluntary. Facilities utilizing electronic signatures must demonstrate both in policy and procedure that the patient has been informed and has voluntarily consented. The Department expects the following conditions to be satisfied:

- The patient must sign each form individually, with the form visually displayed as the patient signs the signature pad. In essence, a patient may not sign his/her name without the assurance that the signature is intended for that specific document only.
- Policies and procedures must be in place that describe how the system digitally links the electronic signature to that specific document, and that the signature will be voided if the document is altered after signature.
- Protections are in place that prevent the patient's electronic signature from being replicated or attached to other documents.
- The facility must be able to print a hard copy of all electronically signed documents that include the patient's signature.

The written procedures addressing treatment and rehabilitation management must be amended to incorporate the completion of clinical records via an electronic medium. The Department expects facilities using electronic records to fully comply with the charting requirements pertaining to respective treatment activities they provide. In addition, the facility must have the capability to print a hard copy of an electronically maintained document for inspection and survey.

Questions on this alert may be directed to Kim Buffington, Frank Miller or Arvida Wanner at (717) 783-8675.

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