§ 1311.215 Internal audit trail.

(a) The pharmacy application provider must establish and implement a list of auditable events. The auditable events must, at a minimum, include the following:

1. Attempted unauthorized access to the pharmacy application, or successful unauthorized access to the pharmacy application where the determination of such is feasible.
2. Attempted or successful unauthorized modification or destruction of any information or records required by this part, or successful unauthorized modification or destruction of any information or records required by this part where the determination of such is feasible.
3. Interference with application operations of the pharmacy application.
4. Any setting of or change to logical access controls related to the dispensing of controlled substance prescriptions.
5. Attempted or successful interference with audit trail functions.
6. For application service providers, attempted or successful annotation, alteration, or destruction of controlled...