is used to describe edits to electronic controlled substance prescriptions that result in a new order being generated by CPRS and VistA Outpatient Pharmacy.

(35) Pharmacy staff follow the requirements for storage of controlled substance patient medications during an admission and the requirements for accepting back patient controlled substance prescriptions for disposal as described in VHA Directive 1114, Controlled Substance Patient Prescription Disposal, dated September 9, 2016. ***NOTE:*** *Patients participating in an investigational use study may return unused controlled substances received as part of that research to the registered dispenser from which the patient obtained the controlled substance (see 21 CFR 1317.85(b)).*

(36) All compounded controlled substance injectable products, to include both syringes and bags, dispensed to patient care areas must be sealed with a tamper-resistant cap and enclosed in a custom security bag with a serial number.

(a) The custom security bag must be transparent and contain the following information pre-printed on the label:

1. "Do not use if the security bag is not sealed properly or has signs of tampering."

2. "Do not use if the plastic cap on the port is missing or has signs of tampering."

3. "Do not use if the serial number on the security bag does not match the serial number written on the label of the IV bag."

4. "Call the pharmacy immediately to report any signs of tampering, security cap missing, or mismatch in numbers between the security bag and IV label."

(b) The security bag serial number must be written on the label of the compounded controlled substance IV by person doing the compounding.

(c) When checking, the pharmacist must verify the serial number on the label matches the serial number on the bag.

(d) Unused bags returned to pharmacy must be inspected by pharmacy staff, and any signs of tampering, missing security cap, or mismatch in numbers between the security bag and IV label must be reported immediately to the Chief of Pharmacy for further investigation and possible loss reporting per the requirements in Appendix B.

h. **Clinical Research Pharmacy Coordinating Center Facility Director**. The Clinical Research Pharmacy Coordinating Center (CRPCC) facility Director is responsible for ensuring that:

(1) The CRPCC facility is registered with the DEA as a "research" facility as defined in 21 CFR 1300-END.

(2) All written local controlled substance policies, procedures, and records are in compliance with VHA, DEA, and Federal regulatory requirements (see 21 CFR Part 1300-END).