

657—13.14(155A) Immediate-use preparations. For the purpose of emergency or immediate patient care, pharmacies are exempted from requirements described in this chapter for low- and medium-risk preparations when all of the following criteria are met:

1. Only simple aseptic measuring and transfer manipulations are performed with not more than three sterile commercial drug products including an infusion or diluent solution.
2. Unless required for the preparation, the compounding procedure occurs continuously without delays or interruptions and does not exceed one hour.
3. At no point during preparation are critical surfaces and ingredients of the preparation directly exposed to contact contamination, such as human touch, cosmetic flakes or particulates, blood, human body substances (e.g., nasal and oral excretions and secretions), and nonsterile inanimate sources.
4. Administration begins not later than two hours after compounding of the preparation has begun.
5. If administration has not begun within two hours after compounding of the preparation has begun, the preparation is promptly and safely discarded. Immediate-use preparations shall not be stored for later use.