

24 B. An originating pharmacy may outsource a prescription drug order filling to a central fill
25 pharmacy permitted by the Commonwealth if the pharmacy:

26 1. Has the same owner or has entered into a written contract or agreement that outlines the services
27 to be provided and the responsibilities and accountabilities of each pharmacy in compliance with federal
28 and state laws and regulations;

29 2. Shares a common electronic file or has appropriate technology to allow access to sufficient
30 information that is necessary or required to dispense or process a prescription drug order;

31 3. Ensures all state and federal laws regarding patient confidentiality, network security, and use of
32 shared databases are followed; and

33 4. Maintains the prescription information in a readily retrievable manner.

34 C. The pharmacist-in-charge of a central fill pharmacy:

35 1. Shall ensure that the pharmacy maintains and uses adequate storage or shipment containers and
36 shipping processes to ensure drug stability and potency;

37 2. Shall ensure that the filled prescriptions are shipped in containers that are sealed in a manner
38 that would show evidence of having been opened or tampered with;

39 3. May determine the appropriate ratio of technicians and support personnel at the facility per
40 pharmacist; and

41 4. May employ non-technicians to assist in non-dispensing functions such as inventory, delivery,
42 receiving, or packing of completed prescription orders.

43 D. Prescriptions for controlled substances other than ones controlled in Schedule I may be filled
44 by a central fill pharmacy and shall comply with both state and federal statutes and regulations.

45 E. To the extent a pharmacy is acting as a central fill pharmacy, it shall not:

46 1. Fill prescriptions provided directly by a patient or an individual practitioner; or

47 2. Provide or dispense cannabis products not approved by the federal Food and Drug
48 Administration.

49 F. An originating pharmacy that outsources prescription filling to a central fill pharmacy shall,
50 prior to outsourcing the prescription:

- 51 1. Notify patients that their prescription may be filled by another pharmacy; and
52 2. Provide the name of that pharmacy or notify the patient, if the pharmacy is part of a network of
53 pharmacies under common ownership, that any of the network pharmacies may fill the prescription.

54 Patient notification shall be provided through a one-time written notice to the patient or through
55 use of a sign in the pharmacy.

56 G. A central fill pharmacy that delivers prescriptions directly to a patient shall provide written
57 information regarding the prescription with the filled prescription and a toll-free phone number for patient
58 questions. A pharmacist at the originating pharmacy shall offer the patient or the patient's agent
59 information about the prescription drug or device in accordance with Board rules. The provisions of this
60 subsection shall not apply to patients in facilities, including hospitals or nursing homes, where drugs are
61 administered to patients by a person authorized to do so by law.

62 H. The central fill pharmacy shall:

- 63 1. Place on the prescription label:
64 a. The name and address of the originating pharmacy that receives the filled prescription for
65 delivery to the patient or the patient's agent; and
66 b. In some manner indicate which pharmacy filled the prescription;
67 2. Comply with all other labeling requirements of federal and state law; and
68 3. Be exempt from signage requirements intended for patients.

69 I. A central fill policy and procedure manual shall be maintained at both pharmacies and shall be
70 available for inspection. The originating and central fill pharmacies are required to maintain only those
71 portions of the policy and procedure manual that relate to that pharmacy's operations. The manual shall at
72 a minimum contain:

- 73 1. An outline of the responsibilities of the central fill pharmacy and the originating pharmacy,
74 including:
- 75 a. Confidentiality and integrity of patient information procedures;
 - 76 b. Drug utilization review;
 - 77 c. Counseling responsibilities;
 - 78 d. Procedures for return of prescriptions not delivered to a patient and procedures for invoicing
79 medication transfers. Out-of-state pharmacies serviced by a Virginia licensed central fill pharmacy are
80 deemed exempt from subsection A of § 54.1-3434.4 for intra-company transfers of prescription drugs and
81 devices and are not required to register as a non-resident pharmacy;
 - 82 e. Policies for operating a continuous quality improvement program for pharmacy services
83 designed to objectively and systematically monitor and evaluate the quality and appropriateness of patient
84 care, pursue opportunities to improve patient care, and resolve identified problems;
 - 85 f. Requirements for safe delivery of prescriptions to patients;
 - 86 g. Requirements for storage and shipment of prescription medication; and
 - 87 h. Procedures for conducting an annual review of written policies and procedures and for
88 documentation of this review.
- 89 2. Other responsibilities regarding proper handling of a prescription and delivery to a patient or a
90 patient's agent pursuant to federal and state-controlled substances laws and regulations.
- 91 3. The pharmacist verification responsibilities requirements shall be deemed satisfied if:
- 92 a. The pharmacy establishes and follows a policy and procedure manual that complies with
93 subdivision 1; and
 - 94 b. The system is fully automated from the time the medication is stocked into the machine until a
95 completed, labeled, and sealed prescription is produced by the system that is ready for dispensing to the
96 patient. No manual intervention with the medication may occur after the medication is stocked into the

97 system. For purposes of this subdivision, manual intervention shall not include preparing a finished
98 prescription for mailing, delivery, or storage.

99 J. Each central fill pharmacy shall maintain records in accordance with the provisions of federal
100 and state laws and regulations and shall be able to produce records as requested by the Board. The
101 originating pharmacy records shall include the date the request for filling was transmitted to the central
102 fill pharmacy. The central fill pharmacy records shall include:

103 1. The date the filled prescription was mailed or delivered by the central fill pharmacy to the
104 originating pharmacy or patient; and

105 2. If provided directly to a patient, the name and address to which the filled prescription was
106 shipped.

107 K. Any central fill pharmacy may maintain records in an alternative data retention system,
108 including a data processing system or direct imaging system, if:

109 1. The records maintained in the alternative system contain all of the information required on the
110 manual record; and

111 2. The data processing system is capable of producing a hard copy of the record upon the request
112 of the Board, its representative, or other authorized local, state, or federal law-enforcement or regulatory
113 agency.

114 L. A central fill pharmacy shall complete a pharmacy permit application provided by the Board
115 and (i) provide the name of the owner, permit holder, and pharmacist-in-charge of the pharmacy for service
116 of process and (ii) pay the required fee as set by the Board.

117 **2. That the Board of Pharmacy shall promulgate regulations to implement the provisions of this act**
118 **to be effective within 280 days of its enactment.**

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