

# STATE OF NEW YORK

9516

## IN ASSEMBLY

March 16, 2022

Introduced by M. of A. L. ROSENTHAL -- read once and referred to the  
Committee on Insurance

AN ACT to amend the insurance law and the public health law, in relation  
to establishing patient safety and quality assurance measures regard-  
ing the distribution of patient-specific medication from an insurer-  
designated pharmacy

The People of the State of New York, represented in Senate and Assem-  
bly, do enact as follows:

1 Section 1. Section 3217-b of the insurance law is amended by adding a  
2 new subsection (m) to read as follows:

3 (m) (1) No insurer subject to this article shall by contract, written  
4 policy or written procedure allow or require an insurer-designated phar-  
5 armacy to dispense a medication directly to a patient with the intention  
6 that such patient will transport such medication to a physician's  
7 office, hospital or clinic for administration.

8 (2) An insurer subject to this article may offer coverage for, but  
9 shall not require the use of a home infusion pharmacy to dispense ster-  
10 ile intravenous drugs ordered by physicians to patients in their homes  
11 or the use of an infusion site external to a patient's provider office  
12 or clinic.

13 (3) An insurer subject to this article, in order to require the  
14 distribution of patient-specific medication from an insurer-designated  
15 pharmacy to a physician's office, hospital or clinic for administration,  
16 shall establish an agreement with the physician, hospital or clinic  
17 responsible for receiving and administering such medications to ensure  
18 proper receipt, transfer, handling, and storage of the medication prior  
19 to administration that includes, but is not limited to, the following  
20 provisions:

21 (A) provide at least ninety days' notice to providers and insurers  
22 prior to the implementation of such a requirement;

23 (B) have a patient-specific expedited exception process for cases in  
24 which a provider certifies that it is unsafe for a patient to receive  
25 medication from an insurer-designated pharmacy;

26 (C) provide same day delivery of medications;

EXPLANATION--Matter in italics (underscored) is new; matter in brackets  
[-] is old law to be omitted.

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1 (D) make available on-call access to a pharmacist or nurse twenty-four  
2 hours per day, seven days per week;

3 (E) utilize cold chain logistics or other means to ensure a drug  
4 remains at the appropriate temperature through all stages of supply and  
5 storage;

6 (F) provide a medication's pedigree to certify to the physician's  
7 office, hospital or clinic that the drug was handled appropriately  
8 through the supply chain;

9 (G) demonstrate expertise and reliability in risk evaluation and miti-  
10 gation strategy to comply with United States food and drug adminis-  
11 tration reporting requirements;

12 (H) demonstrate the insurer-designated pharmacy is accredited by a  
13 national accreditation organization;

14 (I) demonstrate ability to deliver medications to a physician's  
15 office, hospital or clinic in a clinically appropriate dosage and in a  
16 ready-to-administer dosage form; and

17 (J) offer site neutral payment for such medications to the physician's  
18 office, hospital or clinic administering the medication, which payment  
19 shall include the costs for the providers to intake, store and dispose  
20 of such medications.

21 (4) No insurer subject to this article shall by contract, written  
22 policy or written procedure require (A) a medication requiring sterile  
23 compounding by the provider, or (B) a medication with a patient-specific  
24 dosage requirement to be based upon lab or test results on the day of  
25 the patient visit, to be distributed from an insurer-designated pharmacy  
26 to a physician's office, hospital or clinic for administration.

27 § 2. Section 4325 of the insurance law is amended by adding a new  
28 subsection (n) to read as follows:

29 (n) (1) No corporation organized under this article shall by contract,  
30 written policy or written procedure allow or require an insurer-desig-  
31 nated pharmacy to dispense a medication directly to a patient with the  
32 intention that the patient will transport the medication to a physi-  
33 cian's office, hospital or clinic for administration.

34 (2) A corporation organized under this article may offer coverage for,  
35 but shall not require the use of a home infusion pharmacy to dispense  
36 sterile intravenous drugs ordered by physicians to patients in their  
37 homes or the use of an infusion site external to a patient's provider  
38 office or clinic.

39 (3) A corporation organized under this article, in order to require  
40 the distribution of patient-specific medication from an insurer-desig-  
41 nated pharmacy to a physician's office, hospital or clinic for adminis-  
42 tration, shall establish an agreement with the physician, hospital or  
43 clinic responsible for receiving and administering such medications to  
44 ensure proper receipt, transfer, handling, and storage of the medication  
45 prior to administration that includes, but is not limited to, the  
46 following provisions:

47 (A) provide at least ninety days' notice to providers and insureds  
48 prior to the implementation of such a requirement;

49 (B) have a patient-specific expedited exception process for cases in  
50 which a provider certifies that it is unsafe for a patient to receive  
51 medication from an insurer-designated pharmacy;

52 (C) provide same day delivery of medications;

53 (D) make available on-call access to a pharmacist or nurse twenty-four  
54 hours per day, seven days per week;

1 (E) utilize cold chain logistics or other means to ensure a drug  
2 remains at the appropriate temperature through all stages of supply and  
3 storage;

4 (F) provide a medication's pedigree to certify to the physician's  
5 office, hospital or clinic that the drug was handled appropriately  
6 through the supply chain;

7 (G) demonstrate expertise and reliability in risk evaluation and miti-  
8 gation strategy to comply with United States food and drug adminis-  
9 tration reporting requirements;

10 (H) demonstrate the insurer-designated pharmacy is accredited by a  
11 national accreditation organization;

12 (I) demonstrate ability to deliver medications to a physician's  
13 office, hospital or clinic in a clinically appropriate dosage and in a  
14 ready-to-administer dosage form; and

15 (J) offer site neutral payment for such medications to the physician's  
16 office, hospital or clinic administering the medication, which payment  
17 shall include the costs for the providers to intake, store and dispose  
18 of such medications.

19 (4) No corporation organized under this article shall by contract,  
20 written policy or written procedure require (A) a medication requiring  
21 sterile compounding by the provider, or (B) a medication with a  
22 patient-specific dosage requirement to be based upon lab or test results  
23 on the day of the patient visit, to be distributed from an insurer-de-  
24 signed pharmacy to a physician's office, hospital or clinic for admin-  
25 istration.

26 § 3. Section 4406-c of the public health law is amended by adding a  
27 new subdivision 11 to read as follows:

28 11. (a) No health care plan shall by contract or written policy or  
29 written procedure allow or require a plan-designated pharmacy to  
30 dispense a medication directly to a patient with the intention that the  
31 patient will transport the medication to a physician's office, hospital  
32 or clinic for administration.

33 (b) A health care plan may offer coverage for, but shall not require  
34 the use of a home infusion pharmacy to dispense sterile intravenous  
35 drugs ordered by physicians to patients in their homes or the use of an  
36 infusion site external to a patient's provider office or clinic.

37 (c) A health care plan, in order to require the distribution of  
38 patient-specific medication from an insurer-designated pharmacy to a  
39 physician's office, hospital or clinic for administration, shall estab-  
40 lish an agreement with the physician, hospital or clinic responsible for  
41 receiving and administering such medications to ensure proper receipt,  
42 transfer, handling, and storage of the medication prior to adminis-  
43 tration that includes, but is not limited to, the following provisions:

44 (i) provide at least ninety days' notice to providers and enrollees  
45 prior to the implementation of such a requirement;

46 (ii) have a patient-specific expedited exception process for cases in  
47 which a provider certifies that it is unsafe for a patient to receive  
48 medication from a plan-designated pharmacy;

49 (iii) provide same day delivery of medications;

50 (iv) make available on-call access to a pharmacist or nurse twenty-  
51 four hours per day, seven days per week;

52 (v) utilize cold chain logistics or other means to ensure a drug  
53 remains at the appropriate temperature through all stages of supply and  
54 storage;

1 (vi) provide a medication's pedigree to certify to the physician's  
2 office, hospital or clinic that the drug was handled appropriately  
3 through the supply chain;

4 (vii) demonstrate expertise and reliability in risk evaluation and  
5 mitigation strategy to comply with United States food and drug adminis-  
6 tration reporting requirements;

7 (viii) demonstrate the insurer-designated pharmacy is accredited by a  
8 national accreditation organization;

9 (ix) demonstrate ability to deliver medications to a physician's  
10 office, hospital or clinic in a clinically appropriate dosage and in a  
11 ready-to-administer dosage form; and

12 (x) offer site neutral payment for such medications to the physician's  
13 office, hospital or clinic administering the medication, which payment  
14 shall include the costs for the providers to intake, store and dispose  
15 of such medications.

16 (d) No health care plan shall by contract, written policy or written  
17 procedure require (i) a medication requiring sterile compounding by a  
18 provider, or (ii) a medication with a patient-specific dosage require-  
19 ment to be based upon lab or test results on the day of the patient  
20 visit, to be distributed from a plan-designated pharmacy to a physi-  
21 cian's office, hospital or clinic for administration.

22 § 4. This act shall take effect immediately.