

RESOLUTION 07.2020-05 (A-21)
LOT NUMBER REPLACEMENT ON DISPENSED MEDICATION

ISMS Board Action Taken on 01/30/2021

Did not adopt Resolution 07.2020-05 (A-21).

Medical Legal Council Recommendation to ISMS Board on 01/30/2021

At its October 2020 meeting, the Council was provided with a copy of the resolution, a copy of the relevant section of the Illinois Food, Drug & Cosmetic Act, and a summary of the Drug Supply Chain Security Act, which the Council reviewed. The author of the resolution was able to join the meeting and engaged in a discussion of the issue with the Council. The author provided that the intent of the resolution is to assist patients with recalls of medication, and having the lot number printed on the medication packaging provided to the patient would solve this issue. The Council noted that this is not an infrequent issue, and suggested modifying the language of the resolution to ensure that prescriptions as dispensed to patients include adequate traceability. The Council recommended that the Board of Trustees adopt Resolution 07.2020-05 (A-21) as amended:

RESOLVED, that ISMS support the requirement of including accurate traceability, including but not limited to placing “lot” numbers, on the label of amber pill bottles dispensed; and be it further

RESOLVED, that a similar resolution be forwarded to the AMA.

The Board of Trustees considered the recommendation of the Council at its meeting on October 24, 2020 and expressed concerns about what pharmacists would think of the resolution, and additionally noted that some pharmacy pill bottles come in colors beyond amber. Staff reached out to the Illinois Pharmacists Association (IPhA) and inquired about their opinion on the resolution. The IPhA stated that they have previously opposed the inclusion of lot numbers on prescription labels, as “real estate” on a prescription label is very valuable and already requires a number of needed data elements. They additionally opined that the lot number is not a data element that impacts the patient’s use of the medication, and the label needs to have information for the proper identification and usage of a prescription bottle, vial, tube, etc. The IPhA also stated that most pharmacy management and record systems allow the inputting of the lot number for the medication. Currently, vaccines are the only medication/biologic that are required to have the lot number recorded. In the case of a drug recall, the current process is for wholesalers/manufacturers to inform pharmacies, and the pharmacist to contact

41 patients if they determine a need. Additionally, recent enhancements to the Drug Supply
42 Chain Security Act added a unique QR-like code on stock packages/bottles sent to
43 pharmacies that improve the tracking and identification of a recalled product. The IPhA
44 did not opine whether, in a situation where a patient were to call a pharmacy and inquire
45 if their medication was recalled, the pharmacist would be able to definitively answer
46 that and identify whether that lot of medication was recalled.

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48 Upon second review of the resolution, the Council remained steadfast that
49 pharmaceutical traceability is an issue of importance to Illinois physicians and patients,
50 and that while current prescription labels offer some traceability, there is no way for a
51 patient to know if a prescription drug has been recalled without lot number placement
52 on the label. The Council acknowledged that although there is limited space on the
53 prescription label, it is a matter of patient safety to include traceability information on
54 it. In addition to its previous recommended amendment, the Council recommended that
55 the resolution be modified to address the issue of pill bottles that come in colors beyond
56 amber.

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58 The Medical Legal Council recommends that the ISMS Board of Trustees adopt
59 Resolution 07.2020-05 (A-21), as amended:

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62 traceability, including but not limited to placing “lot” numbers, on the label of ~~amber~~
63 ~~pill bottles~~ medications dispensed; and be it further

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65 RESOLVED, that a similar resolution be forwarded to the AMA.