



# STATE OF CONNECTICUT

## DEPARTMENT OF CONSUMER PROTECTION

**TO:** Legislative Regulation Review Committee  
Capitol Building, Hartford, Connecticut

**DATE:** July 2, 2012

**SUBJECT:** Proposed Regulations Concerning Non-Sterile Compounding

### SUMMARY OF TESTIMONY

The Department held a properly noticed public hearing on **May 30, 2012**. The administrative record was held open for one week to allow additional written testimony.

### IN SUPPORT OF ADOPTION:

1. John Gadea, the Director of the Drug Control Division of the Department of Consumer Protection (verbal and written comments).

### OPPOSED TO ADOPTION:

No verbal or written comments opposed the adoption of the proposed regulations.

### SUGGESTING MODIFICATIONS TO THE TEXT:

1. Connecticut Hospital Association (written comments marked Exhibit "E"); two comments were provided and two specific revisions, to 20-576-69(2) and 20-576-70, were requested.
2. Connecticut Veterinary Medical Association (written comments marked Exhibit "G"); requested that the time limitation within Section 20-576-71(c) for supplies on-hand be extended from two weeks to at least thirty days. Said request was granted by the Department to allow a thirty day supply.

A copy of the official transcript of the public hearing is also being provided with this summary, together with copies of any written testimony. If the members of the Committee should have any questions, they may contact Attorney Jerry Padula at 860-713-6087 or via e-mail at [Jerry.Padula@CT.gov](mailto:Jerry.Padula@CT.gov).

5/30/2012

In Re: Non-Sterile Compounding

Transcription

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REGULATION HEARING  
NON-STERILE COMPOUNDING

MAY 30, 2012

HEARING OFFICER: JERRY PADULA

**TRANSCRIPTION PLUS, LLC**

40 Acorn Lane, Bristol, Connecticut 06010/(860) 583-2818

1 MR. PADULA: Okay. Good morning everyone. My name is  
2 Jerry Padula, and I'm an attorney with the Connecticut  
3 Department of Consumer Protection. I've been designated by  
4 Commissioner William Rubenstein to be the hearing officer for  
5 this morning's Public Hearing on Proposed Regulations Concerning  
6 Non-Sterile Compounding. Today is May 30, 2012. The time right  
7 now is 10:36 in the morning. We're here in Room 119 of the  
8 State Office Building, which is located at 165 Capitol Avenue in  
9 the Capital City of Hartford, Connecticut. On April 24, 2012,  
10 the Department of Consumer Protection published a Notice of  
11 Intent to Amend Regulations in the *Connecticut Law Journal*.  
12 These regulations are being proposed in accordance with the  
13 authority granted in the Connecticut General Statutes, §4-168  
14 and 20-576. For the record, a copy of that **Connecticut Law**  
15 **Journal Notice**, which was published on April 24, 2012, will be  
16 entered as Exhibit A.

17 The **Fiscal Note** prepared by the agency, which reflects no,  
18 uh, no fiscal impact on the department, will be made part of the  
19 record as Exhibit B.

20 And the **Small Business Impact Statement**, which is referred  
21 to in the introduction section of the Law Journal Notice, will  
22 be marked as Exhibit C. And that's a 2-page document.

23 We did not receive any other written submissions, uh, into  
24 the record, but anything submitted today will be marked as an  
25 exhibit accordingly.

1           The department prepared a Small Business Impact Statement  
2 analysis and has notified the Department of Small Business  
3 Affairs at the Department of Economic Development of our intent  
4 to amend these regulations. Pursuant to Connecticut General  
5 Statutes §4-168a, when drafting these proposed regulations, the  
6 Department considered methods that would accomplish the  
7 objectives the applicable statutes while minimizing the adverse  
8 impact on small businesses. This agency has specifically  
9 considered the 5 methods that are listed in subsection(b) of  
10 Connecticut General Statutes §4-168a.

11           Now at this point, we will begin by having the individuals  
12 who signed the speaker sign-up sheet come forward to give their  
13 comments. You may leave written comments with me as well, and  
14 those documents will be entered into the record at this hearing.  
15 The first person to speak is John Gadea, Director of the  
16 Department of Consumer Protection's Drug Control Division.

17           MR. GADEA: This is John Gadea, Director of State Drug  
18 Control, um, regarding the Non-Sterile Compounding, uh,  
19 regulation that had been submitted. Um, the division and the  
20 department are in favor of the, uh, changes and will allow for,  
21 uh, greater flexibility and greater compliance with, uh, the  
22 United States Pharmacopeia 795 and also, uh, creating the  
23 ability to provide, um, office stock of compounded products.

24           MR. PADULA: Thank you, Director Gadea. Uh, I'll note  
25 that there's no one else on the speaker sign-up, uh, sheet. And

1 we did have the hearing today noticed for 10:00, so we did allow  
2 some extra time for interested parties to come before us. Um,  
3 at this point, with no one else here to testify, um, the agency  
4 will be reviewing any of the testimony and documents that have  
5 been submitted. At this point, what we'll do is leave the  
6 record open for written documents, um, for 1 week, and I'll, uh,  
7 I'll put the date on that until the close of business on Friday,  
8 June 8, in case any interested parties wish to submit written  
9 comments since no one else is here to testify, uh, on the record  
10 orally. Again, the record will be open for 1 week up through  
11 the close of business on Friday, June 8, again, to allow any  
12 interested parties an opportunity to provide further written  
13 comment to the department. Those comments can be directed to  
14 the Commissioner, William Rubenstein.

15       The agency will review all those documents and testimony  
16 that's received into the record and consider whether any  
17 revision should be made to the regulations as they are published  
18 in the Connecticut Law Journal. And pursuant to the  
19 Administrative, Uniform Administrative Procedures Act, we will  
20 then forward the proposed regulations to the Attorney General's  
21 office to be reviewed for legal sufficiency. If approved, the  
22 regulations will then be forwarded to the Regulation Review  
23 Committee of the General Assembly for consideration and approval  
24 before filing with the Secretary of State. And these  
25 regulations will be effective upon filing with the Secretary of

1 State.

2           Okay, with that, I'll note the time is now 10:41, and this  
3 public hearing is now adjourned. Thank you all for attending.

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CERTIFICATE

I, Karen Johnson, do hereby certify that the foregoing transcription is a true and accurate record to the best of my ability, transcribed from an audio cassette, of the Regulation Hearing on Non-Sterile Compounds held on Wednesday, May 30, 2012.

IN WITNESS WHEREOF, I sign my name this 28<sup>th</sup> day of June, 2012.

Karen Johnson  
Karen Johnson

June 28, 2012  
June 28, 2012



Commissioner William Rubenstein  
Department of Consumer Protection  
165 Capitol Avenue  
Hartford, CT 06106

June 5, 2012

Commissioner Rubenstein:

We represent the Connecticut Veterinary Medical Association, the professional society of the veterinarians of the State of Connecticut. We write to indicate our opposition to proposed new regulations regarding non-sterile compounding, specifically section 20-576-21 c.

Limiting the quantity of non-sterile compounded medications to practitioners will adversely affect animal health. To limit practitioners to two week supplies will regularly risk exhausting hospital supplies of critical medications, especially in high volume practices or in practices open when compounding pharmacies are not, such as emergency practices. In veterinary medicine this is especially important as many medications we use are not formulated in proper doses for our small patients, or may need to be administered in other forms, such as chewable or transdermal, in order to ensure patient compliance. Further, the effect of the regulations will be to increase costs to pet owners, as more frequent purchasing will increase the cost of in hospital medications. We request at least a 30 day supply of medications be allowed to be on hand.

Thank you,

Christopher Gargamelli DVM  
President, Connecticut Veterinary Medical Association

CC: John Gadea  
Attorney Jerry Padula





May 21, 2012

The Honorable William M. Rubenstein, Commissioner  
Department of Consumer Protection  
Room 103, State Office Building  
165 Capitol Avenue  
Hartford, Connecticut 06106

RE: Non-Sterile Compounding (Proposed Sections 20-576-69 through 20-576-73)

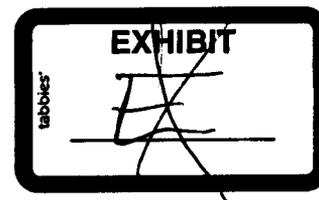
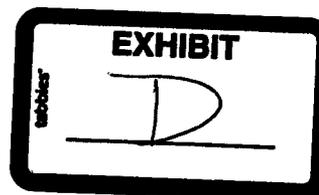
Dear Commissioner Rubenstein:

Recently, the Department of Consumer Protection (the "Department") published a Notice of Intent to Amend Regulations ("Notice") in the April 24, 2012 issue of the Connecticut Law Journal. The Notice indicates that the Department intends to amend the Regulations of Connecticut State Agencies pertaining to the classification of pharmacies licensed by the Department.

Current regulations now provide seven classes of pharmacies licensed by the Department: (1) community pharmacies; (2) infusion therapy pharmacies; (3) long-term care pharmacies; (4) nuclear pharmacies; (5) specialized drug pharmacies; (6) specialty pharmacies; and (7) sterile compounding pharmacies. The proposed regulations would add new sections 20-576-69 to 20-576-73 to create an additional, eighth class of pharmacies, known as "non-sterile compounding" pharmacies.

The Connecticut Hospital Association ("CHA") respectfully offers the following comments and suggested revisions on the Notice and proposed amendment of the regulations.

- **Comment:** The proposed regulations do not clearly indicate that they are intended to apply only to pharmacies licensed by the department. If not revised, the proposed regulations are likely to cause confusion among pharmacists practicing in hospitals and other facilities not licensed by the Department.
- **Comment:** The proposed regulations are inconsistent with existing regulations for other classes of pharmacies, which specifically reference Section 20-594 of the General Statutes. For example, the definition for sterile compounding pharmacies in Section 20-576-64 of the existing regulations specifically applies to pharmacies "licensed pursuant to section 20-594 of the Connecticut General Statutes ... but does not include a pharmacy that is part of a licensed hospital." This will also likely lead to confusion.



CHA respectfully suggests that, to avoid confusion, the proposed regulations be clarified by making the following minor revisions (added language is underlined).

- ***Suggested Revision to proposed Section 20-576-69(2):***

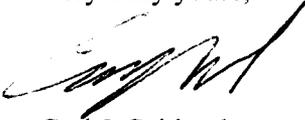
(2) "Non-sterile compounding pharmacy" means a pharmacy **licensed pursuant to section 20-594 of the General Statutes** that dispenses non-sterile compounded pharmaceutical products, **but does not include a pharmacy that is part of a licensed hospital**; and

- ***Suggested Revision to proposed Section 20-576-70:***

The purpose of sections 20-576-69 to 20-576-73, inclusive, of the Regulations of Connecticut State Agencies is to ensure positive patient outcomes through the provision of standards for (1) pharmacist care; (2) the preparation, labeling, and distribution of non-sterile compounded pharmaceuticals by pharmacies **licensed pursuant section 20-594 of the General Statutes**; and (3) product quality and characteristics.

Thank you in advance for your consideration of, and attention to, this matter.

Very truly yours,



Carl J. Schiessl  
Director, Regulatory Advocacy

cc: John Gadea, Jr., Director, Drug Control Division  
Steven J. Schwane, Legal Division  
✓ Jerry P. Padula, Office of the Commissioner