

Report From Agency

**STATE OF WISCONSIN
DEPARTMENT OF SAFETY AND PROFESSIONAL SERVICES**

**IN THE MATTER OF RULEMAKING :
PROCEEDINGS BEFORE THE : REPORT TO THE LEGISLATURE
DEPARTMENT OF SAFETY AND : CR 15-100
PROFESSIONAL SERVICES :**

I. THE PROPOSED RULE:

The proposed rule, including the analysis and text, is attached.

II. REFERENCE TO APPLICABLE FORMS: n/a

III. FISCAL ESTIMATE AND EIA:

The Fiscal Estimate and EIA is attached.

IV. DETAILED STATEMENT EXPLAINING THE BASIS AND PURPOSE OF THE PROPOSED RULE, INCLUDING HOW THE PROPOSED RULE ADVANCES RELEVANT STATUTORY GOALS OR PURPOSES:

Hydrocodone combination products were rescheduled to Schedule II controlled substances by the federal government effective October 6, 2014 and the Wisconsin Controlled Substances Board effective November 1, 2014. The scheduling change removed the ability for optometrists to prescribe hydrocodone combination products due to a statutory prohibition on prescribing schedule II controlled substances. 2015 Act 34 specifically added language to the statutes to allow optometrists to prescribe hydrocodone combination products pursuant to promulgation of rules.

V. SUMMARY OF PUBLIC COMMENTS AND THE BOARD'S RESPONSES, EXPLANATION OF MODIFICATIONS TO PROPOSED RULES PROMPTED BY PUBLIC COMMENTS:

The Department held a public hearing on February 4, 2016. The following people either testified at the hearing, or submitted written comments:

Peter Theo representing the Wisconsin Optometric Association
Robert Schulz representing the Wisconsin Optometry Examining Board

The Department summarizes the comments received either by hearing testimony or by written submission as follows:

The Wisconsin Optometric Association and the Wisconsin Optometry Examining Board support the proposed rules.

The Department explains modifications to its rule-making proposal prompted by public comments as follows:

The Department did not make any modifications prompted by public comments.

VI. RESPONSE TO LEGISLATIVE COUNCIL STAFF RECOMMENDATIONS:

Comment 2b: The listing of the two formulations of hydrocodone should be inserted in s. SPS 10.01 (10) (a), with the other oral analgesics, rather than in sub. (10) (am).

Response: The formulations of hydrocodone are not inserted with the oral analgesics because it addresses hydrocodone combination products regardless of how administered.

Comment 3: Based on the phrasing in s. SPS 10.01 (1) (am) (intro.), it appears to be intended that “only” the two listed formulations of hydrocodone are permitted. However, the phrasing in sub. (1) (intro.), “Therapeutic pharmaceutical agents include but are not limited to:”, is written as a list of examples, which is not an exhaustive list. To reconcile the two phrases, the department should consider amending the second sentence in sub. (10) (intro.) to state that either:

- a. “Each of the following is a therapeutic pharmaceutical agent:”.
- b. “Therapeutic pharmaceutical agents include, and, except as provided in par. [(a) 5. and 6.], are not limited to:”

Response: The Department accepts this comment in part. The Department utilizes current rule manual language and is modifying the second sentence in SPS 10.01 (10) (intro) to read:

“Except as provided in par. (am), therapeutic pharmaceutical agents include all of the following:”

All of the remaining recommendations suggested in the Clearinghouse Report have been accepted in whole.

VII. REPORT FROM THE SBRRB AND FINAL REGULATORY FLEXIBILITY ANALYSIS:

This rule does not affect small businesses.