

Report From Agency

**STATE OF WISCONSIN
PHARMACY EXAMINING BOARD**

**IN THE MATTER OF RULE-MAKING : REPORT TO THE LEGISLATURE
PROCEEDINGS BEFORE THE : ON CLEARINGHOUSE RULE 08-051
PHARMACY EXAMINING BOARD : (s. 227.19 (3), Stats.)**

I. THE PROPOSED RULE:

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

II. REFERENCE TO APPLICABLE FORMS:

No new or revised forms are required by these rules.

III. FISCAL ESTIMATES:

The department estimates that this rule will require staff time in the Office of Legal Counsel. The total one-time salary and fringe costs are estimated at \$2,457. The department finds that this rule has no significant fiscal effect on the private sector.

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

This proposed rule-making order implements the statutory changes set forth in the drug distributor portions of 2007 Wisconsin Act 20 relating to the regulation of wholesale prescription drug distributors. Several key areas are addressed by this proposed rule-making, including, newly required enhanced qualifications for distributor licensing, inspection requirements, identification and qualification of a designated representative, bonding requirements and additional recordkeeping requirements including where appropriate, the maintaining of drug distribution pedigrees.

V. NOTICE OF PUBLIC HEARING:

A public hearing was held on July 23, 2008. There were no appearances at the public hearing.

Written comments were received from Michelle Cope, Manager, Legislative and Regulatory Affairs, National Association of Chain Drug Stores (NACDS), Alexandria, Virginia.

NACDS raised the issue that the change at s. 450.01 (23) (e), Stats., had excluded from the definition of whole distribution “minimal quantities of prescription drugs by retail

pharmacies to licensed practitioners for office use.” NACDS requested that the board clarify this exemption. The board noted that this provision has been codified in s. Phar 13.02 (11) (e).

NACDS also requested an exemption to the bond provision be added to the surety bond section based upon intracompany transfers. The board declines to amend this portion of the rule given that the governing statute contains the intracompany exemption and numerous others, which cannot, and need not, be listed in the surety bond section of the proposed rules.

VI. RESPONSE TO LEGISLATIVE COUNCIL STAFF RECOMMENDATIONS:

Comment 2.b. The rule preface states that s. 227.137, Stats., may require that an economic impact report be prepared prior to agency submission of a rule to the Wisconsin Legislative Council. The statute was amended in 2005 Wisconsin Act 249 to provide that an economic impact report, if required, must be prepared before submission of the rule to the Legislature for final review.

Response: On page 4 of the proposed rule-making order under “Analysis and supporting documents used to determine effect on small business or in preparation of economic impact report,” the Department of Regulation and Licensing is not included as an “agency” in s. 227.137, Stats.

The other recommendations suggested in the Clearinghouse Report were accepted in whole.

VII. FINAL REGULATORY FLEXIBILITY ANALYSIS:

These rules will have no significant economic impact on small businesses, as defined in s. 227.114 (1), Stats.