Report From Agency

STATE OF WISCONSIN CONTROLLED SUBSTANCES BOARD

IN THE MATTER OF	:	
RULE-MAKING PROCEEDINGS	:	REPORT TO THE LEGISLATURE
BEFORE THE CONTROLLED	:	CSB 3
SUBSTANCES BOARD	:	CR 12-010

I. THE PROPOSED RULE:

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

II. REFERENCE TO APPLICABLE FORMS:

All forms currently used for applying, amending, and maintaining special use authorization permits are unchanged by this rule-making proposal. These forms are available at http://drl.wi.gov/prof_docs_list.asp?profid=11&locid=0.

III. FISCAL ESTIMATE AND EIA:

The Fiscal Estimate and EIA are attached.

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 administrative code chapter is promulgated under Wis. Stat. s. 961.335, and relates to the Controlled Substances Board's issuance of special use authorization permits (SUAs). The purposes of the proposed rules are to better facilitate the application process for individuals seeking a permit or an amendment thereof; to guide the Board in determining whether to grant or deny a permit; to clarify procedures related to SUAs for the department's credentialing personnel; and to provide for enforcement of violations of a permit. The rules include definitions of terms used in the chapter; general requirements for SUAs; procedures and criteria for obtaining an initial permit and amending an existing permit; limitations on drugs and drug quantities for use in training narcotics dogs; requirements for recordkeeping, records retention, and disclosure of records related to SUAs; and the acts constituting a violation of an SUA permit, which may result in suspension or revocation of the special use authorization permit.

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

The Controlled Substances Board held a public hearing on February 27, 2012. No testimony was received at the hearing, nor did the Board receive any written comments.

On its own motion, the Board replaced the phrase "dog training" with "euthanasia" under s. CSB 3.04(5)(a), because municipal law enforcement does not train dogs, but rather, euthanizes them.

VI. RESPONSE TO LEGISLATIVE COUNCIL STAFF RECOMMENDATIONS:

Comment 4.a.: In the rule summary and the proposed rule, the references to statutes should be followed by ", Stats." [s. 1.07 (2), Manual.]

Response: Accepted and noted that accepted for citations to Wisconsin statutes only.

Comment 4.b.: In the rule summary, the agency should review its references to federal law and laws in adjacent states for accuracy. For example, in the summary of federal law, it appears that "21 C.F.R. s. 1301 (13)" should be replaced with "21 C.F.R. s. 1303.13".

Response: Accepted and noted that revisions to all citations to federal law and laws in adjacent states were made according to the most current edition of the Bluebook.

Comment 5.a.: Throughout the proposed rule, "will" and "must" should be replaced with "shall". [s. 1.01 (2), Manual.]

Response: Accepted. The Board made all changes suggested in Comment 5.a. Prompted by this Comment, the Board reviewed the entire chapter for instances of the word "may." For example, the Board concluded that the use of "may" in the second sentence of the proposed s. CSB 3.03 (3) should be changed to "shall," to denote that only the authorized substances in the authorized amounts can be used by the permit holder.

Comment 5.d.: In s. CSB 3.02 (4), ", but are not limited to," should be deleted. The term "includes" means "includes, but is not limited to". [s. 1.01 (7) (d), Manual.] In addition, the agency might consider the following definition: "Special use' includes scientific research, instructional activities, chemical analysis, drug-detecting animal training, and euthanasia in humane shelters." The inclusion of "manufacture, obtain, possess, use, administer, or dispense" in the definition appears to be unnecessary.

Response: Rejected in whole. Although the Board recognizes that the term "includes" means "includes, but is not limited to," the Board elected to keep the phrase "includes, but is not limited to" in the proposed rule to make it clear to the reader that the list of special uses shown is not exclusive. The Board also kept the phrase "manufacture, obtain, possess, use, administer, or dispense" in s. CSB 3.02 (4) to explain that all of the specified activities require the individual engaging therein to obtain an SUA permit, unless for a medicinal-related use.

Comment 5.g.: In s. CSB 3.03 (2), "authorized purposes" should be replaced with "purposes authorized in the permit" in the last sentence.

Response: Rejected. The Board found that the phrase "purposes authorized in the permit" does not make the phrase "authorized purposes" more understandable in the rule as drafted, and thus, adds unnecessary words.

Comment 5.p.: In s. CSB 3.04 (2) (b), "Institutional Animal Care and Use Committee approval" should be replaced with "approval by the institutional animal care and use committee". Similarly, in s. CSB 3.04 (2) (c), "Institutional Review Board approval" should be replaced with "approval by the institutional review board". In addition, the agency might consider defining "institutional animal care and use committee" and "institutional review board".

Response: Rejected in whole. In 21 C.F.R. s. 814.124 (2011), the title reference to Institutional Review Board is capitalized. http://edocket.access.gpo.gov/cfr_2011/aprqtr/pdf/21cfr814.124.pdf.

In 9 C.F.R. s. 2.31 (2011), which sets forth the requirements for research facilities using animals as research subjects, the term "Institutional Animal Care and Use Committee" (IACUC) is capitalized. See <u>http://frwebgate2.access.gpo.gov/cgi-bin/PDFgate.cgi?WAISdocID=fGMnjP/0/2/0&WAISaction=retrieve//</u>.

Moreover, on its own website, at <u>http://www.iacuc.org/aboutus.htm</u>, the IACUC's references to itself are capitalized. The two institutions are actual entities, and as such, their names should be capitalized. In addition, the capitalization of these entities' names makes defining them unnecessary.

Comment 5.s.: The contents of s. CSB 3.04 (4) (c) should be placed in s. CSB 3.04 (8).

Response: Rejected. The Board will require all private narcotic dog trainers applying for an SUA permit to appear before the Board. The rule in s. CSB 3.04 (7) (formerly 3.04(8), but the former subsection (7) was deleted in response to the Board's acceptance of Comment 5.w, which moved the former subsection (8) to the current subsection (7)) provides that the Board *may* require an appearance by applicants seeking permits (for other types of activities) if additional information is required. Moreover, the Board concluded that the change proposed by Comment 5.s would be confusing to the reader if one of the requirements for private narcotic dog trainers is located in another subsection other than under s. CSB 3.04 (4).

Comment 5.y.: In s. CSB 3.05, the agency should replace the names of the controlled substances with the technical names of those substances in ch. 961, Stats.

Response: Rejected. The Board concluded that using the commonly-recognized names of the substances included in s. CSB 3.05 will make the rule more user-friendly. For example, law enforcement would not recognize the technical names. Additionally, there is no scientific or technical name for crack cocaine that is different from that used for cocaine powder.

Comment 5.z.: In s. CSB 3.05 (6), use of "i.e." is not appropriate in drafting rules or statutes. The technical name for crack cocaine, as set forth in ch. 961, Stats., should be used and there should be no reference to "crack cocaine".

Response: Accepted in part, rejected in part. No technical name for crack cocaine appears in ch. 961, Stats., and the Schedule II drug cocaine is referred as "cocaine" at s. 961.16 (2) (b) 1., Stats.

All remaining recommendations suggested in the Clearinghouse Report were accepted in whole.

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

These rules will not affect small businesses fiscally or economically, as they track legislation that has been in effect for many years. For that reason, review by the Small Business Regulatory Review Board was unnecessary. The regulatory flexibility analysis for this final draft of the proposal has not changed from the analysis applicable to the initial draft.