

Report From Agency

ADMINISTRATIVE RULES DEPARTMENT OF HEALTH SERVICES REPORT TO THE LEGISLATURE CLEARINGHOUSE RULE 10-091

- Ch. DHS 12, Caregiver Background Checks and Appendix A**
- CH. DHS 83, Community-Based Residential Facilities**
- Ch. DHS 88, Licensed Adult Family Homes**
- Ch. DHS 124, Hospitals**
- Ch. DHS 127, Rural Medical Centers**
- Ch. DHS 148, Cancer and Chronic Disease Drug Repository Program**
- Ch. DHS 165, Laboratory Certification**

Basis and Purpose of Proposed Rule

Sections 50.02 (2), 50.033 (2), 50.065 (1) (ag) 1. a. (2) (d), (4), (5) and (6) (b) and (c), 50.36 (1), 50.51 (2), 227.11 (2) (a), and 255.056 (7), Stats., requires the department to develop regulations and standards for the care, treatment, health, safety, rights, welfare and comfort of residents in community-based residential facilities, licensed adult family homes, hospitals, rural medical centers, to establish standards for caregivers to protect from harm clients served by department-regulated entities, to promulgate rules for medical facilities and pharmacies to accept and dispense donated drugs or supplies.

The department proposes to update, correct or remove outdated rule provisions and cross-references relating to caregiver background checks, community-based residential facilities, licensed adult family homes, hospitals, rural medical centers, the cancer and chronic disease drug repository program and laboratory certification as follows:

Caregiver Background Checks

- Chapter DHS 12, Appendix A, is a list of Wisconsin crimes and other offenses that the legislature under s. 50.065, Stats., determined either require rehabilitation review approval before a person may work as a caregiver, reside as a non-client resident at or contract with an entity, or that act to permanently bar a person from receiving approval to be a foster parent. Over the years, the legislature has revised the crimes and offenses listed in s. 50.065, Stats., making Appendix A incomplete and outdated. To ensure that the list of crimes and offenses now listed by the department in Appendix A is available to the public in an accurate and timely manner, the department proposes to repeal Appendix A and publish the list of crimes and offenses affecting caregiver eligibility on the department's website at dhs.wisconsin.gov. The department also proposes to update the list of entities, as defined under s. 50.065, Stats., which are

subject to the caregiver background law, clarify rule provisions and correct a cross reference.

Community-Based Residential Facilities

- The department proposes to amend ch. DHS 83 to clarify and correct certain provisions in the rule relating to health monitoring, administrator training, resident assessment, doors and construction type, make other minor changes and to update charts, cross-references and links. Specifically, the department proposes to amend s. DHS 83.38 (1) (g), to permit an advanced practice nurse as defined in s. N 8.02 (1) to complete the annual physical health examination of residents. The department proposes to repeal s. DHS 83.59 (2) (e), which requires 2-way hardware on toilet room doors that swing into a toilet room. The requirement applies only to new construction and facilities over 20 beds. When the department revised ch. DHS 83 in January 2009, the department unintentionally made this a requirement for all CBRFs. The rule should not have been changed because the requirement is not appropriate for non-institutional settings. The department also proposes to update Appendix A, which lists contact information for regional offices of the Division of Quality Assurance, Bureau of Assisted Living.

Licensed Adult Family Homes

- Section DHS 88.06 (1) (a) 4. and (4) currently requires an adult family home to provide information and referral of a prospective resident to the aging and disability resource center. These requirements were repealed under 2007 Wisconsin Act 20. 2007 Wisconsin Act 20 repealed s. 50.033 (2r), (2s) and (2t), Stats., making the provisions in s. DHS 88.06 (1) (a) 4. and (4) no longer valid. The department proposes to remove the information and referral requirements from ch. DHS 88. Section DHS 88.10 (5) (b) relating to resident grievance procedures contains an incorrect cross-reference concerning patient storage space. The department proposes to correct the cross-reference and reference the grievance resolution procedures in ch. DHS 94. The department also proposes to update Appendix A which lists contact information for the regional offices of the Division of Quality Assurance, Bureau of Assisted Living.

Hospitals

- Section DHS 124.14 (3) (a) 16., relating to anatomical gifts contains a cross-reference to s. DHS 124.05 (3) (i) 1., which was repealed in a recent revision of ch. DHS 124. The department proposes to correct the cross reference to refer to the patient's health agent as defined in s. 157.06 (2) (a), Stats. The department also proposes to repeal the outdated standard in Appendix A, Food and Nutrition Board, National Academy of Sciences, Recommended Daily Dietary Allowances, revised in 1980, and amend the reference to the standard in s. DHS 124.16 (5) (c). The department does not intend to adopt a replacement standard. Nutritional needs of patients should be met in accordance with physicians' orders and based on current recognized dietary standards.

Rural Medical Centers

- Section DHS 127.02 (2) defines an ambulatory surgery center to have the meaning given in s. 49.45 (6r) (a) 1., Stats. 1997 Wisconsin Act 252 repealed s. 49.45 (6r), Stats., making the definition no longer valid. The department proposes to amend the definition by adopting the federal definition given under 42 CFR 416.2, which defines an ambulatory surgical center (ASC) to mean any distinct entity that operates exclusively for the purpose of providing surgical services to patients not requiring hospitalization, has an agreement with the Centers of Medicare and Medicaid Services (CMS) to participate in Medicare as an ASC, and meets the conditions set forth in subparts B and C. Subparts B and C of 42 CFR 416.2 are the general conditions, requirements and specific conditions for coverage for ambulatory surgical services.

Cancer and Chronic Disease Drug Repository Program

- 2009 Wisconsin Act 142, effective March 18, 2010, removes certain barriers to donating prescription drug samples and expands the drug repository program to allow individuals to donate unused prescription medications that are in the original packaging, not just drugs to treat cancer and other chronic diseases as previously specified. The department intends to amend ch. DHS 148 to reflect these changes.

Laboratory Certification

- The department proposes to repeal ch. DHS 165. The department regulates laboratories testing human specimens under Agreement with the federal department of health and human services for compliance with 42 CFR 493. Under s. 1864 (a) of the Social Security Act, states having a Section 1864 Agreement with the Secretary of the department of health and human services are obligated to perform inspections or laboratories, and other related activities, to determine compliance with the requirements of the Clinical Laboratory Improvement Amendments of 1988 (CLIA) whether or not the laboratories also participate in Medicare. Federal regulations 42 CFR 493 sets forth the conditions that all laboratories must meet to be certified to perform testing on human specimens under the CLIA.

Responses to Legislative Council Rules Clearinghouse Recommendations

The department accepted the comment(s) made by the Legislative Council Rules Clearinghouse and modified the proposed rule where suggested, except as follows.

Clearinghouse Comment 4.c.: In s. DHS 148.07 (1), a more specific reference to the relevant provision or provisions in ch. Med 17 would be helpful.

Department Response: The department chose not to narrow the reference to ch. Med 17 because all provisions in ch. Med 17 are relevant when a practitioner is dispensing drugs. In addition, the provisions listed in ch. Med 17 are equivalent to the provisions in ch. Phar 7.

Clearinghouse Comment 5.j.: In SECTION 5 of the rule, the department is repealing Appendix A to ch. DHS 12 (relating to caregiver background checks), which contains a list of offenses affecting a person's eligibility to be a caregiver. The rule analysis does not indicate whether there is, or previously was, a statutory requirement that the offenses be set forth in

the rules (as there is in s. 50.065 (2m) (d), Stats., which requires the department to promulgate rules specifying crimes for which an entity must disclose a caregiver's conviction to a client or guardian). The reason given for the repeal is that the list of offenses is out-of-date and could more readily be updated on the department's website. However, it is unclear how a reader would know that the information is on the website, or where the offenses are listed in the statutes. A note could be inserted at the beginning of ch. DHS 12, citing the statutory provisions that list the offenses and noting that list may be found on the department's website.

Department Response: The department considered adding a note citing the statutory provisions that list the offenses and noting that a list may be found on the department's website. However, the department is concerned that the information in the note, over a period of time, will become out-of-date and list incorrect information. Stakeholders who use the rule have regular communication with the department through the department's Caregiver Program website and are able to receive the information in an accurate and timely manner. In response to the Legislative Council Rules Clearinghouse comment, there is no statutory requirement that the offenses be set forth in rule.

Final Regulatory Flexibility Analysis

The proposed rules update, correct or remove outdated rule provisions and cross-references. The changes are primarily minor and technical in nature. These rules will not have a fiscal effect on small businesses.

Changes to the Analysis or Fiscal Estimate

Analysis

No changes were made to the rule's analysis except where suggested by the Legislative Council Rules Clearinghouse relating to clarity, grammar, punctuation and use of plain language.

Fiscal Estimate

No changes were made to the fiscal estimate.

Public Hearing Summary

The department began accepting public comments on the proposed rule via the Wisconsin Administrative Rules website on July 22, 2010. A public hearing was held on August 26, 2010, in Madison. No persons attended the hearing. Public comments on the proposed rule were accepted until 4:30 p.m. on August 26, 2010.