

**ADMINISTRATIVE RULES**

**DEPARTMENT OF HEALTH SERVICES**

**NOTICE OF PUBLIC HEARING**

Chapters DHS 12, 83, 88, 124, 127, 148, and 165

NOTICE IS HEREBY GIVEN that pursuant to 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., and interpreting Sections 50.03, 50.035, 50.065 (1) (e), 50.36 (5), 50.37, 255.056, Stats, the Department of Health Services will hold a public hearing on proposed permanent rules to consider revisions to chs. DHS 12, 83, 88, 124, 127, 148, and 165, relating to Caregiver Background Checks, Community-Based Residential Facilities, Licensed Adult Family Homes, Hospitals, Rural Medical Centers, Cancer and Chronic Disease Drug Repository Program and Laboratory Certification.

**Hearing Date(s) and Location(s)**

<b>Date and Time</b>	<b>Location</b>
August 26, 2010 1:00 pm to 3:00 pm	Wisconsin State Office Building 1 West Wilson Street Room 950B Madison, Wisconsin

**Accessibility**

**English**

DHS is an equal opportunity employer and service provider. If you need accommodations because of a disability or need an interpreter or translator, or if you need this material in another language or in an alternate format, you may request assistance to participate by contacting Pat Benesh at 608-264-9896. You must make your request at least 7 days before the activity.

**Spanish**

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**Hmong**

DHS yog ib tus tswv hauj lwm thiab yog ib qhov chaw pab cuam uas muab vaj huam sib luag rau sawv daws. Yog koj xav tau kev pab vim muaj mob xiam oob qhab los yog xav tau ib tus neeg pab txhais lus los yog txhais ntaub ntauv, los yog koj xav tau cov ntaub ntauv no ua lwm hom lus los yog lwm hom

ntawv, koj yuav tau thov kev pab uas yog hu rau Pat Benesh ntawm 608-264-9896. Koj yuav tsum thov qhov kev pab yam tsawg kawg 7 hnuv ua ntej qhov hauj lwm ntawd.

### **Copies of the Rule**

A copy of the rules may be obtained from the department at no charge by downloading the documents from [www.adminrules.wisconsin.gov](http://www.adminrules.wisconsin.gov) or by contacting:

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### **Analysis Prepared by the Department of Health Services**

#### **Statute interpreted**

Sections 50.03, 50.035, 50.065 (1) (e), 50.36 (5), 50.37, 255.056, Stats.

#### **Statutory authority:**

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.

#### **Explanation of agency authority:**

- Section 50.02 (2), Stats., authorizes the department to develop regulations and standards for the care, treatment, health, safety, rights, welfare and comfort of residents in community-based residential facilities for the construction, general hygiene, maintenance and operation to promote safe and adequate accommodations, care and treatment of residents and to promulgate rules consistent with this section.
- Section 50.033 (2), Stats., authorizes the department to establish rules for the operation of licensed adult family homes designed to protect and promote the health, safety and welfare of adults receiving care and maintenance.
- Section 50.065 (1) (ag) 1. a. (2) (d), (4), (5) and (6) (b) and (c), Stats., authorizes the department to establish standards for caregivers to protect from harm clients served by department-regulated entities by requiring uniform background screening of persons regulated and persons who are employees of or under contract to regulated entities or who are a nonclient resident of regulated entities.

- Section 50.36 (1), Stats., authorizes the department to promulgate rules and standards for the operation of a hospital necessary to provide safe and adequate care and treatment and to protect the health and safety of patients in hospitals.
- Section 50.51 (2), Stats., authorizes the department to promulgate rules for the operation of rural medical centers and standards that are designed to protect and promote the health, safety, rights and welfare of patients who receive health care services in rural medical centers.
- Section 227.11 (2) (a), Stats., allows agencies to promulgate rules interpreting the provision of any statute enforced or administered by the agency if the agency considers it necessary to effectuate the purpose of the statute.
- Section 255.056 (7), Stats., authorizes the department to promulgate rules for medical facilities and pharmacies to accept and dispense donated drugs or supplies including standards for accepting and dispensing donated drugs or supplies, eligibility criteria for individuals to receive donated drugs or supplies, the maximum handling fee that a medical facility or pharmacy may charge for accepting, distributing, or dispensing donated drugs or supplies and drugs that are ineligible for donation.

**Related statute or rule:**

See the “Statutes Interpreted” section.

**Plain language analysis:**

- 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 intends to repeal Appendix A and publish the list of crimes and offenses affecting caregiver eligibility on the department’s website at [dhs.wisconsin.gov](http://dhs.wisconsin.gov).

The department also intends 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.

- The department intends 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. The department also intends to update Appendix A which lists contact information for the Division of Quality Assurance, Bureau of Assisted Living, Regional Offices.

- 2007 Wisconsin Act 20 repealed ss. 50.033 (2r), (2s) and (2t), Stats., making the provisions in ss. DHS 88.06 (1) (a) 4. and (4) no longer valid. Section DHS 88.06 (1) (a) 4. and (4) 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. The department intends 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 intends to correct the cross-reference and reference the grievance resolution procedures in ch. DHS 94. The department also intends to update Appendix A which lists contact information for the Division of Quality Assurance, Bureau of Assisted Living, Regional Offices.
- 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 intends to correct the cross reference and refer to the patient's health agent as defined in s. 157.06 (2) (a), Stats. The department also intends 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 DHS 124.16 (5) (c).
- 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 intends to amend the definition of ambulatory surgical center at s. DHS 127.02 (2), 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.
- 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.
- The department proposes to repeal ch. DHS 165 because the department has no statutory authority for the rule. In Wisconsin, laboratories are monitored under federal regulations contained in 42 CFR 493 and 42 CFR 1310 to 405.1317.

**Summary of, and comparison with, existing or proposed federal regulations:**

Chapter DHS 12, Caregiver Background Checks. There appear to be no existing or proposed federal regulations that address the activities to be regulated by the proposed rule.

Chapter DHS 83, Community-Based Residential Facilities. There appear to be no existing or proposed federal regulations that address the activities to be regulated by the proposed rule.

Chapter DHS 88, Licensed Adult Family Homes. There appear to be no existing or proposed federal regulations that address the activities to be regulated by the proposed rule.

Chapter DHS 124, Hospitals. There appear to be no existing or proposed federal regulations that address clinical records to be maintained for anatomical gifts.

Chapter DHS 127, Rural Medical Centers. There appear to be no existing or proposed federal regulations that address the activities to be regulated by the proposed rule.

Chapter DHS 148, Cancer and Chronic Disease Drug Repository Program. The proposed rules are affected by 21 CFR 200-299, 21 CFR 1300-1302, and 21 CFR 1304-1308. These regulations constitute the Food and Drug Administration (FDA) and Drug Enforcement Agency (DEA) regulations that affect the type of medications that can be donated to the drug repository.

Chapter DHS 165, Laboratory Certification. Similar federal regulations are contained in the 42 CFR 493 and 42 CFR 1310 to 405.1317.

**Comparison with rules in adjacent states:**

**Illinois:**

Not applicable.

**Iowa:**

Not applicable.

**Michigan:**

Not applicable.

**Minnesota:**

Not applicable.

**Summary of factual data and analytical methodologies:**

The department reviewed statutes, Acts, and the rules presented in this order to determine which rules needed to be repealed or revised.

**Analysis and supporting documents used to determine effect on small business:**

The rules will not have a fiscal effect on businesses.

**Effect on small business:**

The rules will not have a fiscal effect on businesses.

**Agency contact person:**

Pat Benesh, Quality Assurance Program Spec-Senior

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**Place where comments are to be submitted and deadline for submission:**

The department will hold one public hearing on August 26, 2010, 1:00 p.m. to 3:00 p.m. at 1 West Wilson Street, Room 950B, Madison, Wisconsin. Comments may be submitted to the agency contact person that is listed above until August 26, 2010, 4:30 p.m.