

Clearinghouse Rule 10-091

PROPOSED ORDER OF DEPARTMENT OF HEALTH SERVICES TO ADOPT RULES

The Wisconsin Department of Health Services proposes **to repeal** Chapter DHS 12, Appendix A, 88.06 (1) (a) 4., 148.03 (3) and (3m), 148.03 (13), and Chapter DHS 165; **to amend** DHS 12.02 (1) (b) 12.06 (intro.), 12.08, 12.12 (6) (g), DHS 83.05 (2) (g) Note, 83.15 (1) (c) and (d), 83.28 (7), 83.35 (1) (a), 83.35 (4) Note, 83.35 (5) Note, 83.37 (1) (h) 1.; 83.38 (1) (g) 1., 83.50 (2) (a) 3., 83.59 (2) (e), DHS 83.64 (4) Chart, 88.10 (5) (b), 124.14 (3) (a) 16., 127.02 (2), 127.08 (3) (a) 3. Note, Chapter DHS 148 (title), 148.01, 148.02 (1) and (2), 148.03 (1), 148.03 (2), 148.04 (1), (2) (a) (intro.), (b) and Note, and (3) and Note, 148.05, 148.06 (title), (1) (intro.), (2) (a) (title), (intro.), 1. to 3., and (b) (title), (intro.), 3. and Note, 148.06 (3) (intro.) and (a), 148.06 (title), 148.09 (title), 148.07 (1), (2), (3), and (4) (c) and Note, 148.08, 148.09 (title), (1), (2) and (3), 148.11 (1), 148.11 (2) (b); **to repeal and recreate** Chapter DHS 83 Appendix A and Chapter DHS 88 Appendix A; and **to create** 83.02 (5m), 148.03 (11m), and 148.06 (3) (c) relating to miscellaneous minor and technical changes.

SUMMARY OF PROPOSED RULE

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.

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

Division of Quality Assurance

1 West Wilson St., Room 534

Madison, WI 53701

Phone: 608-264-9896

Fax: 608-267-0352

patricia.benesh@wisconsin.gov

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.

TEXT OF PROPOSED RULE

SECTION 1. DHS 12.02 (1) (b) is amended to read:

DHS 12.02 (1) (b) *Entities covered.* The entities subject to this chapter are those regulated under: chs. DHS 34, ~~35, 36,~~ 40, 61, 63, ~~75,~~ 82, 83, ~~85,~~ 88, 89, ~~105,~~ 110, 111, 112, 124, 127, 131, 132, 133, and 134, and chs. DCF 38, 52, 54, 56, 57, 59, 250, 251, and 252, any other direct client care or treatment program that may be licensed or certified or registered by the department.

SECTION 2. DHS 12.06 (intro.) is amended to read:

DHS 12.06 Determining whether an offense is substantially related to client care. To determine whether a crime, or delinquency adjudication under s. 48.685 (5m) or 50.065 (5m), Stats., ~~or conduct relating to a governmental finding of abuse or neglect of another or of misappropriation of another's property~~ is substantially related to the care of a client, the agency or entity may consider all of the following:

SECTION 3. DHS 12.08 is amended to read:

DHS 12.08 Armed forces background searches. If a person who is the subject of a background search under s. 48.685 or 50.065, Stats., served in a branch of the U.S. armed forces within the last 3 years, including any reserve component, the agency or entity shall make a good faith effort to obtain the discharge status of that person, either from the discharge papers issued to the person or from the armed forces branch in which the person served. If the discharge status is other than honorable, the agency or entity shall obtain information on the nature and circumstances of the discharge.

SECTION 4. DHS 12.12 (6) (g) is amended to read:

DHS 12.12 (6) (g) *Appeal rights.* Any person who has his or her rehabilitation approval withdrawn under par. ~~(e)~~ (f) may file an appeal of this decision as provided in sub. (5) (a).

SECTION 5. Chapter DHS 12, Appendix A is repealed.

SECTION 6. DHS 83.02 (5m) is created to read:

DHS 83.02 (5m) “Advanced practice nurse” has the meaning given in s. N 8.02 (1).

SECTION 7. DHS 83.05 (2) (g) Note is amended to read:

DHS 83.05 (2) (g) Note: A copy of the application form, F60287, can be obtained at http://dhs.wisconsin.gov/r1_dsl/CBREF/CBRFinqResp.htm

<http://dhs.wisconsin.gov/forms/DQAnum.asp> or by contacting the Division of Quality Assurance Regional Office listed in Appendix A.

SECTION 8. DHS 83.15 (1) (c) and (d) is amended to read:

DHS 83.15 (1) (c) A bachelor's degree in a field other than in health care from an accredited college and have successfully completed a department-approved or a designee-approved assisted living administrator's training course.

(d) At least 2 years experience working in a health care related field having direct contact with one or more of the client groups identified under s. DHS 83.02 (16) and have successfully completed a department-approved or a designee-approved assisted living administrator's training course.

SECTION 9. DHS 83.28 (7) is amended to read:

DHS.28 (7) ADVANCED DIRECTIVES. At the time of admission, the CBRF shall determine if the resident has executed an advanced directive. An advanced directive describes, in writing, the choices about treatments the resident may or may not want and about how health care decisions should be made for the resident if the resident becomes incapacitated and cannot express their wishes. A copy of the document shall be maintained in the resident record as required under s. DHS 83.42 (1) ~~(p)~~(s). A CBRF may not require an advanced directive as a condition of admission or as a condition of receiving any health care service. An advanced directive may be a living will, power of attorney for health care, or a do-not-resuscitate order under chs. 154 or 155, Stats., or other authority as recognized by the courts of this state.

SECTION 10. DHS 83.35 (1) (a) is amended to read:

DHS 83.35 (1) ASSESSMENT. (a) *Scope.* The CBRF shall assess each resident's needs, abilities, and physical and mental condition before admitting the person to the CBRF, when there is a change in needs, abilities ~~and~~or condition, and at least annually. The assessment shall include all areas listed under par. (c). This requirement includes individuals receiving respite care in the CBRF. For emergency admissions the CBRF shall conduct the assessment within 5 days after admission.

SECTION 11. DHS 83.35 (4) Note is amended to read:

DHS 83.35 (4) Note: The CBRF Resident Satisfaction Evaluation form, F62372, can be found at <http://dhs.wisconsin.gov/forms1/oqa/oqa2372.pdf> <http://dhs.wisconsin.gov/forms/DQAnum.asp> or by contacting the Division of Quality Assurance Regional Office listed in Appendix A.

SECTION 12. DHS 83.35 (5) Note is amended to read:

Note: The Resident Evacuation Assessment form, F62373, can be found at <http://dhs.wisconsin.gov/forms1/OQA/oqa2373.pdf>

<http://dhs.wisconsin.gov/forms/DQAnum.asp> or by contacting the Division of Quality Assurance Regional Office listed in Appendix A.

SECTION 13. DHS 83.37 (1) (h) 1. is amended to read:

DHS 83.37 (1) (h) 1. Ensure the resident is reassessed by a pharmacist, practitioner or registered nurse, as needed, but at least quarterly for the desired responses and possible side effects of the medication. The results of the assessments shall be documented in the resident's record as required under s. DHS 83.42 (1) ~~(a)(n)~~.

SECTION 14. DHS 83.38 (1) (g) 1. is amended to read:

DHS 83.38 (1) (g) *Health monitoring*. 1. The CBRF shall monitor the health of residents and make arrangements for physical health, oral health or mental health services unless otherwise arranged for by the resident. Each resident shall have an annual physical health examination completed by a physician or an advanced practice nurse, unless seen by a physician or an advanced practice nurse more frequently.

SECTION 15. DHS 83.50 (2) (a) 3. is amended to read:

DHS 83.50 (2) (a) 3. Construction Type VB means wood frame unprotected construction consisting of exterior walls of wood studs covered, for example, with metal or wood siding, brick, stone, slate, vinyl, metal, or wood, wood floors and roof, and interior partitions of wood stud and plaster or drywall.

SECTION 16. DHS 83.59 (2) (e) is repealed.

SECTION 17. DHS 83.64 (4) Chart is amended to read:

Sprinkler System Chart for New Construction

Facility Class and Size	Sprinkler System Requirement
CBRF Large 'A'-class (21 or more)	NFPA 13 R or NFPA 13
CBRF Medium 'A'-class (9-20)	NFPA 13 R or NFPA 13 <u>or NFPA 13 D</u>
CBRF Small 'A'-class (5-8)	Not Required
CBRF Large 'C'-class (21 or more)	NFPA 13
CBRF Medium 'C'-class (9-20)	NFPA 13 D or NFPA 13 <u>or NFPA 13 R</u>
CBRF Small 'C'-class (5-8)	NFPA 13 D or NFPA 13 R

SECTION 18. Chapter DHS 83, Appendix A is repealed and recreated to read:

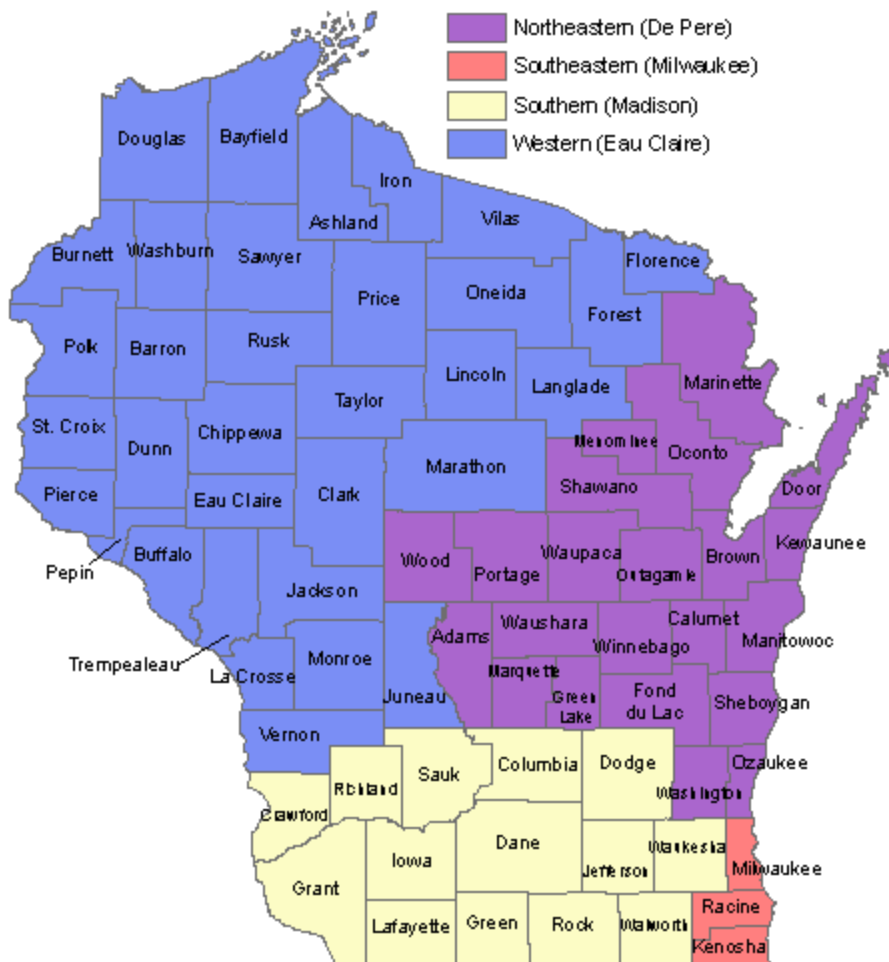
DHS 83

Appendix A

Wisconsin Regional Offices

Bureau of Assisted Living

Division of Quality Assurance



Northeastern Regional Office

1325 South Broadway
DePere, WI 54115
Office: (920) 983-3200
Fax: (920) 983-3201

Counties Covered: Adams, Brown, Calumet, Door, Fond du Lac, Green Lake, Kewaunee, Manitowoc, Marinette, Marquette, Menominee, Oconto, Outagamie, Ozaukee, Portage, Shawano, Sheboygan, Washington, Waushara, Waupaca, Winnebago, Wood

Southeastern Regional Office

819 N. 6th St., Room 609B
Milwaukee, WI 53203-1606
Office: (414) 227-2005
Fax: (414) 227-3903

Counties Covered: Kenosha, Milwaukee, Racine

Southern Regional Office

P.O. Box 7940
Madison, WI 53707-7940
Office: (608) 266-7474
Fax: (608) 266-8975

Counties Covered: Columbia, Crawford, Dane, Dodge, Grant, Green, Iowa, Jefferson, Lafayette, Richland, Rock, Sauk, Walworth, Waukesha

Western Regional Office

610 Gibson St., Suite 1
Eau Claire, WI 54701-3687
Office: (715) 836-4752
Fax: (715) 836-2535

Counties Covered: Ashland, Barron, Bayfield, Buffalo, Burnett, Chippewa, Clark, Douglas, Dunn, Eau Claire, Florence, Forest, Iron, Jackson, Juneau, Langlade, La Crosse, Lincoln, Marathon, Monroe, Oneida, Pepin, Pierce, Polk, Price, Rusk, Sawyer, St. Croix, Taylor, Trempealeau, Vernon, Vilas, Washburn

7/2010

SECTION 19. DHS 88.06 (1) (a) 4. is repealed.

SECTION 20. DHS 88.10 (5) (b) is amended to read:

DHS 88.10 (5) (b) *Grievance procedure.* The grievance procedure of the adult family home shall be established in accordance with ch. DHS 94. If a resident is placed or funded by a county agency, the county grievance procedure under s. DHS ~~94.27(3)~~ 94.29 shall be used.

SECTION 21. Chapter DHS 88, Appendix A is repealed and recreated to read:

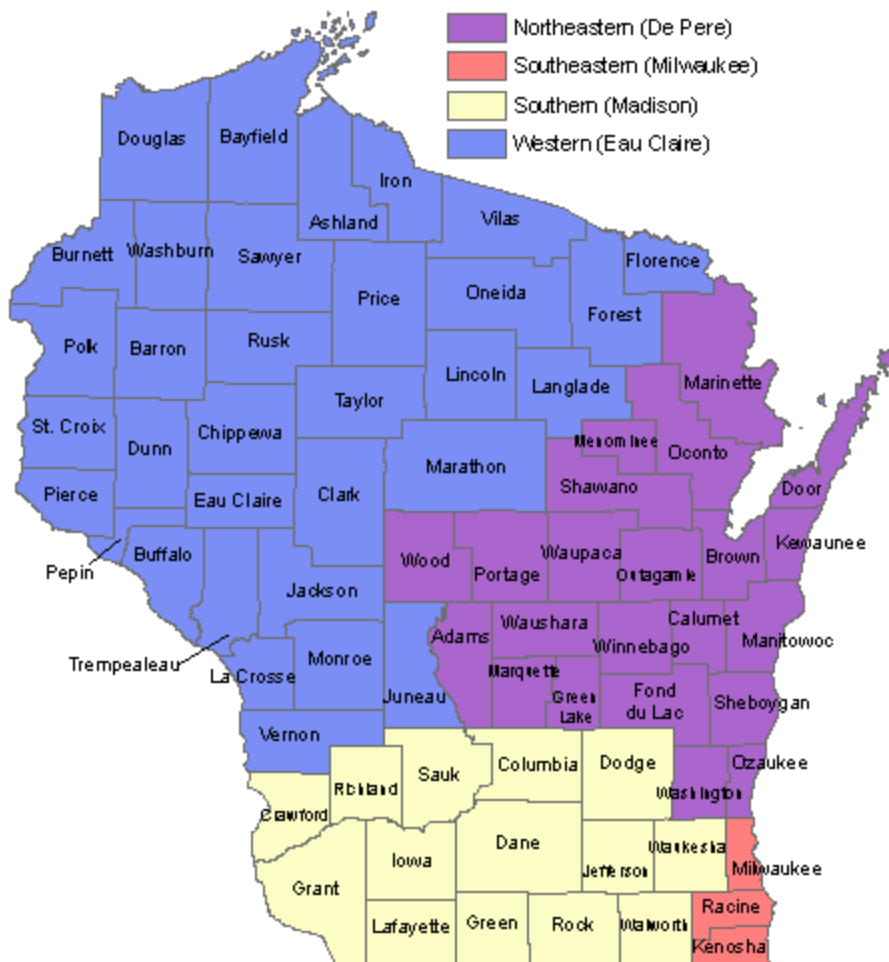
DHS 88

Appendix A

Wisconsin Regional Offices

Bureau of Assisted Living

Division of Quality Assurance



Northeastern Regional Office

1325 South Broadway
DePere, WI 54115
Office: (920) 983-3200
Fax: (920) 983-3201

Counties Covered: Adams, Brown, Calumet, Door, Fond du Lac, Green Lake, Kewaunee, Manitowoc, Marinette, Marquette, Menominee, Oconto, Outagamie, Ozaukee, Portage, Shawano, Sheboygan, Washington, Waushara, Waupaca, Winnebago, Wood

Southeastern Regional Office

819 N. 6th St., Room 609B
Milwaukee, WI 53203-1606
Office: (414) 227-2005
Fax: (414) 227-3903

Counties Covered: Kenosha, Milwaukee, Racine

Southern Regional Office

P.O. Box 7940
Madison, WI 53707-7940
Office: (608) 266-7474
Fax: (608) 266-8975

Counties Covered: Columbia, Crawford, Dane, Dodge, Grant, Green, Iowa, Jefferson, Lafayette, Richland, Rock, Sauk, Walworth, Waukesha

Western Regional Office

610 Gibson St., Suite 1
Eau Claire, WI 54701-3687
Office: (715) 836-4752
Fax: (715) 836-2535

Counties Covered: Ashland, Barron, Bayfield, Buffalo, Burnett, Chippewa, Clark, Douglas, Dunn, Eau Claire, Florence, Forest, Iron, Jackson, Juneau, Langlade, La Crosse, Lincoln, Marathon, Monroe, Oneida, Pepin, Pierce, Polk, Price, Rusk, Sawyer, St. Croix, Taylor, Trempealeau, Vernon, Vilas, Washburn

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SECTION 22. DHS 124.14 (3) (a) 16. is amended to read:

DHS 124.14 (3) (a) 16. Anatomical gift information obtained under s. DHS 124.05 (3) (i). Documentation shall include the name and title of the person who requests the anatomical gift, the name of the ~~appropriate individual as defined under s. DHS 124.05 (3) (i) 1. b. that individual's relationship to the patient,~~ patient's agent as defined in s. 157.06 (2) (a) Stats., the response to the request for an anatomical gift and, if a determination is made that a request should not be made, the basis for that determination. This information shall be recorded promptly in the medical record where it shall be prominently set out.

SECTION 23. DHS 124.16 (5) (c) is amended to read:

DHS 124.16 (5) (c) Nutritional needs shall be in accordance with physicians' orders and, to the extent medically possible, ~~in accordance with the "recommended daily dietary allowances" of the Food and Nutrition Board of the National Research Council, National Academy of Sciences, as contained in Appendix A of this chapter. A current edition of these standards shall be available in the dietary service~~ that meet the nutritional needs of each patient.

SECTION 24. Chapter DHS 124, Appendix A is repealed.

SECTION 25. DHS 127.02 (2) is amended to read:

DHS 127.02 (2) "Ambulatory surgery center" has the meaning given in ~~s. 49.45 (6r) (a) 1., Stats.~~ 42 CFR 416.2.

SECTION 26. DHS 127.08 (3) (a) 3. Note is amended to read:

DHS 127.08 (3) (a) 3. Note: A request for a waiver or variance should be addressed to the ~~Division~~Division of Quality Assurance, P.O. Box 2969, Madison, Wisconsin 53701-2969.

SECTION 27. Chapter DHS 148 (title) is amended to read:

DHS 148 (title) ~~CANCER AND CHRONIC DISEASE~~ DRUG REPOSITORY PROGRAM

SECTION 28. DHS 148.01 is amended to read:

DHS 148.01 Authority and purpose. This chapter is promulgated under the authority of s. 255.056, Stats., to establish and maintain a ~~cancer and chronic diseases~~ drug repository program under which unused ~~cancer and chronic disease~~ drugs and ~~cancer and chronic disease~~ supplies may be donated and dispensed to individuals ~~who are diagnosed with cancer or chronic disease.~~

SECTION 29. DHS 148.02 (1) and (2) are amended to read:

DHS 148.02 (1) This chapter applies to the department and any person who donates, receives, dispenses or otherwise participates or wishes to participate in the ~~cancer and chronic diseases~~ drug repository program.

(2) ~~Over-the-counter~~ medications and supplies not used to administer ~~cancer and chronic disease~~ drugs such as bandages or drainage bags are not subject to the provisions of this chapter. Accepting such items is at the discretion of the individual pharmacy or medical facility.

SECTION 30. DHS 148.03 (1) is amended to read:

DHS 148.03 (1) ~~“Cancer or chronic disease drug” or “Drug” means a prescription drug that is used to treat any one of the following:~~

~~(a) Cancer or chronic disease or side effects of cancer or chronic disease.~~

~~(b) The side effects of any prescription drug under par. (a). “Drug” has the meaning given in s. 450.01 (10).~~

SECTION 31. DHS 148.03 (2) is amended to read:

DHS 148.03 (2) ~~“Cancer or chronic diseases Drug repository”~~ “Drug repository” means a medical facility or pharmacy that has notified the department of its election to participate in the ~~cancer or chronic diseases~~ drug repository program.

SECTION 32. DHS 148.03 (3) and (3m) are repealed.

SECTION 33. DHS 148.03 (11m) is created to read:

DHS 148.03 (11m) “Practitioner” has the meaning given in ch. Med 17.02 (2).

SECTION 34 DHS 148.03 (13) is repealed.

SECTION 35. DHS 148.04 (1), (2) (a) (intro.), (b) and Note, and (3) and Note are amended to read:

DHS 148.04 (1) **ELIGIBILITY.** To be eligible for participation in the ~~cancer or chronic disease~~ drug repository program a pharmacy or medical facility shall be in compliance with all applicable federal and state laws, and administrative rules.

(2) **NOTICE OF PARTICIPATION.** (a) Participation in the ~~cancer or chronic disease~~ drug repository program is voluntary. A pharmacy or medical facility may elect to participate in the ~~cancer or chronic disease~~ drug repository program by providing written notification to the department of all of the following:

(b) A pharmacy or medical facility may fully participate in the ~~cancer or chronic disease~~ drug repository program by accepting, storing, and dispensing donated drugs and supplies, or

may limit its participation to only accepting and storing donated drugs and supplies. If a pharmacy or facility chooses to limit its participation, the pharmacy or facility shall distribute any donated drugs to a fully participating ~~cancer or chronic disease~~ drug repository following the requirements under s. DHS 148.09.

Note: Notices of participation in the ~~cancer or chronic disease~~ drug repository program can be sent to the Department of Health Services, ~~Bureau~~ Division of Quality Assurance, 1 West Wilson St., Madison, WI 53701.

(3) WITHDRAWAL FROM PARTICIPATION. A pharmacy or medical facility may withdraw from participation in the ~~cancer or chronic disease~~ drug repository program at any time upon written notice to the department.

Note: A notice to withdraw participation from the ~~cancer or chronic disease~~ drug repository program should be sent to the Department of Health Services, ~~Bureau~~ Division of Quality Assurance, 1 West Wilson St., Madison, WI 53701.

SECTION 36. DHS 148.05 is amended to read:

DHS 148.05 Recipient eligibility requirements. Any Wisconsin resident ~~who is diagnosed with cancer or chronic disease~~ is eligible to receive drugs or supplies under the ~~cancer and chronic diseases~~ drug repository program.

SECTION 37. DHS 148.06 (title), (1) (intro.), (2) (a) (title), (intro.), 1. to 3. , and (b) (title), (intro.), 3. and Note are amended to read:

DHS 148.06 (title) Donations of ~~cancer or chronic disease~~ drugs and supplies. (1) PERSONS ELIGIBLE TO DONATE DRUGS OR SUPPLIES. Any one of the following persons may donate legally obtained ~~cancer or chronic disease~~ drugs or supplies to a ~~cancer~~ drug repository, if the drugs or supplies meet the requirements under sub. (2), as determined by a pharmacist who is employed by or under contract with a ~~cancer and chronic diseases~~ drug repository:

(2) DRUGS AND SUPPLIES ELIGIBLE FOR DONATION. (a) ~~Cancer and chronic disease drugs~~ Drugs. A ~~cancer or chronic disease~~ drug is eligible for donation under the ~~cancer and chronic diseases~~ drug repository program only if all of the following requirements are met:

1. The donation is accompanied by a completed ~~cancer and chronic diseases~~ drug repository donor form that is signed by the person making the donation or that person's authorized representative.

2. The drug's expiration date is at least ~~6 months~~ 90 days later than the date that the drug was donated.

3. The drug is in its original, unopened, tamper-evident ~~unit-dose~~ packaging that includes the drug's lot number and expiration date. Single-unit dose drugs may be accepted if the single-unit-dose packaging is unopened.

(b) ~~Cancer and chronic disease s~~ Supplies. ~~Cancer and chronic disease s~~ Supplies are eligible for donation under the ~~cancer and chronic diseases~~ drug repository program only if the supplies meet all of the following requirements:

3. The supplies are accompanied by a completed ~~cancer and chronic diseases~~ drug repository donor form that is signed by the person making the donation or that person's authorized representative.

Note: ~~Cancer and chronic diseases drug~~ Drug repository donor forms can be obtained from the Department's website at <http://www.dhs.wisconsin.gov/forms>

SECTION 38. DHS 148.06 (3) (intro.) and (a) are amended to read:

DHS 148.06 (3) DRUGS AND SUPPLIES NOT ELIGIBLE FOR DONATION. All of the following drugs are ineligible for donation or acceptance under the ~~cancer and chronic diseases~~ drug repository program:

(a) Controlled substances as defined in s. 961.01 (4).

SECTION 39. DHS 148.06 (3) (c) is created to read:

DHS 148.06 (3) (c) A drug for which the U.S. food and drug administration requires that a patient using the drug be enrolled in a registry as provided under 21 USC 355-1 (f) (3) (F).

SECTION 40. DHS 148.06 (4) and (5) are amended to read:

DHS 148.06 (4) LOCATIONS WHERE DONATIONS MAY BE MADE. Drugs and supplies may be donated on the premises of a ~~cancer and chronic diseases~~ drug repository to a person designated by the repository. A drop box may not be used to deliver or accept donations.

(5) STORAGE. ~~Cancer and chronic disease d~~ Drugs and supplies donated under the ~~cancer and chronic diseases drug~~ repository program shall be stored in a secure storage area under environmental conditions appropriate for the drugs or supplies being stored. Donated drugs and supplies may not be stored with non-donated inventory.

SECTION 41. DHS 148.06 (title) amended to read:

DHS 148.06 (title) Donations of ~~cancer or chronic disease~~ drugs and supplies.

SECTION 42. DHS 148.09 (title) is amended to read:

DHS 148.09 (title) Distribution of donated ~~or chronic disease~~ drugs and supplies.

SECTION 43. DHS 148.07 (1), (2), (3), and (4) (c) and Note are amended to read:

DHS 148.07 (1) Drugs and supplies shall be dispensed by a licensed pharmacist consistent with the requirements in s. 450.11, Stats., and ch. Phar 7 or a practitioner consistent with the requirements in ch. Med 17.

(2) The pharmacist shall inspect ~~cancer and chronic disease~~ drugs and supplies for adulteration, misbranding, and the date of expiration before dispensing. Drugs or supplies that are expired, adulterated, or misbranded may not be dispensed.

(3) Before a ~~cancer or chronic disease~~ drug or supply may be dispensed to a recipient, the recipient shall sign a ~~cancer and chronic disease~~ drug repository recipient form and shall be orally notified that the drug or supply may have been previously dispensed.

(4) (c) All other individuals who are otherwise eligible under s. DHS 148.05 to receive drugs or supplies from a ~~cancer and chronic disease~~ drug repository.

Note: ~~Cancer and chronic disease Drug~~ Drug repository recipient forms can be obtained from the Department's website at <http://www.dhs.wisconsin.gov/forms>.

SECTION 44. DHS 148.08 is amended to read:

DHS 148.08 Handling fees. A ~~cancer and chronic disease~~ drug repository may charge the recipient of a drug or supply a handling fee of no more than 300% of the Medicaid dispensing fee for each ~~cancer or chronic disease~~ drug or supply dispensed.

SECTION 45. DHS 148.09 (title), (1), (2) and (3) are amended to read:

DHS 148.09 (1) ~~Cancer and chronic disease drug~~ Drug repositories may distribute drugs and supplies donated under the ~~cancer and chronic disease~~ drug repository program to other repositories if requested by a participating repository.

(2) A ~~cancer and chronic disease~~ drug repository that has elected not to dispense donated drugs or supplies shall distribute those drugs and supplies to a participating repository upon request of the repository.

(3) If a ~~cancer and chronic disease~~ drug repository distributes drugs or supplies under sub. (1) or (2), the repository shall complete a ~~cancer and chronic disease~~ drug repository donor form. The completed form and a copy of the donor form that was completed by the original donor under s. DHS 148.06 (2) (a) 1. shall be provided to the fully participating ~~cancer and chronic disease~~ drug repository at the time of distribution.

SECTION 46. DHS 148.11 (1) is amended to read:

DHS 148.11 (1) DONOR AND RECIPIENT FORMS. ~~Cancer and chronic diseases drug~~
Drug-repository donor and recipient forms shall be maintained for at least 5 years.

SECTION 47. DHS 148.11 (2) (b) is amended to read:

DHS 148.11 (2) (b) The name, strength and quantity of the ~~cancer or chronic disease~~ drug destroyed.

SECTION 48. Chapter DHS 165 is repealed.

EFFECTIVE DATE: This rule shall take effect on the first day of the month following publication in the Wisconsin administrative register, as provided in s. 227.22 (2), Stats.

Wisconsin Department of Health Services

Dated:

Karen E Timberlake, Department Secretary

SEAL: