

Clearinghouse Rule 16-077

PROPOSED ORDER OF DEPARTMENT OF HEALTH SERVICES TO ADOPT PERMANENT RULES

The Wisconsin Department of Health Services (department) proposes an order to **renumber** DHS 133.02 (5m); to **amend** DHS 133.01, 133.02 (3), 133.06 (5), 133.09 (1), 133.09 (3) (a) 1. and 3., 133.09 (3) (b), 133.13, 133.14 (2) (g), 133.20 (1), (3), and (4), and 133.21 (4) and (5) (e); and to **create** DHS 133.02 (5g), 133.02 (9m) of the Wisconsin Administrative Code, relating to home health agencies.

RULE SUMMARY

Statute interpreted

Sections 50.49 (2) (a), 227.11 (2) (a), Stats.

Statutory authority

Sections 50.49 (2) (a), 227.11 (2) (a), Stats.

Explanation of agency authority

The department's authority to promulgate rules is as follows:

Section 50.49 (2) (a), Stats., reads: The department may develop, establish and enforce standards for the care, treatment, health, safety, welfare and comfort of patients by home health agencies and for the maintenance and operation of home health agencies which, in the light of advancing knowledge, will promote safe and adequate care and treatment of such patients by home health agencies.

Section 227.11 (2) (a), Stats., reads: Each agency may promulgate rules interpreting the provisions of any statute enforced or administered by the agency, if the agency considers it necessary to effectuate the purpose of the statute, but a rule is not valid if the rule exceeds the bounds of correct interpretation. All of the following apply to the promulgation of a rule interpreting the provisions of a statute enforced or administered by an agency:

- 1.** A statutory or nonstatutory provision containing a statement or declaration of legislative intent, purpose, findings, or policy does not confer rule-making authority on the agency or augment the agency's rule-making authority beyond the rule-making authority that is explicitly conferred on the agency by the legislature.
- 2.** A statutory provision describing the agency's general powers or duties does not confer rule-making authority on the agency or augment the agency's rule-making authority beyond the rule-making authority that is explicitly conferred on the agency by the legislature.

3. A statutory provision containing a specific standard, requirement, or threshold does not confer on the agency the authority to promulgate, enforce, or administer a rule that contains a standard, requirement, or threshold that is more restrictive than the standard, requirement, or threshold contained in the statutory provision.

Related statute or rule

See the “Statutes interpreted” and “Statutory authority” sections.

Plain language analysis

On April 12, 2012, 2011 Wisconsin Act 161 went into effect, amending the definition of *home health services* found in s. 50.49 (1) (b), Stats., to include services that are provided to an individual who is under the care of a physician assistant. This change authorizes physician assistants to complete certain medically related actions in home health agencies. The department proposes to conform ch. DHS 133 to s. 50.49 (1) (b), Stats., and therefore broaden the scope of home health services. There is no reasonable alternative to rulemaking. Pursuant to s. 227.10 (01), Stats., the department is required to promulgate rules for each interpretation of a statute which it specifically adopts to govern its enforcement or administration of that statute.

In addition, the department proposes to revise provisions in ch. DHS 133 relating to patient records and infection control and prevention programs. The department has determined that these revisions are necessary in order to reduce confusion, and provide greater flexibility to home health agencies in meeting regulatory requirements.

Specifically, ch. DHS 133 currently requires that an abstract of the patient’s record accompany the patient when the patient is transferred to another agency or health care facility. The department intends to clarify that an abstract of a patient’s record is the same as a summary of a patient’s record and that it must be provided to the receiving agency or facility. Additionally, ch. DHS 133 currently only specifies the CDC as an authority for reference in the development of the agency’s infection control and prevention program. The department proposes to clarify that agencies may use other nationally recognized subject authorities, in addition to the Centers for Disease Control and Prevention, to assist in the development of their infection control and prevention program.

There is no reasonable policy alternative to rulemaking, because without needed revisions, provisions relating to patient records and infection control and prevention programs would remain unclear. Entities that may be affected by the proposed rule revisions are home health agencies, health care providers receiving patients from home health agencies, and consumers of home health services and their representatives.

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

All searches conducted April 2016.

Physician assistants: There appears to be no existing or proposed federal regulations that address the activities to be regulated by the proposed rule.

Abstract of a patient record: The federal regulations contain similar requirements (42 CFR Part 484.48 (a) Federal Conditions of Participation for Home Health Agencies).

Infection control and prevention program: There appears to be no existing federal regulations that address the activities to be regulated by the proposed rule. On October 6, 2014 the Centers for Medicare & Medicaid Services (CMS) issued a proposed rule that would require each home health agency to maintain and document a program to prevent and control infections and communicable diseases. The infection control program would follow accepted standards of practice, including standard precautions, and educate staff, patients, and caregivers about proper infection control procedures. The proposed rule was published in the Federal Register for public comments but has not, as of this date, been published as a final rule.

Comparison with rules in adjacent states

Illinois:

Physician assistants: Illinois law does not specifically address the practice of care provided by a physician assistant nor does it preclude the practice of a physician assistant in a home health agency.

Abstract of a patient record: Illinois rules require that each home health agency develop a discharge summary giving a brief review of service, patient status, reason for discharge, and plans for post-discharge needs of the patient. A discharge summary may suffice as documentation to close the patient record for one-time visits, and short-term, event-focused or diagnoses-focused interventions. The discharge summary need not be a separate piece of paper and may be incorporated into the routine summary of reports already furnished to the physician. A copy of appropriate patient transfer information shall be provided, when requested, if the patient is transferred to another health facility or health agency. (Illinois Home Health Agency, 79 III. Adm. Code Part 245).

Infection control and prevention program: Illinois rules require each home health agency to develop and implement policies and procedures for investigating, controlling and preventing infections. Placement agencies must provide to in-home services workers the CDC publication "Guidelines for Hand Hygiene in Health-Care Settings." Each agency must also adhere, at a minimum and as appropriate, to the guidelines of the CDC, United States Public Health Service, and Department of Health and Human Services, as incorporated in Section 245.25(b). (Illinois Home Health Agency, 79 III. Adm. Code Part 245).

Iowa:

Iowa does not appear to have an administrative rule governing home health agencies.

Michigan:

Michigan does not appear to have an administrative rule governing home health agencies.

Minnesota:

Physician assistants: Minnesota law does not specifically address the practice of care provided by a physician assistant nor does it preclude the practice of a physician assistant in a home health agency.

Abstract of a patient record: If a client transfers to another home care provider or other health care practitioner or provider, or is admitted to an inpatient facility, the home care provider, upon request of the client or the client's representative, must take steps to ensure a coordinated transfer including sending a copy or summary of the client's record to the new home care provider, the facility, or the client, as appropriate. (Minn. R. Chapter 4668)

Infection control and prevention program: A home care provider must establish and maintain a comprehensive tuberculosis infection control program according to the most current tuberculosis infection control guidelines issued by the CDC, Division of Tuberculosis Elimination, as published in CDC's Morbidity and Mortality Weekly Report. The program must include a tuberculosis infection control plan that covers all paid and unpaid employees, contractors, students, and volunteers. The state department of health must provide technical assistance regarding implementation of the guidelines. (Minn. R. Chapter 4668)

Summary of factual data and analytical methodologies

The department relied on the following sources to draft the proposed rule and to determine the impact on home health agencies.

- The department formed an Advisory Committee consisting of home health agency administrators and registered nurses. Committee members reviewed the initial draft of the rule and were asked for comments. Their comments guided the development of the proposed rule.
- The 2012 Economic Census – Wisconsin Geographic Series, compiled by the U.S. census bureau every 5 years for each year ending in “2” and “7” and contains the latest available economic data compiled on businesses located in Wisconsin.
- Criteria adopted by the department and approved by the Wisconsin Small Business Regulatory Review Board to determine whether the department’s proposed rules have a significant economic impact on a substantial number of small businesses. Pursuant to the department’s criteria, a proposed rule will have a significant economic impact on a substantial number of small businesses if at least 10% of the businesses affected by the proposed rules are small businesses and if operating expenditures, including annualized capital expenditures, increase by more than the prior year’s consumer price index or reduces revenues by more than the prior year’s consumer price index. For the purposes of this rulemaking, 2008 is the index year. The consumer price index is compiled by the U.S. Department of Labor, Bureau of Labor Statistics; the preliminary rate for medical care services in 2016 is currently estimated at 3.3 percent.
- DHS databases including the ASPEN Information System which contains demographic, licensing, program, and compliance history of home health agencies in Wisconsin.

- Data reported by the 129 home health agencies responding to the Department's 2005 home health agency survey and published in "Wisconsin Home Health Agency Directory, 2005," was used to determine the number of small businesses. (Wisconsin Department of Health and Family Services, Division of Public Health, Bureau of Health Information Policy, *Wisconsin Home Health Agency Directory, 2005*, (PPH 5378-05) December 2006)
- Data reported in the Wisconsin Department of Health and Family Services, Division of Public Health, Bureau of Health Information Policy, *Wisconsin Home Health Agencies and Patients*, 2005, (PPH 5354-05) February 2007.

Analysis and supporting documents used to determine effect on small business

All home health agencies, both publicly and privately owned, are regulated by the department under ch. DHS 133 and ch. 50, Stats. These agencies are commonly referred to as *state-only licensed home health agencies*. If a home health agency participates as a provider in the Medicaid and Medicare programs, the home health agency is also regulated by the department under 42 CFR 484 and commonly referred to as a *state licensed and federally certified home health agency*. The department estimates that at least 50% of all licensed agencies may be considered small businesses, as defined in s. 227.114 (1), Stats., with estimated average gross annual revenues of \$4.8 million and annual payroll of 2.5 million per agency.

The proposed changes codify statute enacted in 2012 and clarify existing requirements. None of these proposed changes will have an economic impact on home health agencies. Pursuant to the foregoing analysis, the proposed rules will affect a substantial number of small businesses that are home health agencies, but the proposed rules will not have an economic impact on these businesses.

In addition, pursuant to s. 227.114 (2), Stats., the department considered the methods for reducing the impact of proposed rule revisions on small businesses. The department believes that proposed rule revisions will result in less stringent and simplified compliance requirements.

Effect on small business

Based on the foregoing analysis, the rules are anticipated to have little to no economic impact on small businesses.

Statement on quality of agency data

The data sources used to draft the rules and analyses are accurate, reliable and objective and are listed in the Summary of Factual Data and Analytical Methodologies section of this rule order.

Agency contact person

Patricia Benesh

Patricia.Benesh@wisconsin.gov

Phone: (608) 264-9896

Place where comments are to be submitted and deadline for submission

Comments may be submitted to the agency contact person that is listed above until the deadline given in the upcoming notice of public hearing. The deadline for submitting comments and the notice of public hearing will be posted on the Wisconsin State Legislature's Administrative Rules website <http://docs.legis.wisconsin.gov/code>.

RULE TEXT

SECTION 1. DHS 133.01 is amended to read:

DHS 133.01 **Authority and purpose.** This chapter is promulgated under the authority of s. 50.49 (2), Stats. The chapter establishes minimum standards for the care, treatment, health, safety, welfare and comfort of patients by home health agencies and for the maintenance and operation of home health agencies which, in the light of advancing knowledge, will promote safe and adequate care and treatment of such ~~operation of home health agencies which primarily provide in-home part-time or intermittent nursing care and other therapeutic services. These minimum standards are intended to foster safe and adequate care and treatment of patients by~~ home health agencies.

SECTION 2. DHS 133.02 (3) is amended to read:

DHS 133.02 (3) "Home health agency" ~~means an organization that primarily provides both skilled nursing and other therapeutic services to patients in their homes~~ has the meaning given in s. 50.49 (1)(a), Wis. Stats.

SECTION 3. DHS 133.02 (5g) is created to read:

DHS 133.02 (5g) "home health services" has the meaning given in s. 50.49 (1) (b), Stats.

SECTION 4. DHS 133.02 (5m) is renumbered to DHS 133.02 (5r):

SECTION 5. DHS 133.02 (9m) is created to read:

DHS 133.02 (9m) "Physician assistant" has the meaning given in s. 448.01 (6), Stats.

SECTION 6. DHS 133.06 (5) (a) is amended to read:

DHS 133.06 (5) (a) Develop and implement initial orientation and ongoing education and training for all staff having direct patient contact, including students, trainees and volunteers, in the epidemiology, modes of transmission and prevention of infections and the need for routine use of current infection control measures as recommended by the U.S. centers for disease control and prevention; or any other nationally recognized subject authority.

SECTION 7. DHS 133.09 (1) is amended to read:

DHS 133.09 (1) ACCEPTANCE OF PATIENTS. A patient shall be accepted for service on the basis of a reasonable expectation that the patient's medical, nursing and social needs can be met adequately by the home health agency ~~in the patient's place of residence~~. No patient may be provided services except under a plan of care established by a physician, an advanced practice nurse prescriber or a physician assistant.

SECTION 8. DHS 133.09 (3) (a) 1. and (3) (a) 3. and (3) (b) are amended to read:

DHS 133.09 (3) (a) 1. A home health agency may not discharge a patient for any reason until the agency has discussed the discharge with the patient or the patient's legal representative and the patient's attending physician, advanced practice nurse prescriber or physician assistant, and has provided written notice to the patient or the patient's legal representative in the timelines specified in this paragraph.

DHS 133.09 (3) (a) 3. The home health agency shall provide the written notice under subd. 1. to the patient or the patient's legal representative at the time of discharge if the reason for discharge is any of the following:

- a. The safety of staff is compromised, as documented by the home health agency.
- b. The attending physician, ~~or~~ advanced practice nurse prescriber, or physician assistant orders the discharge for emergency medical reasons.
- c. The patient no longer needs home health care as determined by the attending physician, ~~or~~ advanced practice nurse prescriber, or physician assistant.

DHS 133.09 (3) (b) *Discharge summary*. The home health agency shall complete a written discharge summary within 30 calendar days following discharge of a patient. The discharge summary shall include a description of the care provided and the reason for discharge. The home health agency shall place a copy of the discharge summary in the former patient's medical record. Upon request, the home health agency shall provide a copy of the discharge summary to the former patient, the patient's legal representative, the attending physician, ~~or~~ advanced practice nurse prescriber, or physician assistant.

SECTION 9. DHS 133.13 is amended to read:

DHS 133.13 Emergency notification. Home health agency personnel shall promptly notify a patient's physician, advanced practice nurse prescriber, physician assistant, or other appropriate medical personnel and guardian, if any, of any significant changes observed or reported in the patient's condition.

SECTION 10. DHS 133.14 (2) (g) is amended to read:

DHS 133.14 (2) (g) Promptly inform either the physician, ~~or~~ advanced practice nurse prescriber, or physician assistant, as well as ~~and~~ other personnel participating in the patient's care of changes in the patient's condition and needs;

SECTION 11. DHS 133.20 (1) and (3) and (4) are amended to read:

DHS 133.20 (1) REQUIREMENT. A plan of care, including physician's, ~~or~~ advanced practice nurse prescriber's, or physician assistant's orders, shall be established for every patient accepted for care and shall be incorporated in the patient's medical record. An initial plan shall be developed within 72 hours of acceptance. The total plan of care shall be developed in consultation with the patient, home health agency staff, contractual providers, and the patient's physician, advanced practice nurse prescriber or physician assistant and shall be signed and dated by the physician, advanced practice nurse prescriber or physician assistant within 20 working days following the patient's admission for care.

DHS 133.20 (3) REVIEW OF PLAN. The total plan of care shall be reviewed by the attending physician, ~~or~~ advanced practice nurse prescriber, or physician assistant, and appropriate agency personnel as often as required by the patient's condition, but no less often than every 60 days. The agency shall promptly notify the physician, the advanced practice nurse prescriber, or the physician assistant of any changes in the patient's condition that suggest a need to modify the plan of care.

DHS 133.20 (4) ORDERS. Drugs and treatment shall be administered by the agency staff only as ordered by the attending physician, ~~or~~ advanced practice nurse prescriber, or physician assistant. The nurse or therapist shall immediately record and sign and date oral orders and obtain the physician's, the advanced practice nurse prescriber's or physician assistant's countersignature and date within 20 working days.

SECTION 12. DHS 133.21 (4) and (5) (e) are amended to read:

DHS 133.21 (4) TRANSFER. If a patient is transferred to another health facility or agency, a copy of the record or ~~abstract shall accompany the patient.~~ summary of the record shall be provided to the receiving agency or facility.

DHS 133.21 (5) (e) Physician's, ~~or~~ advanced practice nurse prescriber's, or physician assistant's orders;

SECTION 13. 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), Wis. Stats.