JUN 26 1995

Infection Control Rules Program

2700 University Avenue West • Suite 40 • St. Paul, Minnesota 55114

Telephone (612) 642-0402 • Fax (612) 643-3535

To: **Maryanne Hruby, Executive Director**
Legislative Commission to Review Administrative Rules

From: **Frank Fly**
Administrative Rules Writer

Date: **June 26, 1995**

Subject: **SONAR**

Five health-related licensing boards are proposing a rule relating to infection control.

Pursuant to Minnesota Statutes, section 14.23, I am enclosing a copy of the SONAR.

I am also enclosing a copy of the proposed rule and a copy of the Notice of Intent to Adopt a Rule.

Although the SONAR has not yet been signed by the authorized representative of each board, I do not anticipate any changes, as the draft has been reviewed by all parties. I will inform you, however, if any changes are made.

Please let me know if you have any questions.

Board of Chiropractic Examiners
2700 University Ave. West
Suite 20
St. Paul, MN 55114

Board of Dentistry
2700 University Ave. West
Suite 70
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Board of Medical Practice
2700 University Ave. West
Suite 106
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Board of Nursing
2700 University Ave. West
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Board of Podiatric Medicine
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BOARDS OF CHIROPRACTIC EXAMINERS, DENTISTRY, MEDICAL PRACTICE, NURSING, PODIATRIC MEDICINE

In the Matter of the Proposed Adoption

of the Rule of the Minnesota Boards of Chiropractic Examiners, Dentistry, Medical Practice, Nursing, Podiatric Medicine

Governing Standards for HBV and HIV Infection Control Procedures

DUAL NOTICE:

NOTICE OF INTENT TO ADOPT A RULE WITHOUT A PUBLIC HEARING UNLESS 25 OR MORE PERSONS REQUEST A HEARING, AND

NOTICE OF HEARING IF 25 OR MORE REQUESTS FOR HEARING ARE RECEIVED

Introduction. The Minnesota Boards of Chiropractic Examiners, Dentistry, Medical Practice, Nursing, and Podiatric Medicine intend to adopt a permanent rule without a public hearing following the procedures set forth in the Administrative Procedure Act, Minnesota Statutes, sections 14.22 to 14.28. If, however, 25 or more persons submit a written request for a hearing on the rule within 30 days or by July 31, 1995, a public hearing will be held on September 8, 1995. To find out whether the rule will be adopted without a hearing or if the hearing will be held, you should contact the boards' contact person after July 31, 1995 and before September 8, 1995.

Boards' Contact Person. Comments or questions on the rule and written requests for a public hearing on the rule must be submitted to:

Frank Fly, Administrative Rules Writer
Infection Control Program
2700 University Avenue West, Suite 40
St. Paul, Minnesota 55114
Telephone: 612-642-0402

Subject of Rule and Statutory Authority. The proposed rule is about standards for HBV and HIV infection control procedures. The statutory authority to adopt the rule is Minnesota Statutes, section 214.24, subdivision 4. A copy of the proposed rule is published in the State Register and attached to this notice as mailed.

Comments. You have until 4:30 p.m. on July 31, 1995 to submit written comment in support of or in opposition to the proposed rule or any part or subpart of the rule. Your comment must be in writing and received by the boards' contact person by the due date. Comment is encouraged. Your comments should identify the portion of the proposed rule addressed, the reason for the comment, and any change proposed.

Request for a Hearing. In addition to submitting comments, you may also request that a hearing be held on the rule. Your request for a public hearing must be in writing and must be received by the boards' contact person by 4:30 p.m. on July 31, 1995. Your written request for a public hearing must include your name, address, and telephone number. You are encouraged to identify the portion of the proposed rule which caused your request, the reason for the request, and any changes you want made to the proposed rule. If 25 or more persons submit a written request for a hearing, a public hearing will be held unless a sufficient number withdraw their requests in writing.

Modifications. The proposed rule may be modified, either as a result of public comment or as a result of the rule hearing process. Modifications must not result in a substantial change in the proposed rule as printed in the State Register and must be supported by data and views submitted to the boards or presented at the hearing. If the proposed rule affects you in any way, you are encouraged to participate in the rulemaking process.

Cancellation of Hearing. The hearing scheduled for September 8, 1995 will be canceled if the boards do not receive requests from 25 or more persons that a hearing be held on the rule. If you requested a public hearing, the boards will notify you before the scheduled hearing whether or not the hearing will be held. You may also call Frank Fly at 612-642-0402 after July 31, 1995 to find out whether a hearing will be held.

Notice of Hearing. If 25 or more persons submit written requests for a public hearing on the rule, a hearing will be held following the procedures in Minnesota Statutes, sections 14.14 to 14.20. The hearing will be held on September 8, 1995 in Conference Room A of the Colonial Office Building, 2700 University Ave. West, St. Paul beginning at 8:30 a.m. and will continue until all interested persons have been heard. The hearing will continue, if necessary, at additional times and places as determined during the hearing by the administrative law judge. The administrative law judge assigned to conduct the hearing is Steve Mihalchick. Judge Mihalchick can be reached at the Office of Administrative Hearings, 1700 100 Washington Square, Minneapolis 55401; telephone 612-349-2544.

Hearing Procedure. If a hearing is held, you and all interested or affected persons including representatives of associations or other interested groups, will have an opportunity to participate. You may present your views either orally at the hearing or in writing at any time prior to the close of the hearing record. All evidence presented should relate to the proposed rule. You may also mail written material to the administrative law judge to be recorded in the hearing

record for five working days after the public hearing ends. This five-day comment period may be extended for a longer period not to exceed 20 calendar days if ordered by the administrative law judge at the hearing. Comments received during this period will be available for review at the Office of Administrative Hearings. You and the boards may respond in writing within five business days after the submission period ends to any new information submitted. All written materials and responses submitted to the administrative law judge must be received at the Office of Administrative Hearings no later than 4:30 p.m. on the due date. No additional evidence may be submitted during the five-day period. This rule hearing procedure is governed by Minnesota Rules, parts 1400.0200 to 1400.1200 and Minnesota Statutes, sections 14.14 to 14.20. Questions about procedure may be directed to the administrative law judge.

Statement of Need and Reasonableness. A statement of need and reasonableness is now available from the boards' contact person. This statement describes the need for and reasonableness of each provision of the proposed rule. It also includes a summary of all the evidence and argument which the boards anticipate presenting at the hearing, if one is held. The statement may also be reviewed and copies obtained at the cost of reproduction from the Office of Administrative Hearings.

Small Business Considerations. Minnesota Statutes, section 14.115, subdivision 2 requires that when an agency proposes a new or amended rule which may affect small businesses, it must consider methods for reducing the impact of the rule on small businesses and document how it has considered these methods and the results. Subdivision 4 requires the agency to provide an opportunity for small businesses to participate in the rulemaking process.

The boards' position is that the requirements of section 14.115 do not apply to the proposed rule, because subdivision 7, clause (2) provides that the section does not apply to agency rules that do not affect small business directly. The boards' authority relates only to the qualifications of health professionals to provide health services; the boards have no authority over the businesses in which they practice. Therefore the proposed rule does not affect businesses as such, and the boards are exempt from the requirements of section 14.115.

The issue of small business considerations is addressed in the statement of need and reasonableness.

Expenditure of Public Money by Local Public Bodies. Minnesota Statutes, section 14.11, subdivision 1 requires that if the adoption of a rule by an agency will require the expenditure of public money by local public bodies, the appropriate notice of the agency's intent to adopt a rule shall be accompanied by a written statement giving the agency's reasonable estimate of the total cost to all local public bodies.

It is the boards' position that the proposed rule will not require the expenditure of public money by local public bodies.

The issue of expenditure of public money by local public bodies is addressed in the

statement of need and reasonableness.

Impact on Agricultural Land. Minnesota Statutes, section 14.11, subdivision 2 requires that if an agency proposing the adoption of a rule determines that the rule may have a direct and substantial adverse impact on agricultural land in the state, the agency shall comply with the requirements of sections 17.80 to 17.84.

The boards' position is that the proposed rule will not have a direct and substantial adverse impact on agricultural land in the state.

The issue of impact on agricultural land is addressed in the statement of need and reasonableness.

Lobbyist Registration. Minnesota Statutes, chapter 10A requires each lobbyist to register with the Ethical Practices Board. Questions regarding this requirement may be directed to the Ethical Practices Board at 100 Centennial Office Building, 658 Cedar Street, St. Paul, Minnesota 55155; telephone 612-296-5148.

Adoption Procedure if No Hearing. If no hearing is required, after the end of the comment period the boards may adopt the rule. The rule and supporting documents will then be submitted to the attorney general for review as to legality and form to the extent form relates to legality. You may request to be notified of the date the rule is submitted to the attorney general or be notified of the attorney general's decision on the rule. If you want to be so notified, or wish to receive a copy of the adopted rule, submit your request to the boards' contact person listed above.

Adoption Procedure After the Hearing. If a hearing is held, after the close of the hearing record, the administrative law judge will issue a report on the proposed rule. You may request to be notified of the date on which the administrative law judge's report will be available, after which date the boards may not take any final action on the rule for a period of five working days. If you want to be notified about the report, you may so indicate at the hearing. After the hearing, you may request notification by sending a written request to the administrative law judge. You may also request notification of the date on which the rule is adopted and filed with the Secretary of State. The board's notice of adoption must be mailed on the same day that the rule is filed. If you want to be notified of the adoption, you may so indicate at the hearing or send a request in writing to the boards' contact person listed above at any time prior to the filing of the rule with the Secretary of State.

June 12, 1995

Larry A. Spicer, Executive Director
Board of Chiropractic Examiners

Patricia H. Glasrud, Executive Director
Board of Dentistry

H. Leonard Boche, Executive Director
Board of Medical Practice

Joyce M. Schowalter, Executive Director
Board of Nursing

Lois E. Mizuno, Executive Director
Board of Podiatric Medicine

Health Licensing Boards
Infection Control Program

2700 University Ave W #40 St Paul MN 55114 ◆ *tel 612-642-0402* ◆ *fax 612-643-3535*

Proposed Rule on HBV and HIV
Statement of Need and Reasonableness

June 23, 1995

Introduction

In 1992, in response to concerns raised about the possibility of transmission of infectious diseases from health care workers to patients, the State Legislature established an infection control program for five health-related boards: Chiropractic Examiners, Dentistry, Medical Practice, Nursing, and Podiatric Medicine.

The infectious diseases of particular concern under the program are the human immunodeficiency virus (hereinafter, "HIV") and the hepatitis B virus with the e antigen present in the most recent blood test (hereinafter, "HBV").

The program has the following components:

- requires licensees to obtain instruction or continuing education in infection control, pursuant to rules adopted by the boards;
- establishes reporting requirements regarding regulated persons who are infected with HIV or HBV or who do not comply with accepted and prevailing infection control procedures related to the prevention of HIV and HBV transmission;
- establishes a monitoring program for regulated persons infected with HIV or HBV;
- authorizes the boards to refuse to grant a license or registration or impose disciplinary or restrictive action against a regulated person who (1) fails to follow accepted and prevailing infection control procedures or fails to comply with infection control rules promulgated by the board; (2) fails to comply with any requirement of the infection control law; or (3) fails to comply with any monitoring or reporting requirement; and
- authorizes the boards to conduct inspections of the clinical practice of a regulated person to determine whether the regulated person is following accepted and prevailing infection control procedures.

The proposed rule is intended to clarify accepted and prevailing infection control procedures related to the prevention of HIV and HBV transmission for purposes of (1) educating health care professionals and the public on appropriate standards and (2) providing clear standards to use for disciplinary or restrictive action.

Statutory Authority

Joint Rulemaking. Minnesota Statutes, section 214.04, subdivision 4 provides that "two or more health-related licensing boards or two or more non-health-related licensing boards may hold joint rulemaking proceedings on proposed rules relating to similar subject matters."

HIV and HBV Prevention Program. Minnesota Statutes, section 214.18, subdivision 1 provides that " 'board' means the boards of dentistry, medical practice, nursing, and podiatric medicine. For purposes of sections 214.19, subdivisions 4 and 5; 214.20, paragraph (1); and 214.24, board also includes the board of chiropractic examiners."

Minnesota Statutes, section 214.24, subdivision 4 provides that "a board is authorized to adopt rules setting standards for infection control procedures. Boards shall engage in joint rulemaking. Boards must seek and consider the advice of the commissioner of health before adopting rules."

Small Business Considerations

Minnesota Statutes, section 14.115, subdivision 2 requires that when an agency proposes a new or amended rule which may affect small businesses, it must consider "methods for reducing the impact of the rule on small business" and "document how it has considered these methods." Subdivision 4 requires the agency to "provide an opportunity for small businesses to participate in the rulemaking process." Subdivision 7, clause 2 states that section 14.115 does not apply to rules that do not affect small business directly, and clause 3 states that section 14.115 does not apply to "service businesses regulated by government bodies for standards and costs, such as ... providers of medical care ..."

It is the boards' position that the proposed rule does not directly affect businesses in general, whether large or small, because the proposed rule governs the professional activity of regulated persons irrespective of whether they are owners of professional practices, employees of another entity, or not gainfully employed at all. Rules on professional activity are related solely to the right to practice in this state and are not at all concerned with the economic status or condition of the individuals granted the right to practice or with where the individuals practice. Neither the existing rules nor the proposed rule impact on business aspects of any regulated person.

It is also the boards' position that subdivision 7, clause 3 clearly exempts rules proposed by the boards from compliance with section 14.115, subdivision 2.

Despite the fact that the proposed rule does not directly affect small business, and by definition appears to be exempt from small business considerations, the boards examined the methods specified in subdivision 2 for lessening the impact of the proposed rule on small business.

Clause (a) cannot be implemented because licensure requirements must be equally applied to every licensee or individual seeking licensure in order to protect the public adequately and because no reporting requirements are imposed on businesses by the proposed rule.

Clause (b) cannot be implemented because a less stringent schedule for compliance would result in chaos with respect to assuring uniformity and fairness in applying licensure standards and because no reporting requirements are imposed on businesses by the proposed rule.

Clause (c) cannot be implemented because businesses are not required to comply with or report under the proposed rule.

Clause (d) cannot be implemented because no performance or operational standards are imposed on businesses by the proposed rule.

Clause (e) cannot be implemented because businesses are not directly impacted by the proposed rule.

Should the rule be modified as a result of any of the provisions of subdivision 2, the rule would be contrary to the statututory objectives that are the basis for the proposed rule; i.e., to implement statutory requirements in a fair and equitable manner for the protection of the public.

In consideration of the above, it is the boards' position that section 14.115 does not apply to the proposed rule; but if it does apply, the small business considerations have been examined and determined to be not applicable.

Expenditure of Public Money by Local Public Bodies

Minnesota Statutes, section 14.11, subdivision 1 requires that if the adoption of a rule by an agency will require the expenditure of public money by local public bodies, the appropriate notice of the agency's intent to adopt a rule shall be accompanied by a written statement giving the agency's reasonable estimate of the total cost to all local public bodies.

The boards' position is that the proposed rule will require little, if any, expenditure of additional funds by individuals seeking licensure and none at all by local public bodies. The cost of implementation should be minimal because the rule specifies infection control standards that are consistent with accepted and prevailing procedures and therefore should already be being followed. What little cost, if any, that may be required to implement the proposed rule would be absorbed by the regulated person.

Impact on Agricultural Land

Minnesota Statutes, section 14.11, subdivision 2 requires that if an agency proposing the adoption of a rule determines that the rule may have a direct and substantial adverse impact on agricultural land in the state, the agency shall comply with the requirements of sections 17.80 to 17.84. The boards' position is that the proposed rule does not relate at all to agricultural land and therefore cannot not have a direct and substantial adverse impact on agricultural land.

Purpose of Rule

The proposed rule is intended to promote the health and safety of patients and regulated persons by reducing the risk of transmission of HBV and HIV in the provision of health care through the use of universal precautions and other infection control procedures.

Under universal precautions, all blood and other body fluids are assumed to be carriers of HIV and HBV and therefore capable of transmitting these viruses. While history shows that the probability of such transmission from health care professionals to patients is extremely low, treating blood and other body fluids as though they contaminated ensures that blood or body fluids which are contaminated do not cause infection in others. Standards in use nationwide are designed to reach this objective, and the proposed rule employs the same reasoning to reach the same objective.

Two national sources of standards relating to HBV and HIV are in use. One is the rule promulgated pursuant to the Occupational Safety and Health Act (hereinafter, "OSHA"). While this rule is designed to provide protection for employees, it does not (and by law, cannot) attempt to address safety concerns for employers, patients, and the public. The proposed rule, by contrast, attempts to provide protection for everyone in a health care setting.

The other national standard is the recommendations of the Centers for Disease Control (hereinafter, "CDC"). These have the advantage that, unlike the OSHA rule, they are designed to provide protection for everyone. The disadvantage of the CDC recommendations is that they are only guidelines and not requirements. Although under Minnesota Statutes, section 214.20, they are enforceable by the boards, they are written in a less precise manner than is normally expected of requirements established by rule.

The proposed rule is intended to fulfill the following objectives:

- to supplement the current national standards by having more universal application than the OSHA rule and more precise requirements than the CDC recommendations;

- to provide guidance to regulated persons on what standards are most important for reducing the risk of HBV/HIV transmission; and

- to state requirements that are reasonable; i.e., requirements that are essential for minimizing risk while at the same time are not unduly burdensome on practitioners.

The boards have authority to adopt different standards for different regulated persons, but the boards decided that the rule should, to the extent practicable, be identical for all the boards so as to avoid confusion among regulated persons. The boards determined that there is no reason to establish different rules; therefore the same rule is being proposed by each of the five boards.

Rule Development Process

In March, 1993 the Executive Directors of the five participating boards formed a Steering Committee to develop an infection control rule to be submitted to the boards for their approval and joint adoption. Voting members consisted of ten persons, one staff representative and one board member from each board. Each board had one vote. The commissioner of health was also asked to appoint two nonvoting members to give advice to the boards. A list of Steering Committee members is attached.

The boards published a Notice of Intent to Solicit Outside Information Regarding Proposed Rules Governing Infection Control Procedures in the April 19, 1993 *State Register*, Vol. 17, No. 42, page 2519. To date the boards have received two written comments which will be made part of the rulemaking record.

The Steering Committee appointed an Advisory Committee to make recommendations to the Steering Committee on standards for infection control procedures. The Steering Committee asked the Advisory Committee to advise the boards on (1) whether a rule on standards is needed, given that there are already rules on infection control adopted under OSHA as well as relevant recommendations by the CDC, and (2) if a rule is needed, what standards would be reasonable.

The Advisory Committee consisted of 30 persons, including representatives of the various professions who would be affected by the rule, health care professionals who specialize in infection control, faculty from the University of Minnesota Infection Control Department, members of the general public, and staff from the Minnesota Department of Health. A list of Advisory Committee members is attached.

The Advisory Committee began meeting in May, 1993, and held meetings approximately once a month until February, 1994, when it submitted its recommendations to the Steering Committee. The Advisory Committee recommended that the boards adopt a rule on standards, and submitted a draft of the rule it recommended that the boards adopt. The Committee recommended the same rule for all five boards, as the Committee determined there is no need for different standards.

In May, 1994 the Steering Committee approved a draft of the rule to be submitted to the five participating boards. The draft's provisions on infection control standards were based largely on the recommendations of the Advisory Committee but also reflected revisions agreed upon by the Steering Committee. The draft also included requirements pertaining to the inspections authorized by Minnesota Statutes, section 214.24, subdivision 1, which states that "the board is authorized to conduct inspections of the clinical practice of a regulated person to determine whether the regulated person is following accepted and prevailing infection control procedures."

The proposed rule was subsequently approved for publication by the Boards of Chiropractic Examiners, Nursing, and Podiatric Medicine. In July, 1994, however, the Board of Medical Practice voted not to authorize adoption of the proposed rule. The Board of Dentistry took no action.

Following the action of the Board of Medical Practice, the Steering Committee reviewed the proposed rule. Members of the Advisory Committee were consulted. The Commissioner of Health was also asked for her advice. Minnesota Statutes, section 214.24, subdivision 4 states that the "boards must seek and consider the advice of the commissioner of health before adopting rules." The Steering Committee's position is that asking for written advice from the Commissioner, as well as having two representatives of the Commissioner on the Steering Committee and one on the Advisory Committee, satisfies this requirement.

In December, 1994, the Steering Committee approved a revised draft of the rule for submission to the boards. A major difference between the revised draft and the previous one was the deletion of provisions relating to inspections. Minnesota Statutes, section 214.24, subdivision 1 authorizes the boards to conduct inspections to determine whether regulated persons are in compliance with infection control requirements. Subdivision 2 specifies that if inspections are conducted, they are to be performed by the Commissioner of Health under contract with the boards. In consideration of the possibility of conducting inspections, the boards proposed in their first draft provisions which would have governed the inspections. Despite a recommendation from the Commissioner of Health that these provisions be retained, the revised draft deleted them because:

- the Attorney General's Office advised the boards that their statutory authority to adopt rules on inspections is in doubt;
- under Minnesota Statutes, section 214.24, subdivision 4, the boards are authorized to conduct inspections provided only that they adopt rules setting standards for infection control procedures, which the proposed rule does; and
- much of the controversy regarding the first version of the proposed rule centered on the provisions relating to the inspections, rather than on the standards being proposed, so that it appeared unlikely that all five boards would approve of the rule unless the inspections provisions were deleted.

Between January and April, 1995, the revised draft was approved for publication by all five boards.

All meetings of the Advisory Committee, the Steering Committee, and the participating boards were open to the public.

General Statement of Need and Reasonableness

The general intent of the proposed standards is to minimize the transmission of potentially infectious materials from one person to another at a clinical practice location while at the same time not imposing unduly burdensome requirements on regulated persons.

The proposed rule is needed because:

- the existing national standards contained in the CDC recommendations are not always clear, precise, and consistent;
- the existing national standards contained in the OSHA rules do not provide adequate protection for all persons in health care settings; and
- regulated persons need to clearly know what standards they can be held accountable for by licensing boards, and the boards need to clearly know what standards to use in determing whether regulated persons are in violation of accepted and prevailing infection control procedures.

The proposed rule is reasonable because it is consistent with accepted and prevailing infection control procedures and thus does not impose any standards beyond what regulated persons should already be following.

Although OSHA rules and CDC recommendations were relied upon to provide general guidance on accepted and prevailing infection control procedures, those rules and recommendations have, as appropriate, been adapted or revised in the proposed rule in order to make the standards:

- more clear and precise;
- more internally consistent;
- more closely comply with the requirements of Minnesota statutes;
- apply more comprehensively to health care procedures;
- provide better protection against the possibility of HBV/HIV transmission; and

- less burdensome for health care professionals.

Discussion of Specific Provisions

6950.1000 STATEMENT OF PURPOSE.

The statement of purpose is modeled after the statement of purpose provided in Minnesota Statutes, section 214.17, creating the HIV and HBV prevention program. The one significant change made is that whereas in the statutes the statement refers to reducing the risk of "infection," in the rule the statement refers to reducing the risk of "transmission of HBV and HIV."

This part is needed to spell out the scope of the rule because the statutory language in sections 214.17 to 214.25 clearly allows HBV and HIV infection to be addressed in rule, but does not unequivocally grant the boards the authority to adopt rules relating to other infectious diseases. It is reasonable to limit the scope of the rule to what the boards clearly have statutory authority to address, and to make this clear in the statement of purpose so that regulated persons are aware of the scope.

6950.1010 DEFINITIONS.

Subpart 1. Scope. This subpart is needed in order to clarify that the terms used in the rule have the meanings given in the rule and in the applicable statute. The subpart is reasonable because the terms and definitions are commonly used by health care professionals.

Subp. 2. Clinical practice location. This term is defined to mean a site at which a regulated person practices. In the body of the rule, the term is used in order to clarify that a requirement applies only to behavior or equipment at a clinical practice location, and not to behavior followed or equipment used in another context. This subpart is needed in order to make clear how the term is used. The subpart is reasonable because it is consistent with statutory intent.

Subp. 3. Contaminated. Contaminated is defined to mean the presence or the reasonably anticipated presence of potentially infectious materials on an item or surface. The subpart is needed in order to make clear how the term is used. The definition is reasonable because it is consistent with the definition used by OSHA.

Subp. 4. Decontamination. The definition of "decontamination" is needed in order to clarify how the term is used in the rule. The definition is reasonable because it is modeled after the definition in the OSHA rule.

Subp. 5. Exposure incident. The proposed definition is needed in order to clarify how

the term is used in the rule. The proposed definition is reasonable because it is modeled after OSHA's.

Subp. 6. High-level disinfection. The proposed definition is necessary in order to clarify how the term is used in the rule. The definition is reasonable because it is consistent with accepted and prevailing usage.

Subp. 7. Infection control requirements. This definition is needed to clarify that the requirements are those established by relevant statute and rule. The definition is reasonable because it is consistent with statutory intent.

Subp. 8. Parenteral. This subpart is needed in order to clarify how the term is used in the rule. The definition is reasonable because it is consistent with accepted and prevailing usage.

Subp. 9. Personal protective equipment. The proposed definition is needed in order to clarify how the term is used in the proposed rule. The definition is reasonble because it is adapted from OSHA's.

Subp. 10. Potentially infectious materials. This subpart is needed in order to clarify how the term is used in the proposed rule. The proposed definition is reasonable because it is based on OSHA's definitions.

Subp. 11. Sharps. This subpart is needed in order to clarify how the term is used in the rule. The subpart is reasonable because it is consistent with OSHA's.

Subp. 12. Sterilization. The proposed definition is needed in order to clarify how the term is used in the rule. The definition is reasonable because it is modeled after OSHA's definition.

6950.1020 COMPLIANCE WITH INFECTION CONTROL REQUIREMENTS.

Subpart 1. Scope of responsibility. This provision requires a regulated person to comply with infection control requirements "to the extent that the regulated person has responsibility for, or jurisdiction and control over, a specific infection control procedure to which the requirements apply." The language is needed in order to clarify that (1) regulated persons must comply with infection control requirements for which they have responsibility, jurisdiction, or control; and (2) regulated persons cannot be held accountable for infection control procedures for which they have no responsibility, jurisdiction, or control. The language is reasonable because it clarifies the circumstances under which the boards can hold a regulated person accountable for infection control procedures and informs regulated persons of the circumstances under which the boards will hold them accountable for infection control procedures.

Subp. 2. Exception to compliance. This subpart is necessary in order to give health

care workers discretion to depart from literally applying the requirements in rare and extraordinary situations where strict compliance would prevent the delivery of health care services or impose an increased hazard to the safety of patients or regulated persons. The subpart is reasonable because it allows health care workers to deviate from the standards when it is necessary, for example, in order to save a person's life in a medical emergency.

6950.1030 COMPLIANCE WITH RECOMMENDATIONS OF CENTERS FOR DISEASE CONTROL.

Subpart 1. **Scope of responsibility.** This provision is needed in order to clarify that a regulated person must comply with the recommendations of the Centers for Disease Control to the extent that the recommendations are consistent with the requirements of the rule. An implication of the provision is that a regulated person is required to comply with CDC recommendations on subjects that are not addressed in the rule.

The provision is reasonable because it is modeled after Minnesota Statutes, section 214.20, which provides that a board may take action against a regulated person who "fails to follow accepted and prevailing infection control procedures, including a failure to conform to current recommendations of the Centers for Disease Control for preventing the transmission of HIV and HBV." The rule language clarifies that a regulated person has an affirmative responsibility to conform to CDC recommendations.

The rule is more specific than the statute in that it identifies specific recommendations of the CDC that regulated persons must follow. The recommendations are contained in the following documents:

A. "Guideline for Handwashing and Hospital Environmental Control, 1985." This document provides specific recommendations on handwashing; cleaning, disinfecting, and sterilizing patient-care equipment; microbiologic sampling; infective waste; housekeeping; and laundry.

B. *Morbidity and Mortality Weekly Report*, August 21, 1987: "Recommendations for Prevention of HIV Transmission in Health-Care Settings." This document provides general recommendations for the prevention of HIV transmission.

C. *Morbidity and Mortality Weekly Report*, June 24, 1988: "Update: Universal Precautions for Prevention of Transmission of Human Immunodeficiency Virus, Hepatitis B Virus, and Other Bloodborne Pathogens in Health-Care Settings." This document provides general recommendations for the preventing the transmission of both HBV and HIV.

D. *Morbidity and Mortality Weekly Report*, February 9, 1990: "Protection Against Viral Hepatitis: Recommendations of the Immunization Practices Advisory Committee (ACIP)." This document provides general recommendations for the prevention of HBV transmission.

E. *Morbidity and Mortality Weekly Report*, May 28, 1993: "Recommended Infection-Control Practices for Dentistry, 1993." This document provides specific recommendations for the prevention of HBV and HIV in dental care.

Citing specific documents is necessary because the CDC has made recommendations on a wide variety of subjects; regulated persons need guidance on which recommendations are most relevant to standards on HIV and HBV.

The documents cited are reasonable in that they were identified by the Advisory Committee as those which best reflect accepted and prevailing infection control procedures relating to preventing the transmission of HIV and HBV.

Subp. 2. Inconsistencies. This provision is needed in order to clarify that if there are inconsistencies between the requirements of the rule and the recommendations of the CDC, the rule supercedes the recommendations. The provision is intended to make sure a regulated person understands that on any subject addressed by both the rule and the recommendations, the rule takes precedence.

The statement is necessary because:

- there are areas where the rule provides a different standard than what is recommended by the CDC;
- the CDC recommendations are contained in different documents published over a period of several years, resulting in recommendations which are not always clear or internally consistent; and
- the CDC recommendations are written as guidelines and not as rules, and therefore may not be written with the same precision and specificity as the provisions in the proposed rule.

Subpart 2 is reasonable because it is consistent with the legal advice given to the boards by the Attorney General's Office. In a November 9, 1993 memorandum, the Attorney General advised the boards as follows:

> ... since Minn. Stat. § 214.24, subd. 4 (1992), gives the boards the authority to adopt rules on infection control standards, it is proper for the boards to adopt rules on standards which may vary or modify CDC standards. However, the boards' rules on standards for infection control must conform to "accepted and prevailing" infection control procedures. In addition, they should clearly indicate to regulated persons which standards are controlling, since violation of either a rule or a CDC recommendation is grounds for discipline.
>
> ... Once the boards have adopted their rules, some of them may differ from or

conflict with the standards created by the CDC. If this occurs, the rules adopted by the boards should state clearly which standards are controlling.

Accordingly, I suggest that the boards consider adopting a provision which states essentially that if the rules on standards for infection control adopted by the boards conflict with or differ from CDC recommendations for a particular infection control standard, the regulated person must comply with the standard adopted by the boards.

6950.1040 EXPOSURE INCIDENTS.

The proposed provision is adapted from a recommendation of the Centers for Disease Control. The CDC recommendation, entitled "Management of Exposures," is stated in the August 21, 1987 *Morbidity and Mortality Weekly Report.* The recommendation reads, in part, as follows:

> If a health-care worker has a parenteral (e.g., needlestick or cut) or mucous-membrane (e.g., splash to the eye or mouth) exposure to blood or other body fluids or has a cutaneous exposure involving large amounts of blood or prolonged contact with blood - especially when the exposed skin is chapped, abraded, or afflicted with dermatitis - the source patient should be informed of the incident and tested for serologic evidence of HIV infection after consent is obtained. Policies should be developed for testing source patients in situations in which consent cannot be obtained (e.g., an unconscious patient).
>
> If the source patient has AIDS, is positive for HIV antibody, or refuses the test, the health-care worker should be counseled regarding the risk of infection and evaluated clinically and seriologically for evidence of HIV infection as soon as possible after the exposure. ...
>
> If a patient has a parenteral or mucous-membrane exposure to blood or other body fluid of a health-care worker, the patient should be informed of the incident, and the same procedure outlined above for management of exposures should be followed for both the source health-care worker and the exposed patient.

Whereas the CDC recommends that a patient be informed whenever the patient is exposed to blood or other body fluid of a health-care worker, the proposed rule would require that the patient be informed only if (1) the source of the exposure incident is a person who tests positive for HBV or HIV; or (2) the source is a person who refuses to be tested for HBV and HIV.

The provision is necessary in order to clarify that the boards are establishing a different requirement than is contained in the CDC recommendations.

This section is reasonable because following the CDC recommendation could result in needlessly alarming a patient. Although the concept of universal precautions assumes that a

person is at risk whenever there is exposure incident, that risk must be weighed against the potential harm that can be done when a patient is informed of a risk that is remote and that can be easily confirmed or disconfirmed. The only action that can be taken following an exposure is to see whether or not an infectious disease has been transmitted. If possible, this should be done without causing needless anxiety in a patient. This can be accomplished by testing the source of the exposure for HBV and HIV. If the source refuses to be tested, then patients should be told of the incident so that they can make a decision about being tested themselves.

The proposed language also makes clear that a patient is not to be informed of the identity of the source of an exposure unless the source has authorized doing so. The intent is to protect the privacy of the source. A regulated person who tests positive for HBV or HIV is required by Minnesota Statutes, section 214.19, subdivision 2 to report to the Commissioner of Health, and an appropriate monitoring plan must be developed pursuant to section 214.23.

6950.1050 COMPLIANCE WITH POLICIES AND PROCEDURES ON INFECTIOUS DISEASES.

This provision is needed for purposes of clarification only. It is intended to make clear that the proposed rule is not to be construed to limit a regulated person's obligation to comply with policies and procedures that are required by a clinic, hospital, or other institution at a clinical practice location. A health care facility may have requirements that address subjects which are not addressed by the rule or that establish more stringent or more specific standards; the rule does not lessen the regulated person's responsibility to abide by those requirements. The provision is reasonable because the rule is not intended to include all infection control policies and procedures that are appropriate for health care professionals to follow. Without the provision, a regulated person might mistakenly assume that the rule replaces infection control procedures established by other entities instead of supplementing them.

6950.1060 GENERAL CONTROLS.

Subpart 1. General requirements.

Item A. This item states that a regulated person must not cut, bend, or break contaminated needles. The item is needed because cutting, bending, or breaking contaminated needles might result in puncturing the skin, resulting in exposing the regulated person to potentially infectious materials from the needles and thereby become infected with HIV or HBV. This requirement is reasonable because it is consistent with OSHA regulations and with accepted and prevailing infection control procedures.

Item B. This item states that a regulated person must not recap or remove a contaminated sharp from its base unless the regulated person can demonstrate that no alternative is feasible, that the action is required by a specific medical procedure, or that the base is reusable, in which case the recapping or removal must be accomplished through the use of a mechanical device or a one-handed technique. The item is needed because recapping or removing a

contaminated sharp from its base might result in puncturing the skin and therefore poses a risk of transmitting HIV or HBV. This provision is reasonable because it is consistent with OSHA requirements and with accepted and prevailing infection control procedures.

Item C. This provision states that a regulated person must minimize splashing, spraying, spattering, and generation of droplets of potentially infectious materials. The provision is necessary because spraying, spattering, or generation of droplets of potentially infectious materials can transmit HIV/HBV to a person exposed to the spraying, spattering, or generating. This provision is reasonable because it is consistent with CDC recommendations and with accepted and prevailing infection control procedures.

Item D. The proposed rule prohibits a regulated person from performing mouth pipetting or suctioning of potentially infectious materials. The item is needed because such pipetting or suctioning exposes the regulated person to potentially infectious materials which can transmit HBV/HIV. The item is reasonable because it is consistent with OSHA requirements and with accepted and prevailing infection control procedures.

Item E. This item states that a regulated person must, before caring for a subsequent patient, remove and replace protective coverings used to cover equipment or work surfaces in work areas if the coverings have become contaminated. This provision is necessary because contaminated coverings can transmit HBV/HIV between patients. The provision is reasonable because it is consistent with OSHA requirements and with accepted and prevailing infection control procedures.

Item F. This provision requires a regulated person to remove debris and residue and decontaminate equipment before the equipment is repaired in the clinical practice location or transported to another site for repair. The requirement is needed because contaminated equipment poses a risk of HBV/HIV transmission when the equipment is repaired or transported. The item is reasonable because decontaminating the equipment is a measure implied by the concept of universal precautions as necessary to minimize the risk of HBV/HIV transmission.

Item G. The proposed rule requires a regulated person to pick up contaminated objects in such a manner that bare or covered skin does not come into contact with contaminated sharp surfaces. This item is necessary because HBV/HIV can be transmitted to bare skin that comes into contact with contaminated sharp surfaces. Covered skin is also at risk because sharp surfaces can cut or break the covering. The item is reasonable because it is consistent with accepted and prevailing infection control procedures.

Subp. 2. Multiple dose vials.

Item A. Under the proposal, a disposable needle or syringe that is used to withdraw fluid from a mutliple dose vial must not be used more than once. This provision is necessary in order to prevent transmission of potentially infectious materials from the disposable

needle or syringe to the vial. The item is reasonable because it is consistent with accepted and prevailing infection control procedures.

Item B. This provision requires that a reusable needle or syringe be sterilized before each use. This provision is necessary in order to prevent transmission of potentially infectious materials from a reusable needle or syringe to the vial. The provision is reasonable because it is consistent with accepted and prevailing infection control procedures.

Subp. 3. Handwashing. The proposed rule requires a regulated person to thoroughly wash hands or other skin surfaces as soon as feasible after hands, other skin surfaces, or gloves are contaminated and in any case prior to treatment of a subsequent patient. The proposed requirement is necessary because gloves do not provide an absolute barrier to bodily fluids; thus it is appropriate for regulated persons to wash their hands when contamination occurs even if they have been wearing gloves. The subpart is reasonable because it is consistent with accepted and prevailing infection control procedures.

Subp. 4. Decontamination and sterilization.

Item A. This item requires all debris and residue from reusable contaminated equipment, instruments, and devices to be completely removed. This item is necessary because it is a minimum precaution to ensure that there is no remaining debris and residue which could be contaminated and therefore transmit HBV/HIV to a person in a health care facility. The item is reasonable because it is consistent with accepted and prevailing infection control procedures.

Item B. The proposed rule requires that equipment, instruments, and devices which come into contact with a patient's vascular system or other normally sterile areas of the body be sterilized. Decontamination of equipment, instruments, and devices is necessary to ensure that HBV/HIV is not transmitted to a patient. Although sterilization is not necessary to prevent HBV/HIV transmission, when such devices come into contact with a sterile area of the body, accepted and prevailing practice is to sterilize those devices in order to prevent the transmission of any infectious disease. The rule requires sterilization in order not to imply that decontamination without sterilization is acceptable when equipment, instruments, or devices come into contact with normally sterile areas of the body. Item B is needed in order to clarify that sterilization is required under these conditions. The provision is reasonable because it is consistent with accepted and prevailing infection control procedures.

Item C. This provision requires equipment, instruments, and devices which come into contact with a patient's intact mucous membranes but do not penetrate body surfaces to be sterilized or high-level disinfected. Decontamination of equipment, instruments, and devices is necessary to ensure that HBV/HIV is not transmitted to a patient. Although sterilization or high-level disinfection is not necessary to prevent HBV/HIV transmission, when such devices come into contact with a patient's intact mucous membranes, accepted and prevailing practice is to sterilize or high-level disinfect those devices in order to prevent the transmission of any infectious disease. The rule requires sterilization or high-level disinfection in order not to imply that

decontamination without sterilization or high-level disinfection is acceptable when equipment, instruments, or devices come into contact with a patient's intact mucous membranes but do not penetrate body surfaces. Item C is needed in order to clarify that sterilization or high-level disinfection is required under these conditions. The provision is reasonable because it is consistent with accepted and prevailing infection control procedures.

Item D. The proposal requires equipment, instruments, and devices which come into contact with a patient's intact skin to be decontaminated. Decontamination of equipment, instruments, and devices is necessary to ensure that HBV/HIV is not transmitted to a patient, since equipment, instruments, and devices may carry potentially infectious materials which can be transmitted when touched. This item is reasonable because when such devices come into contact with a patient's intact skin, accepted and prevailing practice is to decontaminated those devices in order to prevent the transmission of infectious disease.

Item E. This item requires work surfaces to be decontaminated immediately or as soon as feasible after the surfaces become contaminated and prior to treatment of a subsequent patient. This requirement is necessary because work surfaces may contain potentially infectious materials which can transmit HIV/HBV from one patient to another unless the work surfaces are decontaminated. The requirement is reasonable because it is consistent with OSHA's requirements and with accepted and prevailing infection control procedures.

Subp. 5. Transfers. Subpart 5 states that a regulated person must not transfer contaminated disposable sharps or potentially infectious materials from one container to another container. This subpart is needed because transferring contaminated sharps or potentially infectious materials can expose the person to potentially infectious materials and therefore put the person at risk of receiving HIV/HBV. The subpart is reasonable because it is consistent with accepted and prevailing infection control procedures.

Subp. 6. Disposable contaminated sharps.

Item A. Under the proposal, a regulated person must, immediately or as soon as feasible after use and until the sharps are disposed of, store disposable contaminated sharps in containers that are puncture resistant, leakproof on the sides and bottom, closable, and labeled with a biohazard symbol. This provision is necessary in order to ensure that disposable contaminated sharps are stored in a manner that minimizes the risk of HBV/HIV transmission, since containers that are not puncture resistant or leakproof can result in the leakage of potentially infectious materials to which a person could be exposed. A biohazard label provides a warning for the person to make sure the container is not leaking. The requirement is reasonable because it is modeled after OSHA's.

Item B. This provision states that a regulated person must not store or dispose of disposable contaminated sharps in a manner that allows a person to reach by hand into the containers where the sharps are placed. This provision is necessary in order to ensure that disposable contaminated sharps are stored and disposed of in a manner that prevents a person

from reaching into a container and being cut, resulting in the generation of potentially infectious materials which could transmit HIV/HBV to the person. The requirement is reasonable because it is consistent with OSHA requirements and with accepted and prevailing infection control procedures.

Item C. This item requires that a regulated person place containers for disposable contaminated sharps where the containers are easily accessible to health care workers and as close as is feasible to the immediate area where sharps are used or can reasonably be expected to be found. The provision is necessary in order to minimize the extent to which disposable contaminated sharps have to be transported in order to be disposed of. The less such sharps have to be transported, the less the risk of HBV/HIV transmission through accidental spillage. The requirement is reasonable because it is consistent with OSHA requirements and with accepted and prevailing infection control procedures.

Item D. The proposed rule requires that a regulated person replace containers for disposable contaminated sharps before they become full. This requirement is necessary in order to minimize the possibility that disposable contaminated sharps could pile up in such a manner as to fall and contaminate nearby items or surfaces. The requirement is reasonable because it is consistent with OSHA requirements and with accepted and prevailing infection control procedures.

Subp. 7. Reusable contamined sharps.

Item A. This item requires that a regulated person, immediately or as soon as feasible after use and until the sharps are decontaminated, store reusable contaminated sharps in containers that are puncture resistant, leakproof on the sides and bottom, and labeled with a biohazard symbol. This provision is necessary in order to ensure that reusable contaminated sharps are stored in a manner that minimizes the risk of HBV/HIV transmission through leakage of potentially infectious materials. A label with a biohazard symbol cautions persons to make sure the container is not leaking. The requirement is reasonable because it is modeled after OSHA's.

Item B. This provision requires a regulated person to place containers for reusable contaminated sharps where the containers are easily accesssible to health care workers and as close as is feasible to the immediate area where sharps are used or can reasonably be expected to be found. This provision is necessary in order to minimize the extent to which reusable contaminated sharps have to be transported in order to be disposed of. The less such sharps have to be transported, the less the risk of HBV/HIV transmission due to accidental release of potentially infectious materials. The requirement is reasonable because it is modeled after OSHA's.

Item C. Under the proposal, a regulated person must place containers for reusable contaminated sharps where the contents do not impose undue risk of an exposure incident at a clinical practice location. This requirement is necessary in order to ensure that containers for reusable contaminated sharps are placed in a location which minimizes the possibility of an

incident in which a person is exposed to the contents, since the contents contain potentially infectious materials which can transmit HIV/HBV. The item is reasonable because it is consistent with accepted and prevailing infection control procedures.

Item D. The proposed rule requires that a regulated person maintain containers for reusable contaminated sharps upright throughout use. The item is needed because maintaining containers upright minimizes the possibility of spillage, which may transmit HIV/HBV to a person who comes into contact with the spillage. The requirement is reasonable because it is consistent with OSHA requirements and with accepted and prevailing infection control procedures.

Item E. The proposal requires a regulated person to replace containers for reusable contaminated sharps before they become full. This requirement is needed in order to minimize the possibility that reusable contaminated sharps could pile up in such a manner as to fall and contaminate nearby items or surfaces with which a person could come into contact and thereby be infected with HIV or HBV. The requirement is reasonable because it is consistent with OSHA requirements and with accepted and prevailing infection control procedures.

6950.1070 PERSONAL PROTECTIVE EQUIPMENT.

Subpart 1. General requirements.

Item A. This item requires a regulated person to wear appropriate personal protective equipment in situations where it is reasonably anticipated that the person may have skin, eye, mucous membrane, or parenteral contact with potentially infectious materials at a clinical practice location. The requirement is necessary in order to minimize the risk of transmission of HBV/HIV from a patient to a regulated person, since HBV/HIV can be transmitted when there is skin, eye, mucous membrane, or parenteral contact with potentially infectious materials. The requirement is reasonable because it is modeled after OSHA's.

Item B. Under the proposal, disposable contaminated personal protective equipment must not be used in the care of more than one patient. This provision is necessary because contamined personal protective equipment could transmit potentially infectious materials from one patient to another, thereby putting the latter at risk of being infected with HBV or HIV. The requirement is reasonable because it is consistent with OSHA requirements and with accepted and prevailing infection control procedures.

Item C. This item requires that after contaminated personal protective equipment is removed, it be stored so as not to pose undue risk of an exposure incident. The item is needed because contaminated personal protective equipment could, depending on how it is stored, pose a risk of transmitting HBV or HIV to another person who came into contact with the equipment. The requirement is reasonable because it is consistent with OSHA's.

Item D. This requirement is that after the ability of personal protective equipment

to function as a barrier is compromised, the equipment must be discarded. The item is necessary in order to ensure that after personal protective equipment is no longer able to effectively function as a barrier, it is not used for that purpose, since otherwise potentially infectious materials could be transmitted to the person when the equipment was being used. The requirement is reasonable because it is consistent with OSHA's.

Item E. The proposed rule requires appropriate personal protective equipment to be worn in situations where potentially infectious materials may be splashed, sprayed, spattered, or otherwise generated. The item is necessary in order to ensure that regulated persons wear appropriate protective equipment to minimize the risk of transmission of HBV/HIV through the spashing, spraying, or spattering of potentially infectious materials to which the person could otherwise be exposed. The item is reasonable because it is consistent with accepted and prevailing infection control procedures.

Item F. This item requires personal protective equipment to be replaced as necessary to protect self and patients from transmission of HBV or HIV. The item is needed in order to ensure that personal protective equipment is replaced as needed in order to continue to provide protection from HBV/HIV transmission through contact with potentially infectious materials. The item is reasonable because it is consistent with accepted and prevailing infection control procedures.

Subp. 2. Gloves.

Item A. Under the proposal, a regulated person must wear gloves when (1) it can be reasonably anticipated that contact with potentially infectious materials, mucous membranes, or nonintact skin may occur; (2) vascular access procedures are performed; or (3) contaminated items or surfaces are handled or touched. The provision is needed because the concept of universal precautions implies that gloves be worn whenever there is contact with potentially infectious materials or in performing activity where such contact may be reasonably anticipated. This provision is reasonable because it is modeled after OSHA's requirements.

Item B. This item requires a regulated person to wear sterile gloves in preparation for and during surgery requiring sterile technique. The item is needed in order to clarify that although the risk of HBV/ HIV transmission can be minimized through wearing decontaminated gloves, regulated persons must wear sterile gloves for and during surgery requiring sterile technique in order to prevent the transmission of any infectious disease. Requiring regulated persons to wear only decontaminated gloves would imply that it would be acceptable to wear them for and during surgery requiring sterile technique, which is not consistent with accepted and prevailing standards. The item is reasonable because it is consistent with accepted and prevailing infection control procedures.

Item C. The proposal requires a regulated person to replace gloves before caring for a subsequent patient. This item is needed in order to ensure that HBV/HIV is not transmitted from one patient to another through potentially infectious materials which adhere to the gloves.

The item is reasonable because it is consistent with accepted and prevailing infection control procedures.

Item D. This item requires a regulated person to discard gloves which have become worn or punctured, or after their ability to function as a barrier is otherwise compromised. The provision is needed in order to ensure that after gloves are not able to function as a barrier for the transmission of HBV or HIV, they are no longer used for that purpose. Otherwise the gloves would not effectively prevent contact with potentially infectious materials and thereby put the person at risk of being infected with HIV or HBV. The requirement is reasonable because it is modeled after OSHA's.

Item E. The proposed rule requires that a regulated person must not use disposable examination gloves on more than one patient. The requirement is needed in order to reduce the risk of transmission of HBV/HIV from one patient to another through potentially infectious materials adhering to the gloves. The item is reasonable because it is consistent with accepted and prevailing infection control procedures.

Item F. This item requires a regulated person to discard reusable utility gloves used for decontamination procedures or housekeeping tasks if the gloves are cracked, peeling, torn, punctured, exhibit other signs of deterioration, or if their ability to function as a barrier is otherwise compromised. The requirement is necessary in order to ensure that when reusable utility gloves are not able to effectively function as a barrier against HBV/HIV transmission, they are no longer used, since they would not prevent the person from coming into contact with potentially infectious materials to which the person was exposed. The requirement is reasonable because it is consistent with accepted and prevailing infection control procedures.

Subp. 3. Masks, face shields, and eye protection equipment.

Item A. Under this item, a regulated person must wear either (1) a mask and eye protection equipment or (2) a chin-length plastic face shield in situations where it is reasonably anticipated that potentially infectious materials may be splashed, spattered, or otherwise generated. The item is needed in order to ensure that a regulated person's face is adequately protected in situations where potentially infectious materials may be generated and thereby transmit HIV/HBV. The requirement is reasonable because it is consistent with OSHA's.

Item B. The proposal requires that a regulated person replace a disposable mask before caring for a subsequent patient if the mask becomes contaminated. The requirement is needed in order to minimize the risk of HBV/HIV transmission from one patient to another by potentially infectious materials adhering to the mask. The provision is reasonable because it is consistent with accepted and prevailing infection control procedures.

Item C. Under the proposal, a regulated person must decontaminate a reusable mask, face shield, safety glasses, or eye protection equipment before caring for a subsequent

patient if the item becomes contaminated. This item is necessary in order to minimize the risk of HBV/HIV transmission from one patient to another through potentially infectious materials which adhere to the reusable mask, face shield, safety glasses, or eye protection equipment. The item is reasonable because it is consistent with accepted and prevailing infection control procedures.

6950.1080 SPILLS AND LAUNDRY.

Subpart 1. Spills. This item requires surfaces to be decontaminated immediately or as soon as feasible after potentially infectious materials are spilled. The requirement is necessary in order to minimize the risk of HBV/HIV transmission after potentially infectious materials are spilled, since another person may come into contact with the materials and thereby be infected with HIV or HBV. The requirement is reasonable because it is consistent with accepted and prevailing infection control procedures.

Subp. 2. Laundry.

Item A. The proposed rule requires that contaminated linen be handled as little as possible and with minimum agitation. The item is needed because the possibility of HBV/HIV transmission is minimized when contaminated linen is handled as little as possible and with minimum agitation, since handling and agitation of linen increases the possibility of exposure to potentially infectious materials. This requirement is reasonable because it is consistent with OSHA requirements and with accepted and prevailing infection control procedures.

Item B. This item requires contaminated linen to be placed in bags that prevent leakage at the location where it is used. This provision is needed in order to minimize leakage of potentially infectious materials with which a person may come into contact, thereby putting the person at risk of being infected with HBV or HIV. The requirement is reasonable because it is consistent with OSHA's.

Item C. The proposal states that contaminated linen must not be sorted or rinsed in patient-care areas. This provision is necessary in order to minimize the possibility of transmitting HBV or HIV from linen to a patient or other person in a patient-care area, since contaminated linen can transmit potentially infectious materials to people, surfaces, or items with which the linen comes into contact. The requirement is reasonable because it is consistent with OSHA's.

6950.1090 PREVENTING ESCAPE OF FLUIDS.

The proposed rule requires that a regulated person refrain from having hands-on contact with patients or handling equipment, instruments, or devices with which patients may come into contact when the regulated person has an injury, sore, wound, or dermatitis which is oozing or dripping with potentially infectious materials and which is not covered by a mask or dressing that prevents the escape of all fluids. This provision is adapted from a CDC guideline which recommends that a health care worker who has exudative lesions or weeping dermatitis refrain

from (1) all direct patient care; and (2) handling patient-care equipment and devices used in performing invasive procedures. The provision is necessary because the CDC guideline is not appropriate to be adopted as a rule. As a guideline, the CDC recommendation can be interpreted to be flexible enough to allow direct patient care and equipment handling in some situations, provided that appropriate precautionary measures are taken. The proposed rule acknowledges such circumstances by permitting patient care and equipment handling when the regulated person has taken measures to prevent the escape of fluids. A rigid prohibition would not allow, for example, a doctor with a minor cut to treat a patient in a situation where the patient's life would be endangered without treatment. It would not serve the interests of the public to adopt a rule that would not allow health care professionals to exercise discretion so as to be able to act in the best interests of the patient. The proposal is reasonable because it provides public protection while at the same time does not impose an undue burden on health care professionals.

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