

contains 40 international units (IU) of insulin.

(b) *Sponsor.* See No. 057926 in § 510.600 of this chapter.

(c) *Conditions of use in dogs*—(1) *Amount.* (i) Administer by subcutaneous injection. An initial once-daily dose, administered by

subcutaneous injection concurrently with or right after a meal, is calculated as follows:

| Body Weight | Initial Dose |
|--|----------------|
| <10 kg ¹ (<22 lb ²) | 1 IU/kg + 1 IU |
| 10 to 11 kg (22 to 24 lb) | 1 IU/kg + 2 IU |
| 12 to 20 kg (25 to 44 lb) | 1 IU/kg + 3 IU |
| >20 kg (>44 lb) | 1 IU/kg + 4 IU |

¹ kg means kilograms.

² lb means pounds.

(ii) Adjust the once-daily dose described in paragraph (c)(1)(i) of this section at appropriate intervals based on clinical signs, urinalysis results, and glucose curve/spot check values until adequate glycemic control has been attained. Twice-daily therapy should be initiated if the duration of insulin action is determined to be inadequate. If twice-daily treatment is initiated, the two doses should be 25 percent less than the once daily dose required to attain an acceptable nadir.

(2) *Indications for use.* For the reduction of hyperglycemia and hyperglycemia-associated clinical signs in dogs with diabetes mellitus.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

Dated: April 23, 2004.

Catherine P. Beck,

Acting Director, Center for Veterinary Medicine.

[FR Doc. 04-10498 Filed 5-7-04; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

23 CFR Part 655

[Docket No. FHWA-2004-17321]

RIN 2125-AF02

National Standards for Traffic Control Devices; the Manual on Uniform Traffic Control Devices for Streets and Highways; Specific Service and General Service Signing for 24-Hour Pharmacies

AGENCY: Federal Highway Administration (FHWA), (DOT).

ACTION: Interim final rule; request for comments.

SUMMARY: This interim final rule amends the rule that prescribes the use of the 2003 edition of the Manual on

Uniform Traffic Control Devices (MUTCD) to permit the use of Specific Service and General Service signing to assist motorists in locating licensed 24-hour pharmacy services open to the public. These changes are designated as Revision No. 1 to the 2003 Edition of the MUTCD.

DATES: *Effective date:* This interim final rule is effective July 21, 2004. The incorporation by reference of the publication listed in this rule is approved by the Director of the Federal Register as of July 21, 2004.

Comment date: Comments relating to the technical details of the MUTCD amendment must be received on or before June 30, 2004.

ADDRESSES: Mail or hand deliver comments to the U.S. Department of Transportation, Dockets Management Facility, Room PL-401, 400 Seventh Street, SW., Washington, DC 20590, or submit comments electronically at <http://dms.dot.gov/submit>, or fax comments to (202) 493-2251. Alternatively, comments may be submitted via the Federal eRulemaking Portal at <http://www.regulations.gov> (follow the on-line instructions for submitting comments). All comments should include the docket number that appears in the heading of this document. All comments received will be available for examination and copying at the above address from 9 a.m. to 5 p.m., *e.t.*, Monday through Friday, except Federal holidays. Those desiring notification of receipt of comments must include a self-addressed, stamped postcard or you may print the acknowledgment page that appears after submitting comments electronically. All comments received into any docket may be searched in electronic format by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, *etc.*). Persons making comments may review U.S. DOT's complete Privacy Act Statement in the **Federal**

Register published on April 11, 2000 (Volume 65, Number 70, Pages 19477-78), or you may view the statement at <http://dms.dot.gov>.

FOR FURTHER INFORMATION CONTACT: Mr. Ernest Huckaby, Office of Transportation Operations (HOTO-1), (202) 366-9064, or Mr. Raymond Cuprill, Office of the Chief Counsel (202) 366-0791, Federal Highway Administration, 400 Seventh Street, SW., Washington, D.C. 20590-0001. Office hours are from 7:45 a.m. to 4:15 p.m., *e. t.*, Monday through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION:

Electronic Access and Filing

You may submit or retrieve comments online through the Document Management System (DMS) at: <http://dms.dot.gov/submit>. Acceptable formats include: MS Word (versions 95 to 97), MS Word for Mac (versions 6 to 8), Rich Text File (RTF), American Standard Code Information Interchange (ASCII)(TXT), Portable Document Format (PDF), and WordPerfect (versions 7 to 8). The DMS is available 24 hours each day, 365 days each year. Electronic submission and retrieval help and guidelines are available under the help section of the web site.

An electronic copy of this document may also be downloaded by using a computer, modem and suitable communications software from the Government Printing Office's Electronic Bulletin Board Service at (202) 512-1661. Internet users may also reach the Office of the Federal Register's Home page at: http://www.archives.gov/federal_register and the Government Printing Office's Web page at: <http://www.gpoaccess.gov>.

Background

On January 23, 2004, the President signed, thereby enacting into law, the Consolidated Appropriations Act, Fiscal Year 2004 (the Act), Public Law 108-199, 118 Stat. 3. Division F of the Act

(the Transportation, Treasury, and Independent Agencies Appropriations Act, 2004, at 118 Stat. 279), Title I, section 124, directs the Secretary of Transportation to amend the MUTCD to include a provision permitting information to be provided to motorists to assist motorists in locating licensed 24-hour pharmacy services open to the public. The Act also allows placement of logo panels that display information disclosing the names or logos of pharmacies that are located within three miles of an interchange on the Federal-aid system¹. The FHWA has developed changes to the text and figures of the MUTCD to implement the requirements of the Act and provide for the uniformity of signing for pharmacy services when jurisdictions choose to install such signs.

Discussion of Amendments Related to Pharmacy Signing—Part 2 Signs

1. In Section 2D.45 General Service Signs (D9 Series), the FHWA revises the second STANDARD statement to remove the list of legends for various services. This list was incomplete in that it did not include some of the types of services that had been previously added to the MUTCD for General Service signing. Rather than adding Pharmacy and other services that had been missing from the list, the FHWA amends the sentence to be general in nature, applying to all types of General Service signs, including Pharmacy signs. The text of the second standard statement will now state: "General Service signs, if used at intersections, shall be accompanied by a directional message."

Consistent with the requirements of the Act, the FHWA revises the third STANDARD statement to add the requirement that the Pharmacy (D9–20) sign shall only be used to indicate the availability of a pharmacy that is open, with a State-licensed pharmacist on duty, 24 hours per day, seven days per week and that is located within 3 miles of an interchange on the Federal-aid system. The D9–20 sign shall have a 24 HR (D9–20) plaque mounted below it. The Act refers to "licensed pharmacy services." The States license pharmacy service by requiring pharmacists to be licensed, according to criteria set by each State, in order to practice the profession of pharmacy and dispense prescription medicines to the public. Retail pharmacies employ State-licensed

pharmacists to perform this service in their stores².

The FHWA also revises Figure 2D–11 General Service Signs to add a new D9–20 Pharmacy symbol sign, with a white "Rx" symbol and border on a blue background, and a D9–20a plaque having white "24 HR" text and border on a blue background. The "Rx" symbol is widely used in commercial signing and other media to denote medicinal prescriptions available at pharmacies. The textbook "Remington's Pharmaceutical Sciences" states: "The Rx symbol generally is understood to be a contraction of the Latin verb recipe, meaning 'take thou' or 'you take.' Some historians believe this symbol originated from the sign of Jupiter, employed by the ancients in requesting aid in healing. Gradual distortion through the years has led to the symbol currently used. Today, the symbol is representative of both the prescription and pharmacy itself."³ Also, in 1997 the Attorney General of the State of Kansas issued Opinion No. 97–8 that "the taking, use or exhibition of the symbol 'Rx' is limited to licensed pharmacists and entities which employ licensed pharmacists."⁴ The FHWA believes that the simplicity and boldness of the Rx symbol as shown in Figure 2D–11 will aid in recognition, conspicuity, and legibility for road users, as compared to other possible symbols involving mortar and pestle or other similar devices.

2. In Section 2E.51 General Service Signs, the FHWA revises the first guidance statement to renumber existing item F to become item G and to insert as new item F the recommended criteria for availability of pharmacy services shown on General Service signs. The criteria for pharmacy services are that the pharmacy must be open, with a State-licensed pharmacist on duty, 24 hours per day, seven days per week and located within 4.8 km (3 miles) of an interchange on the Federal-aid system. These criteria correspond to the requirements of the Act.

Also, in the third STANDARD statement, the FHWA adds Pharmacy to the list of services for which one or more legends shall be carried on General Service signs.

The FHWA amends the fourth option statement to allow the Pharmacy (D9–20) symbol as well as the Tourist Information (D9–18) symbol to be

substituted on symbolic (D9–18) General Service signs in the last position. Further, the FHWA changes the parenthetical phrase "(four services)" in the first sentence of this paragraph to "(four or six services)" for clarity and to correctly reflect that six services may be displayed on symbolic General Service signs, as stated previously in Section 2E.51.

3. The FHWA revises Figure 2E–42 Examples of General Service Signs (with Exit Numbering) to include additional examples of the D9–18a and D9–18 General Service signs that illustrate the use of the pharmacy word legend and pharmacy symbol on these signs.

4. In Section 2F.01 Eligibility, the FHWA adds to the second standard a statement that distances to eligible 24-hour pharmacies shall not exceed 4.8 km (3 miles) in either direction of an interchange on the Federal-aid system.

In addition, the FHWA amends the third guidance statement to indicate that distances to eligible services other than pharmacies should not exceed 4.8 km (3 miles) in either direction.

The FHWA also amends the second option statement to specifically exempt pharmacies from the provision that allows the 4.8 km (3 mi) limit to be extended for eligibility for Specific Service signs when eligible facilities are not available within the 4.8 km (3 mi) limit or choose not to participate.

Finally, the FHWA adds a standard statement at the end of the section listing criteria that must be met for a pharmacy to qualify for Specific Service signing if a jurisdiction elects to provide Specific Service signing for pharmacies. Both of the following criteria must be met: (1) The pharmacy shall be continuously operated 24 hours per day, seven days per week, and shall have a State-licensed pharmacist on duty at all times, and (2) the pharmacy shall be located within 4.8 km (3 miles) of an interchange on the Federal-aid system. These criteria correspond to those specified in the Act.

5. In Section 2F.02 Application, the FHWA amends the standard statement to include 24-hour pharmacy as the first service type that is to be displayed in successive Specific Service signs in the direction of traffic. In this same standard, the FHWA adds the word message 24-hour pharmacy to the list of word messages on Specific Service signs.

In the option statement, the FHWA also removes the list of various specific services that may be signed on any class of highway. This list was incomplete in that it did not include some of the types of services that had been previously added to the MUTCD for Specific

² Information about licensing of pharmacists may be found on the website of the National Association of Boards of Pharmacy, at the following URL: <http://www.nabp.net>.

³ Remington: The Science and Practice of Pharmacy, 20th edition, 2000, page no. 1688.

⁴ This Opinion may be viewed at <http://kscourts.org/opinions/1997/1997-008.htm>.

¹ Federal-aid systems are defined in 23 U.S.C. 101 and 103.

Service signing. Rather than adding Pharmacy and other services that had been missing from the list, the FHWA amends the sentence to be general in nature, applying to all types of Specific Service signs, including those for Pharmacy services. The text will now indicate that Specific Service signs may be used on any class of highway.

6. In Section 2H.04 Regulatory and Warning Signs, in Table 2H-1 Category Chart for Symbols, the FHWA amends the Motorist Services series to add the 24-Hour Pharmacy symbol as new number RM-230. With the establishment of the new symbol for pharmacy in the D9 series of symbols for General Service signing, the FHWA believes it is appropriate for consistency and uniformity to provide for this symbol to be used in Recreational and Cultural Interest Area signing as well. The other D9 series symbols are already included in Chapter 2H for use with Recreational and Cultural Interest Area signing.

7. In Section 2H.08 Placement of Recreational and Cultural Interest Area Symbol Signs, the FHWA amends Figure 2H-5 Recreational and Cultural Interest Area Symbol Signs (Sheet 2 of 5) to include the 24-hour Pharmacy (RM-230) symbol sign. This sign consists of a white "Rx" symbol and border on a square brown background with an integral supplemental plaque having a white "24 HR" legend and border on a rectangular brown background.

Rulemaking Analyses and Notices

Under the Administrative Procedure Act (APA) (5 U.S.C. 553(b)), an agency may waive the normal notice and comment requirements if it finds, for good cause, that they are impracticable, unnecessary, or contrary to the public interest. The FHWA has determined that prior notice and comment is impracticable and contrary to the public interest due to a congressionally imposed deadline. Section 124, Division F, Title I Consolidated Appropriations Act, 2004, requires that the Secretary of Transportation amend the MUTCD within 6 months of the effective date of the Act to include a provision permitting information to be provided to motorists to assist motorists in locating licensed 24-hour pharmacies. Therefore, taking into account Congress's expectation that this regulation will be issued in July 2004, the FHWA is faced with a situation in which the necessary and timely required execution of the required changes to the MUTCD would be prevented by undertaking a rulemaking proceeding prior to the adoption of the necessary changes to the

MUTCD. In order to meet the congressionally mandated deadline, the FHWA is adopting the change to the MUTCD with as much notice as practicable by issuing this interim final rule and inviting public comment before the final regulation is issued. Furthermore, it is contrary to the public interest to further delay the ability of the States to provide this pertinent information to the traveling public. Accordingly, for the reasons listed above the agency finds good cause under 5 U.S.C. 553(b)(3)(B) to waive prior notice and opportunity for comment.

Comments received will be considered in evaluating whether any changes to the technical details of the revised MUTCD text and figures in this interim final rule are required. All comments received before the close of business on the comment closing date indicated above will be considered and will be available for examination in the docket at the above address. Comments received after the comment closing date will be filed in the docket and will be considered to the extent practicable. In addition to late comments, the FHWA will also continue to file relevant information in the docket as it becomes available after the comment period closing date, and interested persons should continue to examine the docket for new material.

Executive Order 12866 (Regulatory Planning and Review) and DOT Regulatory Policies and Procedures

The FHWA has determined that this action is not a significant regulatory action within the meaning of Executive Order 12866 or significant within the meaning of the U.S. Department of Transportation regulatory policies and procedures. It is anticipated that the economic impact of this rulemaking will be minimal. Including 24-hour pharmacies in General and Specific Service signs is required by law (see section 124 Division F, Title I, of Public Law 108-199, January 23, 2004.) States and other jurisdictions are not required to install signs for pharmacy services, but if they elect to do so, these amendments to the MUTCD will create uniformity in how the Pharmacy signs are used on public roads.

These changes will not adversely affect, in a material way, any sector of the economy. In addition, these changes will not interfere with any action taken or planned by another agency and will not materially alter the budgetary impact of any entitlements, grants, user fees, or loan programs.

Regulatory Flexibility Act

In compliance with the Regulatory Flexibility Act (Pub. L. 96-354, 5 U.S.C. 601-612) the FHWA has evaluated the effects of this action on small entities and has determined that this action will not have a significant economic impact on a substantial number of small entities. This action adds General Service and Specific service signing for optional use by States to provide motorist information concerning pharmacies in order to aid the traveling public. States are not included in the definition of small entity set forth in 5 U.S.C. 601. For these reasons, the FHWA certifies that this action will not have a significant economic impact on a substantial number of small entities. The FHWA will reexamine this certification after reviewing the comments to this rule.

Unfunded Mandates Reform Act of 1995

This interim final rule does not impose unfunded mandates as defined by the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4, March 22, 1995, 109 Stat. 48). This rule will not result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100 million or more in any one year. States and other jurisdictions are not required to install signs for pharmacy services, but if they elect to do so, these amendments to the MUTCD will create uniformity in how the signs are used on public roads.

Additionally, the definition of "Federal mandate" in the Unfunded Mandates Reform Act excludes financial assistance of the type in which State, local, or tribal governments have authority to adjust their participation in the program in accordance with changes made by the Federal government. The Federal-aid highway program permits this type of flexibility to the States.

Executive Order 13132 (Federalism Assessment)

This action has been analyzed in accordance with the principles and criteria contained in Executive Order 13132, and the FHWA has determined that this action does not have sufficient federalism implications to warrant the preparation of a federalism assessment. The FHWA has also determined that this action does not preempt any State law or State regulation or affect the States' ability to discharge traditional State governmental functions.

The MUTCD is incorporated by reference in 23 CFR part 655, subpart F. These amendments are in keeping with the Secretary of Transportation's

authority under 23 U.S.C. 109(d), 315, and 402(a) to promulgate uniform guidelines to promote the safe and efficient use of the highway. The overriding safety benefits of the uniformity prescribed by the MUTCD are shared by all of the State and local governments, and changes made to this rule are directed at enhancing safety. To the extent that these amendments override any existing State requirements regarding traffic control devices, they do so in the interest of national uniformity.

Executive Order 12372 (Intergovernmental Review)

Catalog of Federal Domestic Assistance Program Number 20.205, Highway Planning and Construction. The regulations implementing Executive Order 12372 regarding intergovernmental consultation on Federal programs and activities apply to this program.

Paperwork Reduction Act

This action does not contain a collection of information requirement under the Paperwork Reduction Act of 1995, 44 U.S.C. 3501–3520.

National Environmental Policy Act

The agency has analyzed this action for the purpose of the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4347) and has determined that this action will not have any effect on the quality of the environment.

Executive Order 13175 (Tribal Consultation)

The FHWA has analyzed this action under Executive Order 13175, dated November 6, 2000, and concluded that this interim final rule will not have substantial direct effects on one or more Indian tribes; will not impose substantial direct compliance costs on Indian tribal government; and will not preempt tribal law. The requirements set forth in this interim final rule do not directly affect one or more Indian tribes. Therefore, a tribal summary impact statement is not required.

Executive Order 12988 (Civil Justice Reform)

This interim final rule meets applicable standards in section 3(a) and 3(b)(2) of Executive Order 12988, Civil Justice Reform, to minimize litigation, eliminate ambiguity, and reduce burden.

Executive Order 13045 (Protection of Children)

Under Executive Order 13045, Protection of Children from Environmental Health and Safety Risks,

this interim final rule is not economically significant and does not involve an environmental risk to health and safety that may disproportionately affect children.

Executive Order 12630 (Taking of Private Property)

This interim final rule will not effect a taking of private property or otherwise have taking implications under Executive Order 12630, Governmental Actions and Interference with Constitutionally Protected Property Rights.

Executive Order 13211 (Energy Effects)

This interim final rule has been analyzed under Executive Order 13211, Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use. The FHWA has determined that it is not a significant energy action under that order because it is not a significant regulatory action under Executive Order 12866 and this interim final rule is not likely to have a significant adverse effect on the supply, distribution, or use of energy.

Regulation Identification Number

A regulation identification number (RIN) is assigned to each regulatory action listed in the Unified Agenda of Federal Regulations. The Regulatory Information Service Center publishes the Unified Agenda in April and October of each year. The RIN contained in the heading of this document can be used to cross reference this action with the Unified Agenda.

List of Subjects in 23 CFR Part 655

Design standards, Grant programs—transportation, highways and roads, Incorporation by reference, Signs and symbols, Traffic regulations.

Issued on: May 3, 2004.

Mary E. Peters,
Federal Highway Administrator.

■ In consideration of the foregoing, the FHWA is amending title 23, Code of Federal Regulations, part 655, subpart F as follows:

PART 655—TRAFFIC OPERATIONS

■ 1. The authority citation for part 655 continues to read as follows:

Authority: 23 U.S.C. 101(a), 104, 109(d), 114(a), 217, 315, and 402(a); 23 CFR 1.32; and 49 CFR 1.48(b).

Subpart F—Traffic Control Devices on Federal-Aid and Other Streets and Highways—[Amended]

■ 2. Revise § 655.601(a) to read as follows:

§ 655.601 Purpose.

* * * * *

(a) Manual on Uniform Traffic Control Devices for Streets and Highways (MUTCD), 2003 Edition, including Revision No. 1, FHWA, dated July 21, 2004. This publication is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51 and is on file at the National Archives and Record Administration (NARA). For information on the availability of this material at NARA call (202) 741–6030, or go to http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html. It is available for inspection and copying at the Federal Highway Administration, 400 Seventh Street, SW., Room 3408, Washington, DC 20590, as provided in 49 CFR part 7. The text is also available from the FHWA Office of Transportation Operations' Web site at: <http://mutcd.fhwa.dot.gov>.

* * * * *

[FR Doc. 04–10491 Filed 5–7–04; 8:45 am]

BILLING CODE 4910–22–P

DEPARTMENT OF THE TREASURY

Alcohol and Tobacco Tax and Trade Bureau

27 CFR Part 9

[T.D. TTB–11; Re: Notice No. 11]

RIN 1513–AC81

Columbia Gorge Viticultural Area (2002R–03P)

AGENCY: Alcohol and Tobacco Tax and Trade Bureau, Treasury.

ACTION: Final rule; Treasury decision.

SUMMARY: This Treasury decision establishes the Columbia Gorge viticultural area in Hood River and Wasco Counties, Oregon, and Skamania and Klickitat Counties, Washington, approximately 60 miles east of Portland, Oregon. We designate viticultural areas to allow bottlers to better describe the origin of wines and allow consumers to better identify the wines they may purchase.

DATES: *Effective Date:* July 9, 2004.

FOR FURTHER INFORMATION CONTACT: N.A. Sutton, Program Manager, Regulations and Procedures Division, Alcohol and Tobacco Tax and Trade Bureau, 6660 Delmonico Drive, #D422, Colorado Springs, CO 80919; telephone (415) 271–1254.

SUPPLEMENTARY INFORMATION: