Authority: 21 U.S.C. 321, 331, 351, 352, 353, 355, 360b–360f, 360j, 361(a), 371, 374, 375, 379e; 42 U.S.C. 216, 241, 242(a), 262, 263b–263n.

4. Section 310.545 is amended by revising the headings of paragraphs (a)(15) and (a)(15)(i), and by revising paragraph (a)(15)(ii) to read as follows:

§ 310.545 Drug products containing certain active ingredients offered over-the-counter (OTC) for certain uses.

(a) * * *

(15) *Topical otic drug products*—(i) *For the prevention of swimmer's ear and for the drying of water-clogged ears, approved as of May 7, 1991.*

* * * * *

(ii) *For the prevention of swimmer's ear, approved as of August 15, 1995.*

Glycerin and anhydrous glycerin

Isopropyl alcohol

* * * * *

PART 344—TOPICAL OTIC DRUG PRODUCTS FOR OVER-THE-COUNTER HUMAN USE

5. The authority citation for 21 CFR part 344 continues to read as follows:

Authority: 21 U.S.C. 321, 351, 352, 353, 355, 360, 371.

6. Section 344.3 is amended by adding paragraphs (c) and (d) to read as follows:

§ 344.3 Definitions.

* * * * *

(c) *Water-clogged ears.* The retention of water in the external ear canal, thereby causing discomfort and a sensation of fullness or hearing impairment.

(d) *Ear drying aid.* A drug used in the external ear canal to help dry water-clogged ears.

7. Section 344.10 is amended by revising the section heading to read as follows:

§ 344.10 Earwax removal aid active ingredient.

* * * * *

8. Section 344.12 is added to subpart B to read as follows:

§ 344.12 Ear drying aid active ingredient.

The active ingredient of the product consists of isopropyl alcohol 95 percent in an anhydrous glycerin 5 percent base.

9. Section 344.50 is amended by revising the section heading and by removing paragraph (e) to read as follows:

§ 344.50 Labeling of earwax removal aid drug products.

* * * * *

10. Section 344.52 is added to subpart C to read as follows:

§ 344.52 Labeling of ear drying aid drug products.

(a) *Statement of identity.* The labeling of the product contains the established name of the drug, if any, and identifies the product as an ''ear drying aid.''

(b) *Indications.* The labeling of the product states, under the heading ''Use,'' the following: ''dries water in the ears'' (optional, which may be followed by: ''and relieves water-clogged ears'') (which may be followed by any or all of the following: ''after: [bullet] [1] swimming [bullet] showering [bullet] bathing [bullet] washing the hair''). Other truthful and nonmisleading statements, describing only the indications for use that have been established and listed in paragraph (b) of this section, may also be used, as provided in § 330.1(c)(2) of this chapter, subject to the provisions of section 502 of the Federal Food, Drug, and Cosmetic Act (the act) relating to misbranding and the prohibition in section 301(d) of the act against the introduction or delivery for introduction into interstate commerce of unapproved new drugs in violation of section 505(a) of the act.

(c) *Warnings.* The labeling of the product contains the following warnings under the heading ''Warnings'':

(1) ''Flammable [in bold type]: Keep away from fire or flame.''

(2) ''Do not use [in bold type] in the eyes.''

(3) ''Ask a doctor before use if you have [in bold type] [bullet] ear drainage or discharge [bullet] pain, irritation, or rash in the ear [bullet] had ear surgery [bullet] dizziness.''

(4) ''Stop use and ask a doctor if [in bold type] irritation (too much burning) or pain occurs.''

(d) *Directions.* The labeling of the product contains the following statement under the heading ''Directions'': [optional, bullet] ''apply 4 to 5 drops in each affected ear.''

Dated: July 31, 2000.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 00–19992 Filed 8–9–00; 8:45 am]

BILLING CODE 4160–01–F

[1] See § 201.66(b)(4) of this chapter.

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

23 CFR Part 1335

[Docket No. NHTSA–98–4532]

RIN 2127–AH43

State Highway Safety Data and Traffic Records Improvements

AGENCY: National Highway Traffic Safety Administration (NHTSA), Department of Transportation.

ACTION: Final rule.

SUMMARY: This document adopts as a final rule the regulations that were published in an interim final rule to implement a new program established by the Transportation Equity Act for the 21st Century (TEA–21), with modifications to clarify the program's maintenance of effort requirement. Under the final rule, States can qualify for incentive grant funds for improved highway safety data and traffic records systems if they meet the eligibility requirements.

DATES: This final rule becomes effective on September 11, 2000.

FOR FURTHER INFORMATION CONTACT: Ms. Wendi Wilson-John, Office of State and Community Services, NSC–01, National Highway Traffic Safety Administration, 400 Seventh Street, SW, Washington, DC 20590, telephone (202) 366–2121; or Ms. Heidi L. Coleman, NCC–30, NHTSA, 400 Seventh Street, SW., Washington, DC 20590; telephone (202) 366–1834.

SUPPLEMENTARY INFORMATION: The Transportation Equity Act for the 21st Century (TEA–21) was signed into law on June 9, 1998, as Public Law 105–178. Section 2005 of TEA–21 established a new Section 411, entitled State Highway Safety Data Improvements, in Title 23, United States Code (Section 411). Under this new program, States may qualify for incentive grant funds by adopting and implementing effective highway safety data and traffic records improvement programs that meet specified statutory criteria.

Components Required by Section 411

Section 411 provides that a State's highway safety data and traffic records system should have three basic components, all of which must be present if the State is to receive multiple-year grants: a committee to coordinate the development and use of highway safety data and traffic records; a systematic assessment of the State's highway safety data and traffic records;

and a strategic plan for the continued improvement of highway safety data and traffic records.

Types of Grant

Section 411 anticipated that some States may not be able to meet all three prerequisites in the first or even the second year of the Section 411 program. The statute further anticipated that the strategic plan would be the most complex, and the most time-consuming, prerequisite to meet.

Accordingly, the section provided for three types of grants: a ''start-up'' grant, in the amount of $25,000, to each State that is not eligible for the other grants, provided that the State certifies that it will use the grant to meet the requisite components in the following year; an ''initiation'' grant, in the amount of $125,000, to each State that has established a coordinating committee, has performed or updated an assessment within the last five years, and has initiated the development of a strategic plan; and an ''implementation'' grant, in the amount described below, to each State that has established a coordinating committee, has performed or updated an assessment within the last five years, and has developed a strategic plan.

Section 411 provided that the first two types of grants would be available for one year only, and that the third grant would be available for multiple years. In accordance with the statute, a State that initially qualifies for a start-up grant may qualify for an initiation or an implementation grant in a subsequent fiscal year, if the State meets the criteria for these types of grants. A State that qualifies for an initiation or an implementation grant in any fiscal year may receive only implementation grants in subsequent fiscal years.

Section 411 provides that the amount of funds a State receives for an implementation grant is determined by a formula. The amount is determined by multiplying the amount appropriated to carry out 23 U.S.C. 411 by the ratio that the funds apportioned to the State under 23 U.S.C. 402 for fiscal year 1997 bears to the funds apportioned to all States under 23 U.S.C. 402 for fiscal year 1997, with the following exceptions. If the State has not received an initiation or an implementation grant under the Section 411 program in a previous fiscal year, the State shall receive no less than $250,000. If the State has received either of these two grants under the Section 411 program in a previous fiscal year, the State shall receive no less than $225,000.

All grant amounts are subject to the availability of funds.

Limitations on Grant Amounts

Section 411 provided that no State may receive a grant in more than six fiscal years, and a total of $32 million was authorized for the Section 411 program over a period of four years. Specifically, TEA–21 authorized $5 million for fiscal year 1999, $8 million for fiscal year 2000, $9 million for fiscal year 2001, and $10 million for fiscal year 2002. Funds may be used by States only to adopt and implement improvements to their highway safety data and traffic records programs.

Under Section 411, States are required to match the grant funds they receive as follows: the Federal share cannot exceed 75 percent of the cost of implementing the highway safety data and traffic records programs adopted to qualify for these funds in the first and second fiscal years the State receives funds; 50 percent in the third and fourth fiscal years it receives funds; and 25 percent in the fifth and sixth fiscal years.

Interim Final Rule

On October 8, 1998, NHTSA published an interim final rule in the **Federal Register** to implement the Section 411 program. 63 FR 54044. The interim final rule described the criteria States must meet and the procedures States must follow to qualify for funding under the Section 411 program.

Eligibility Criteria

The interim final rule provided that, to qualify for an implementation grant, a State must demonstrate that it has established a coordinating committee, completed or updated an assessment within the five years preceding the date of its application, and developed a strategic plan.

To qualify for an initiation grant, a State need not demonstrate that it has developed a strategic plan, but must demonstrate that it has established a coordinating committee, completed or updated an assessment within the five years preceding the date of its application, and initiated the development of a strategic plan. In addition, a State may qualify for an initiation grant only if it has not received an initiation or an implementation grant under this part in a previous fiscal year.

Any State that is not eligible for an initiation or an implementation grant, and has not received any grant under the Section 411 program in a previous fiscal year can qualify for a start-up grant, in accordance with the interim final rule.

A more detailed discussion of these criteria is contained in the interim final rule.

Application Procedures

The interim final rule stated that, to receive a grant in any fiscal year, the State must submit an application to NHTSA, through the appropriate NHTSA Regional Administrator, which demonstrates that the State meets the requirements of the grant being requested. The State also must submit the documentation listed in the regulation, including such items as a certification that the State will use the funds awarded only for the improvement of highway safety data and traffic records programs and a certification that the State will administer the funds in accordance with relevant regulations and OMB Circulars.

Further details regarding these procedures were described in the interim final rule.

Request for Comments

NHTSA requested comments from interested persons regarding the interim final rule. Comments were due by December 7, 1998. The agency stated in the interim final rule that all comments submitted to the docket would be considered and that, following the close of the comment period, NHTSA would publish a document in the **Federal Register** responding to the comments and, if appropriate, would make revisions to the provisions of Part 1335.

Comments Received

The agency received five comments in response to the interim final rule. Comments were received from: K. Craig Allred, Director of the Utah Highway Safety Office and Chair of the National Association of Governors' Highway Safety Representatives (NAGHSR); Jo Ann Moore, Manager of the Idaho Office of Highway Safety for the State of Idaho Transportation Department (Idaho); Betty J. Mercer, Division Director of the Office of Highway Safety Planning for Michigan's Department of State Police (Michigan); Charles W. Heald, P.E., Executive Director of the Texas Department of Transportation (Texas); and Richard L. Hannerman, President of the Salt Institute (Salt Institute).

General Comments

In general, the comments received in response to the interim final rule were positive. Some of the commenters indicated that they believe it is important for States to have accurate and complete highway safety data and traffic records, and they expressed their appreciation that Congress has established this incentive grant program.

The State of Michigan, for example, stated, ''Traffic records data is the

backbone of an effective and efficient state highway safety program. Timely and accurate data is essential for both problem identification and program evaluation. Michigan appreciates the recognition that Congress has given to this critical highway safety component by making funding available to implement essential improvements to the state highway safety data and traffic records program.'' NAGHSR stated, ''The grant program will provide a small but significant incentive to states to improve their state data systems through a comprehensive, planned approach.''

Other commenters provided general support for the contents of the interim final rule. The Salt Institute, for example, ''wholeheartedly endorse[d] the NHTSA conclusion that an effective highway safety program ''must include a process that identifies highway safety programs, develops measures to address the problems, implements the measures, and evaluates the results' and that this demands and 'depends on the availability of highway safety data and traffic records.' '' In addition, the Salt Institute stated that it ''is pleased to endorse the data elements included in the interim final rule specifying the requirements on states to receive highway safety incentive grants for their safety data and traffic records.'' NAGHSR stated that, ''In general, NAGHSR supports the proposed interim regulations and believes that they are reasonable.''

Some of the commenters suggested that certain limited modifications should be made to the interim final rule, and Michigan stated, ''it is our hope that the implementing regulations will be modified so that they do not deter the states from being able to take full advantage of this very needed funding source.''

The specific modifications that these commenters proposed and the agency's response to those comments are discussed in detail below. The agency notes, however, that the interim regulations did not deter the States from taking advantage of the Section 411 program. A total of $4,806,900 in grants were distributed to 54 jurisdictions (47 States, the District of Columbia, Puerto Rico, 4 U.S. Territories and the Bureau of Indian Affairs) under this program in FY 1999, and a total of $7,600,000 in grants were distributed to 46 jurisdictions (42 States, Puerto Rico and 3 U.S. Territories) under Section 411 in FY 2000.

Specific Comments

1. Establish a Coordinating Committee

In Section 411, Congress outlined the criteria that States must meet to qualify for incentive grants under this program. Under one of these criteria, States must have ''established a highway safety data and traffic records coordinating committee with a multi-disciplinary membership, including the administrators, collectors, and users of such data (including the public health, injury control, and motor carrier communities).'' Section 411 provides also that States must submit their highway safety data and traffic records strategic plans to the coordinating committee for approval.

The interim final rule provided that, to qualify for either an initiation or an implementation grant, States must have established a coordinating committee that meets certain requirements. Specifically, the committee must be made up of members drawn from the agencies and organizations throughout the State that administer, collect and use highway safety data and traffic records and have certain enumerated powers, including the authority to review any of the State's highway safety data and traffic records systems and to review changes to those systems before the changes are implemented.

The agency received comments from NAGHSR, Michigan and Texas, objecting to these requirements. Michigan's comments on this subject are both comprehensive and representative of the others received.

Michigan stated, ''The Committee is a very diverse group, the actual authority to operate the system most likely lies with one of the key agencies on the Committee. The law requires only that the Committee 'continue to operate and support the multi-year plan.' It is more appropriate and realistic to require that the Coordinating Committee review and makes recommendations on the strategic plan but not necessarily have direct authority to approve it.''

Michigan continues, ''To require the Committee to have the authority to review the state highway safety data and traffic records system and changes to the system prior to implementation is impractical and unnecessary. Michigan has had a traffic records coordinating committee for many years. The state long recognized that to have an effective program the key agencies with an interest in the data must work collaboratively. * * * Authority for any specific segment of the traffic records system, however, rests with the state agency responsible for that particular segment.'' [Emphasis in text.]

Similarly, NAGHSR opposed the ''expanded role'' that the interim regulation seems to envision for the coordinating committee, and Texas expressed its belief that ''such a formal committee * * * with such broad control over state agency operations'' should not be required.

As stated previously, the statutory language in Section 411 requires that States must submit their highway safety data and traffic records strategic plans to the coordinating committee for approval. The agency believes that the portion of the interim final rule which provides that the coordinating committee must have the authority to review the State's highway safety data and traffic records systems and to review changes to those systems before the changes are implemented is necessary to implement this statutory requirement properly.

If a coordinating committee did not have this authority, the agency believes there would be no assurance that the improvements identified in the plan that need to be made will in fact be carried out. In addition, NHTSA expects that these strategic plans will be ''living documents,'' which may need to be altered on a continuous basis to take into account the amount of progress that has (or has not) been made and any other changes in circumstances. The agency believes that, by including the coordinating committee in the review process in this way, the committee will remain more fully informed about the State's progress in implementing the strategic plan and about other circumstances as they unfold, which will enable the committee to make adjustments to the plan, if they are needed. Accordingly, this portion of the final rule has been adopted without change.

NAGHSR also asserted in its comments that, in some regions, ''states are being actively encouraged to require state agency members of the coordinating committee to sign a joint Memorandum of Understanding (MOU) * * * [which] would give formal approval authority to the coordinating committee over the state data plan.'' NAGHSR states that this suggestion would be problematic for some State agencies, and suggests that it should be discontinued.

The agency acknowledges that, when some States inquired about the manner in which a State could document that they had the authority mentioned above, some of the agency's regional staff suggested to these States that they could document the authority in a Memorandum of Understanding (MOU). The agency did not mean to suggest,

however, that this was a necessary requirement. As provided in the interim final rule, to demonstrate compliance with the Section 411 criterion that States must establish a coordinating committee, States need only certify that the State ''has established a coordinating committee, and include the name, title and organizational affiliation of each member of'' that committee. State coordinating committees may enter into MOU's if they wish, but this is not a prerequisite to Section 411 compliance.

2. Complete or Update an Assessment

One of the other criteria established by Congress in Section 411 is the requirement that States must have ''completed, within the preceding 5 years, a highway safety data and traffic records assessment or an audit of the highway safety data and traffic records system of the State.''

The interim final rule provided that, to qualify for either an initiation or an implementation grant, States must have completed or updated an assessment within the five years preceding the date of the State's application and, further, it provided that the assessment must meet certain requirements.

Specifically, the interim regulations required that the assessment must be an in-depth, formal review of the State's highway safety data and traffic records system; that it generate an impartial report of the status of the system in the State; and that it be conducted by an organization or group that is knowledgeable about highway safety data and traffic records systems, but independent from the organizations involved in the administration, collection and use of these State systems.

In its comments, Texas objected to the requirement that the assessment must be conducted by an ''organization or group that is knowledgeable about highway safety data and traffic records systems.'' Texas expressed its belief that States ''should be given more latitude to select a consultant experienced in a wide range of disciplines such as business process re-engineering or information systems.'' According to Texas, ''Limiting these efforts to consultants and organizations experienced in crash records will adversely limit the type and number of firms that will be able to compete for these assessments.''

The agency would not object to any State's decision to involve in its assessment a consultant or group with experience in a wide range of disciplines, such as business process re-engineering or information systems. However, to qualify under the Section 411 criterion that States must complete or update an assessment, the organization or group conducting the assessment must also be knowledgeable about highway safety data and traffic records systems.

This portion of the final rule has also been adopted without change.

3. Initiate or Develop a Strategic Plan

Congress also provided, in Section 411, that States either must have ''initiated the development of a multi-year highway safety data and traffic records strategic plan'' that meets certain requirements or that they certify ''that the highway safety data and traffic records coordinating committee of the State continues to operate and supports the multi-year plan.''

The interim final rule provided that States must have initiated the development of a strategic plan to qualify for an initiation grant, and that States must have developed a strategic plan to qualify for an implementation grant. The interim regulation further provided that the strategic plan must be a multi-year plan that identifies and prioritizes the highway safety data and traffic records needs and goals based on the State's assessment, identifies performance-based measures by which progress toward those goals will be determined, and be submitted to the coordinating committee for approval.

Michigan stated, in its comments, that it would have no difficulty meeting the requirement that States must have a strategic plan, but Michigan asserted that this requirement might be difficult for some other States. No other State raised this objection.

Texas raised two questions concerning this criterion. The State asked whether the committee's approval of the plan commits State agencies to implement the plan and it asked how differences between plans of the coordinating committee and of the State agency would be resolved.

The interim regulations provide that, to qualify for an initiation grant, a State must certify that the State ''has established a coordinating committee'' and that it ''has initiated the development of a strategic plan, with the supervision and approval of the coordinating committee.'' A State must also certify that the State ''has established a coordinating committee'' to qualify for an implementation grant (if the State has not received an initiation or an implementation grant under this part in a previous fiscal year). In addition, to qualify for an implementation grant (whether or not the State has received an initiation or an implementation grant under this part in a previous fiscal year), a State must certify that ''the coordinating committee continues to operate and supports the strategic plan.''

The interim regulations do not require that the State submit any certifications or other information concerning the actions that State agencies must take as a result of the plan or the means of resolving issues that may arise between these agencies and the coordinating committee. It is up to each individual State to address these issues. NHTSA does not believe it is appropriate for it to dictate such matters to the States.

However, the States should note that, to qualify for an implementation grant (if the State has received an initiation or an implementation grant under this part in a previous fiscal year), a State must report on its progress in implementing the strategic plan since the State's previous application. If progress is not made in a State, due to a lack of commitment on the part of State, because of the presence of conflicts between these agencies and the coordinating committee, or for other reasons, the State's ability to receive Section 411 grant funds in subsequent years could be jeopardized.

No changes have been made to this portion of the final rule as a result of these comments.

4. Maintenance of Effort and Matching Requirements

In the provisions of Section 411, Congress provided for a maintenance of effort requirement. Specifically, Section 411 provides that, ''No grant may be made to a State under this section in any fiscal year unless the State enters into [an] agreement with the [the agency] * * * that the State will maintain its aggregate expenditures from all other sources for its highway safety data and traffic records programs at or above the average level of such expenditures in [fiscal years 1996 and 1997].''

Section 411 provides also for State matching requirements. Specifically, the statute provides that ''The Federal share of the cost of implementing and enforcing, as appropriate, in a fiscal year a program adopted by a State pursuant to [the Section 411 program] shall not exceed [75 percent] in the first and second fiscal years in which the State receives a grant under this section * * *; [50 percent] in the third and fourth fiscal years in which the State receives a grant under this section * * *; and [25 percent] in the fifth and sixth fiscal years * * *

The interim final rule incorporated all of these requirements into the interim regulations.

In its comments, Idaho raised two objections to these requirements. Regarding the maintenance of effort requirement, Idaho explained that it ''spent an abnormally large amount [of funds] on highway safety data and traffic records systems in [fiscal years 1996 and 1997] from special funding sources that are no longer available, thereby making it impossible to continue expenditures at this inflated level.''

According to Idaho, ''In fiscal year 1995, [it] received a one-time amount of $1.3 million [under the Section 153 transfer program] because the state did not have a universal motorcycle helmet law [and the State] used approximately 23 percent of those funds for highway safety data and traffic records system projects in fiscal years 1996 and 1997. As a result, expenditures for data-related initiatives in those two years, due to this ''windfall'' funding source, were among the highest on record for [the] agency.''

With all of the highway safety problems that the State must address, Idaho asserts that, ''It would be irresponsible [for Idaho] to include in [its] highway safety plans a 25 percent yearly expenditure of 402 funds on highway safety data or traffic records systems.'' Accordingly, Idaho requests that these Section 153 transfer funds not be considered as part of the baseline for the Section 411 maintenance of effort requirement.

The agency recognizes that, in fiscal years 1996 and 1997, some States expended usually large sums of money on their highway safety data and traffic records systems and that these sums were from special funding sources that are no longer available. In particular, many States experienced a transfer of funds in fiscal year 1995, under the Section 153 program, because they did not have in effect conforming motorcycle helmet or seat belt use legislation. Some of these States chose to use these funds to upgrade their highway safety data and traffic records systems and, in many cases, the funds that had been transferred in fiscal year 1995 were expended in fiscal years 1996 and 1997.

The agency believes that the maintenance of effort requirement contained in the Section 411 program was intended to ensure that States maintain their ordinary spending on their highway safety data and traffic records systems and that the funds they receive under the Section 411 program will supplement those expenditures and not replace them. The agency does not believe the requirement was intended to match special or unusual funding resources, such as the Section 153 transfer or other funds made available to States under Chapter 1 of Title 23 of the United States Code, some or all of which a State may choose to use also to supplement its ordinary spending in this area. The agency believes that the inclusion of these special funding sources in the maintenance of effort requirement would impose a hardship on the States and would not result in the most effective use of these resources.

Accordingly, the regulation has been modified to clarify that States must maintain their aggregate expenditures from all other sources, except those authorized under Chapter 1 of Title 23 of the United States Code, for their highway safety data and traffic records programs at or above the average level of such expenditures in fiscal years 1996 and 1997.

Regarding the matching requirements, Idaho observes that these requirements apply each year that a State receives a grant, whether the State receives an implementation, initiation or start-up grant, and Idaho asserts that ''it would be difficult for us to meet the higher match requirements in the third and subsequent years.'' Accordingly, Idaho recommends that the $25,000 start-up grant be excluded from the matching requirements and that these requirements apply instead only to initiation and implementation grants. Idaho asserts that this would assist Idaho and other small States.

The agency appreciates that, over the life of the program, it might be easier for some States to meet the matching requirements if those requirements were to apply only to initiation and implementation, and not to start-up grants. However, the statutory language in Section 411 states specifically that the various matching levels apply to fiscal years ''in which the State receives a grant under this section.'' The statute does not exclude any of the three types of grants that may be awarded. Accordingly, the agency will continue to apply the matching requirements to start-up, as well as to initiation and implementation, grants, and will not make any changes to this portion of the regulations.

The agency notes that the State of Idaho did not apply for a Section 411 start-up grant during FY 1999. It appears that the State decided instead to wait, and applied for and received an initiation grant in FY 2000. By following this course, Idaho was not subject to a matching requirement for the start-up funds that it spent on its data and traffic records system in FY 1999. In addition, the 75 percent Federal matching percentage was applied to the initiation grant that Idaho received in FY 2000 and will be applied also to the first implementation grant for which the State qualifies.

The agency would also like to remind the States that it will accept a ''soft'' match in Section 411's administration, as it has for the agency's Section 402 and 410 programs. By this, the agency means the State's share may be satisfied by the use of either allowable costs incurred by the State or the value of in-kind contributions applicable to the period to which the matching requirement applies. A State cannot, however, use any Federal funds, such as its Section 402 funds, to satisfy the matching requirements. In addition, a State can use each non-Federal expenditure only once for matching purposes.

Michigan also had a comment concerning the maintenance of effort requirement. To implement this requirement, the interim rule requires each State to certify that it will ''Maintain its aggregate expenditures from all other sources for highway safety data and traffic records programs at or above the average level of such expenditures in [State or] Federal fiscal years 1996 and 1997.'' Michigan explained that its funding for traffic records is appropriated by its State Legislature on an annual basis and, therefore, any certification as to the maintenance of expenditures at or above the average 1996 and 1997 level ''can only be based on current year funding levels.''

The agency understands Michigan's concern. To the extent that any State's plan covers years for which the State's legislature has not yet authorized funding, we recognize that the State agency's commitment to maintain its aggregate expenditures must be subject to the availability of funds.

5. Application Procedures

The interim regulations provide that, to be considered for a grant in any fiscal year, a State must submit an application that is ''received by the agency not later than January 15 of that fiscal year.'' Within 30 days of being informed by NHTSA that it is eligible for a grant, a State is required to submit a Program Cost Summary (HS Form 217) obligating the funds. The interim regulations also require the States to document how they intend to use the funds under this part in their Highway Safety Plans, which they submit pursuant to 23 CFR Part 1200.

Mr. Allred of Utah, who submitted comments on behalf of NAGHSR, raised several concerns regarding this portion of the interim regulations. In particular,

Mr. Allred asserted that, ''Unlike other grant programs, a state must satisfy a two-step approval process that is different than the process for the Section 402 program. The application deadline is different than other grant programs. The amount of time for federal review and approval is not specified which leaves approval rather open-ended. The deadline for submitting a spending plan is different than the prior October deadline for the annual Highway Safety Plan (HSP).''

To be consistent with the timetables followed in other NHTSA programs, Mr. Allred suggests that the application deadline should be changed instead to August 1. In addition, he suggests that the applications should include a spending plan, ''just as States must do under the 402 program,'' that NHTSA should decide which States qualify for funding under this program by September 1 and then obligate the Section 411 funds ''on October 1.''

When NHTSA was developing its interim final rules for the various grant programs authorized in TEA–21, we made a conscious decision to avoid establishing the same deadline for all of these programs. We believed that, if the States were required to submit and the agency was required to review all of these applications at the same time, the workload for both the agency and the States would be extraordinary. In addition, we were concerned about the risks of delay should all of these deadlines fall near the end of each fiscal year.

Under some of the grant programs, such as the Section 405 Occupant Protection and the Section 410 Impaired Driving Incentive Grant Programs, States must enact certain types of laws to qualify for funding. Accordingly, the agency established an August 1 deadline for these programs, to provide States with additional time to enact conforming legislation.

However, State compliance with the Section 411 incentive grant program is not dependent on the enactment of legislation. Moreover, the agency believed it had established a grant application process that was relatively simple and straight-forward to follow. Accordingly, we believed that, with the publication of an interim final rule on October 8, 1998, that States would be able to submit applications for funding by the following January 15. For all of these reasons, the interim regulations established a January 15 deadline for the receipt of applications under this program.

The agency believes that the January 15 deadline has not been a limiting factor for the States. For example, in the first year of the program (the year in which the deadline would have been most likely to have had a negative impact), the agency received and approved applications from 54 jurisdictions (47 States, the District of Columbia, Puerto Rico, 4 U.S. Territories and the Bureau of Indian Affairs). In addition, this ''early'' application deadline permitted the agency to make early releases of Section 411 grant funds. In FY 1999, the Section grant funds were awarded in March of 1999 and, in FY 2000, these grant funds were awarded in March of 2000. We expect that Section 411 grant funds will continue to be released in future fiscal years on a similar timetable.

Regarding Mr. Allred's comment that the interim regulations require States to ''satisfy a two-step approval process that is different than the process for the Section 402 program,'' we believe this reference is to the provisions of the interim regulations that require that, ''Within 30 days of being informed by NHTSA that it is eligible for a grant, a State shall submit to the agency a Program Cost Summary (HS Form 217) obligating the funds under this part to highway safety data and traffic records programs,'' and that ''The State shall document how it intends to use the funds under this part in the Highway Safety Plan it submits pursuant to 23 CFR Part 1200.''

We note that States may meet these requirements in two separate steps or they may choose to meet both of these requirements at once. The agency believes this should not be difficult for States to do, especially when applying for subsequent year grants. Accordingly, no changes are being made to the regulation as a result of this comment.

6. MMUCC

In subsection (a)(2) of Section 411, Congress stated that, ''The Secretary, in consultation with States and other appropriate parties, shall determine the model data elements necessary to observe and analyze national trends in crash occurrences, rates, outcomes, and circumstances.''

In the interim final rule, NHTSA indicates that, it has determined that the Model Minimum Uniform Crash Criteria (MMUCC) serve the purposes of the law and has defined ''model data elements'' to mean the elements specified in the MMUCC. While conformity to the MMUCC is not required for grant eligibility under Section 411, the agency strongly encouraged States in the interim final rule to employ the criteria in their highway safety data and traffic records systems, and to consider these criteria when conducting their assessments and developing their strategic plans.

In its comments, the Salt Institute recommends a change to the MMUCC, related to data element C13 ''Road Surface Condition.''

The agency notes that the Salt Institute's recommended change to the MMUCC is beyond the scope of this rulemaking action. As explained in the interim final rule, the MMUCC is a minimum set of crash data elements with standardized definitions that are relevant to injury control, and highway and traffic safety. Its use is encouraged to help States reduce the collection and processing burden of motor vehicle crash data.

The MMUCC was developed collaboratively. The effort to develop the MMUCC involved private and public safety, engineering, transportation and research experts from the local, State and Federal levels, and drafts of the data set were distributed for comment to national, State and local associations, representing highway traffic safety, injury control, emergency medical services, State health departments and others, and to the general public via the World Wide Web. The final version of the MMUCC was prepared by an expert panel, which considered the feedback it received at meetings and by mail, fax, telephone and electronic communication. The effort was supported by the National Association of Governors' Highway Safety Representatives (NAGHSR), with assistance from NHTSA and the FHWA.

Any decisions regarding the contents of the MMUCC would need to be considered through separate proceedings.

Regulatory Analyses

Executive Order 12778 (Civil Justice Reform)

This final rule will not have any preemptive or retroactive effect. The enabling legislation does not establish a procedure for judicial review of rules promulgated under its provisions. There is no requirement that individuals submit a petition for reconsideration or other administrative proceedings before they may file suit.

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

The agency has examined the impact of this action and has determined that it is not significant under Executive Order 12866 and the Department of Transportation's Regulatory Policies and Procedures.

The action will not have an annual effect on the economy of $100 million

or more or adversely affect in a material way a sector of the economy, competition, jobs, the environment, public health or safety, or State, local or tribal governments or communities. It will not create a serious inconsistency or otherwise interfere with an action taken or planned by another agency, and it will not materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof. Nor does it raise novel legal or policy issues.

Regulatory Flexibility Act

In compliance with the Regulatory Flexibility Act (Pub. L. 96–354, 5 U.S.C. 601–612), the agency has evaluated the effects of this action on small entities. Based on the evaluation, the agency certifies that this action will not have a significant impact on a substantial number of small entities. States are the recipients of any funds awarded under the Section 411 program, and they are not considered to be small entities, as that term is defined under the Regulatory Flexibility Act.

Paperwork Reduction Act

The requirements relating to the regulations that this rule is amending that States retain and report to the Federal government information which demonstrates compliance for incentive grant funds for improved highway safety data and traffic records systems, are considered to be information collection requirements, as that term is defined by the Office of Management and Budget (OMB) in 5 CFR Part 1320.

Accordingly, these requirements have been submitted and approved by OMB, pursuant to the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*). These requirements have been approved through June 30, 2003, under OMB No. 2127–0606.

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 *et seq.*) and have determined that it will not have any significant impact on the quality of the human environment.

The Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (Public Law 104–4) requires agencies to prepare a written assessment of the costs, benefits and other affects of final rules that include a Federal mandate likely to result in the expenditure by State, local or tribal governments, in the aggregate, or by the private sector, of more than $100 million annually. This final rule does not meet the definition of a Federal mandate, because the resulting annual expenditures will not exceed the $100 million threshold. In addition, this incentive grant program is completely voluntary and States that choose to apply and qualify will receive incentive grant funds.

Executive Order 12612 (Federalism)

This action has been analyzed in accordance with the principles and criteria contained in Executive Order 12612, and it has been determined that this action will not have sufficient federalism implications to warrant the preparation of a Federalism Assessment. Accordingly, a Federalism Assessment has not been prepared.

List of Subjects in 23 CFR Part 1335

Grant programs—transportation, Highway safety, Reporting and recordkeeping requirements.

In consideration of the foregoing, the interim final rule published in the **Federal Register** of October 8, 1998, 63 FR 54055, adding a new Part 1335 to chapter II of Title 23 of the Code of Federal Regulations, is adopted as final, with the following changes:

PART 1335—STATE HIGHWAY SAFETY DATA IMPROVEMENTS

1. The authority citation for Part 1335 continues to read as follows:

Authority: 23 U.S.C. 411; delegation of authority at 49 CFR 1.50.

2. Section 1335.12 is amended by revising paragraph (d)(3) to read as follows:

§ 1335.12 Contents of application.

* * * * *

(d) * * *

(3) Maintain its aggregate expenditures from all other sources, except those authorized under Chapter 1 of Title 23 of the United States Code, for highway safety data and traffic records programs at or above the average level of such expenditures in Federal fiscal years 1996 and 1997 (either State or federal fiscal year 1996 and 1997 can be used).

Issued on: August 7, 2000.

Rosalyn G. Millman,

Deputy Administrator, National Highway Traffic Safety Administration.

[FR Doc. 00–20339 Filed 8–9–00; 8:45 am]

BILLING CODE 4910–59–P

DEPARTMENT OF DEFENSE

Office of the Secretary

32 CFR Part 199

Civilian Health and Medical Program of the Uniformed Services (CHAMPUS); Expansion of Dependent Eligibility for TRICARE Retiree Dental Program

AGENCY: Office of the Secretary, DoD.

ACTION: Final rule.

SUMMARY: This final rule implements a change to the TRICARE Retiree Dental Program (TRDP) required by the Strom Thurmond National Defense Authorization Act for Fiscal Year 1999. This change expands eligibility for enrollment in the program to allow dependents of certain retired members of the Uniformed Services to enroll in the program even if the retired member does not enroll. In addition, this rule clarifies the existing regulatory provisions for election of TRDP coverage and disenrollment.

EFFECTIVE DATE: This rule is effective August 10, 2000.

ADDRESSES: TRICARE Management Activity, 16401 East Centretech Parkway, Aurora, CO 80011–9043.

FOR FURTHER INFORMATION CONTACT: Linda Winter, TRICARE Management Activity, (303) 676–3682.

SUPPLEMENTARY INFORMATION:

Background and Legislative Changes

A. Congressional Action

Implementation of the TRICARE Retiree Dental Program (TRDP), a program completely funded by enrollee premiums, was directed by Congress in Section 703 of the National Defense Authorization Act for Fiscal Year 1997, Public Law 104–201, which amended Title 10, United States Code, by adding Section 1076c. Section 1076c was subsequently amended by the National Defense Authorization Act for Fiscal Year 1998 to expand eligibility to retirees of the Public Health Service and the National Oceanic and Atmospheric Administration and to surviving spouses and dependents of deceased active duty members. As amended, the law directs the implementation of a dental program for: (1) Members of the Uniformed Services who are entitled to retired pay, (2) members of the Retired Reserve who would be entitled to retired pay, but are under the age of 60, (3) eligible dependents of a member in (1) or (2) who are covered by the enrollment of the member, and (4) the unremarried surviving spouse and eligible child dependents of a deceased