Dated: April 8, 2015.

Daniel B. Abel,

Rear Admiral, U.S. Coast Guard, Commander, Seventeenth Coast Guard District.

[FR Doc. 2015–10376 Filed 5–1–15; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

45 CFR Part 98

[Docket No. ACF–2013–0001–0001]

RIN 0970–AC53

Child Care and Development Fund (CCDF) Program

AGENCY: Office of Child Care (OCC), Administration for Children and Families (ACF), Department of Health and Human Services (HHS).

ACTION: Notice of proposed rulemaking; withdrawal.

SUMMARY: The Office of Child Care (OCC) in the Administration for Children and Families (ACF) within the Department of Health and Human Services (HHS) is withdrawing a previously published notice of proposed rulemaking that solicited public comment on reforms to the Child Care and Development Fund (CCDF) program.

DATES: The notice of proposed rulemaking published at 78 FR 29442, May 20, 2013, is withdrawn, effective immediately.

FOR FURTHER INFORMATION CONTACT: Andrew Williams, Director, Office of Child Care Policy Division, Administration for Children and Families, 370 L'Enfant Promenade SW., Washington, DC 20447; 202–401–4795 (this is not a toll-free number).

SUPPLEMENTARY INFORMATION: On May 20, 2013, HHS published a notice of proposed rulemaking (NPRM) to the regulations at 45 CFR part 98 for the Child Care and Development Fund (CCDF) program at 78 FR 29442. Subsequently, the Child Care and Development Block Grant Act, which governs the CCDF program, was reauthorized in November 2014 (Public Law 113–186). In light of this statutory change, HHS is hereby withdrawing the May 2013 NPRM, and will begin a new regulatory process with a proposed rule based on the new law.

Dated: April 9, 2015.

Mark H. Greenberg,

Acting Assistant Secretary for Children and Families.

Approved: April 27, 2015.

Sylvia Matthews Burwell,

Secretary.

[FR Doc. 2015–10351 Filed 5–1–15; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

49 CFR Part 391

[Docket No. FMCSA–2005–23151]

RIN 2126–AA95

Qualifications of Drivers; Diabetes Standard

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: FMCSA proposes to permit drivers with stable, well-controlled insulin-treated diabetes mellitus (ITDM) to be qualified to operate commercial motor vehicles (CMVs) in interstate commerce. Currently, drivers with ITDM are prohibited from driving CMVs in interstate commerce unless they obtain an exemption from FMCSA. This NPRM would enable individuals with ITDM to obtain a Medical Examiner's Certificate (MEC), from a medical examiner (ME) at least annually in order to operate in interstate commerce if the treating clinician (TC) who is the healthcare professional responsible for prescribing insulin for the driver's diabetes, provides documentation to the ME that the condition is stable and well-controlled.

DATES: You must submit comments on or before July 6, 2015.

ADDRESSES: You may submit comments identified by docket number FMCSA–2005–23151 using any one of the following methods:

- *Federal eRulemaking Portal: www.regulations.gov.*
- *Fax:* 202–493–2251.
- *Mail:* Docket Services (M–30), U.S. Department of Transportation, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590–0001.
- *Hand delivery:* Same as mail address above, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The telephone number is 202–366–9329.

To avoid duplication, please use only one of these four methods. See the ''Public Participation and Request for Comments'' heading under the **SUPPLEMENTARY INFORMATION** section below for instructions regarding submitting comments.

FOR FURTHER INFORMATION CONTACT: If you have questions about this proposed rule, contact Ms. Linda Phillips, Medical Programs Division, FMCSA, 1200 New Jersey Ave SE., Washington DC 20590–0001, by telephone at 202–366–4001, or by email at *fmcsamedical@dot.gov.* If you have questions about viewing or submitting material to the docket, call Ms. Barbara Hairston, Program Manager, Docket Services, telephone 202–366–9826.

SUPPLEMENTARY INFORMATION:

Table of Contents for Preamble

I. Executive Summary

A. Purpose and Summary of Major Provisions

Under the current regulations, a driver with ITDM may not operate a CMV in interstate commerce unless the driver obtains an exemption from FMCSA, which must be renewed at least every 2 years. FMCSA proposes to allow individuals with well-controlled ITDM to drive CMVs in interstate commerce if they are examined at least annually by an ME who is listed in the National Registry of Certified Medical Examiners (National Registry), have received the MEC from the ME, and are otherwise physically qualified. FMCSA believes that this procedure will adequately

ensure that drivers with ITDM manage the condition so that it is stable and well-controlled, and that such a regulatory provision creates a clearer, equally effective and more consistent framework than a program based entirely on exemptions under 49 U.S.C. 31315(b).

FMCSA evidence reports, ADA studies, and MRB conclusions and recommendations indicate that drivers with ITDM are as safe as other drivers when their condition is well-controlled. In order to determine if a driver with ITDM meets FMCSA's physical qualification standards and is able to obtain a MEC, the driver must be evaluated at least annually by his or her TC. The evaluation by the TC would ensure that the driver is complying with an appropriate standard of care for individuals with ITDM and would allow the TC to monitor for any of the progressive conditions associated with diabetes (*e.g.,* nerve damage to the extremities, diabetic retinopathy, cataracts and hypoglycemia unawareness). The ME must obtain information from the TC to demonstrate the driver's condition is stable and well-controlled.

B. Benefits and Costs

FMCSA believes that this rulemaking would not have a significant economic impact. Compared to other CMV drivers, drivers with ITDM will incur costs for an additional Department of Transportation (DOT) medical examination of $151 annually; however, they will have the ability to earn a living without the inconvenience and added costs of obtaining and maintaining an exemption. The increased monitoring of the driver with ITDM could lead to better driver health while ensuring that the physical condition of CMV drivers enables them to operate CMVs safely. The total annual cost of medically qualifying drivers with ITDM would increase in comparison to the cost of the current exemption program based on a projected increase in the population of drivers who would seek medical certification, as shown in Table 1 below for ITDM drivers:

TABLE 1—TOTAL ANNUAL COSTS

[In millions of $]

	Current exemption program	Proposed rule (100% ITDM-qualified drivers (209,664 drivers) [1]	Proposed rule (66.7% ITDM-qualified drivers (139,846 drivers)	Proposed rule (33.3% ITDM-qualified drivers (69,818 drivers)
Cost of Visits to Endocrinologist ($m)	$0.26	$0.00	$0.00	$0.00
Cost of Annual Exam of Eye Specialist ($m)	0.40	0.00	0.00	0.00
Cost of Issuing Annual Medical Certificates ($m)	0.13	16.35	10.91	5.45
Cost of Applying for Exemption ($m)	0.03	0.00	0.00	0.00
Driver Time Costs of Medical Exams ($m)	0.06	7.55	5.03	2.51
Cost to Government ($m)	0.91	0.00	0.00	0.00
Total Costs ($m)	1.79	23.90	15.94	7.96

As the Agency lacks data to project the affected population changes in subsequent years, the analysis projects this rule's total annual costs to remain constant in real terms during each of the ten years from the initial compliance date. Therefore, for this rule a separate discussion of the *annualized* costs at the 7% discount rate is unnecessary, as the annualized costs are identical to the corresponding discounted annual costs.

II. Public Participation and Request for Comments

FMCSA encourages you to participate in this rulemaking by submitting comments and related materials. Where possible, we would like you to provide scientific, peer-reviewed data to support your comments. On March 17, 2006, the Agency published an Advance Notice of Proposed Rulemaking (ANPRM) on the diabetes standard (71 FR 13810). In this NPRM, the Agency does not respond to comments submitted in response to the ANPRM. If you believe your previous comments are relevant to today's proposed rule, please reference them in your new comments to the docket FMCSA–2005–23151.

A. Submitting Comments

If you submit a comment, please include the docket number for this rulemaking (FMCSA–2005–23151), indicate the heading of the specific section of this document to which each comment applies, and provide a reason for each suggestion or recommendation. You may submit your comments and material online, by fax, mail, or hand delivery, but please use only one of these means. FMCSA recommends that you include your name and a mailing address, an email address, or a phone number in the body of your document so the Agency can contact you if it has questions regarding your submission.

To submit your comment online, go to *www.regulations.gov,* type the docket number, ''FMCSA–2005–23151'' in the ''Keyword'' box, and click ''Search.'' When the new screen appears, click the ''Comment Now!'' button and type your comment into the text box in the following screen. Choose whether you are submitting your comment as an individual or on behalf of a third party, and click ''Submit.'' If you submit your comments by mail or hand delivery, submit them in an unbound format, no larger than 8½ by 11 inches, suitable for copying and electronic filing. If you submit comments by mail and would like to know that they reached the facility, please enclose a stamped, self-addressed postcard or envelope.

FMCSA will consider all comments and material received during the comment period and may change this proposed rule based on your comments.

B. Viewing Comments and Documents

To view comments and any document mentioned in this preamble, go to *www.regulations.gov,* insert the docket number, ''FMCSA–2005–23151'' in the ''Keyword'' box, and click ''Search.'' Next, click the ''Open Docket Folder'' button and choose the document listed to review. If you do not have access to the Internet, you may view the docket online by visiting the Docket Services in Room W12–140 on the ground floor of the DOT West Building, 1200 New Jersey Avenue SE., Washington, DC 20590, between 9 a.m. and 5 p.m. ET,

[1] ''ITDM-qualified drivers'' are those the Agency believes would qualify under this proposed rule to receive medical examiner's certificates enabling them to operate CMVs in interstate commerce were they to undergo a DOT medical examination. The derivation of the estimated number of ITDM-qualified drivers at the three participation rates evaluated is shown in section 2.4.1 of the regulatory evaluation.

Monday through Friday, except Federal holidays.

C. Privacy Act

In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, including any personal information the commenter provides, to *www.regulations.gov,* as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at *www.dot.gov/privacy.*

III. Abbreviations and Acronyms

ADA American Diabetes Association
ANPRM Advance Notice of Proposed Rulemaking
CAA Clean Air Act
CE Categorical Exclusion
CDL Commercial Driver's License
CMV Commercial Motor Vehicle
DOT U.S. Department of Transportation
E.O. Executive Order
FHWA Federal Highway Administration's
FMCSA Federal Motor Carrier Safety Administration
FR **Federal Register**
FMCSRs Federal Motor Carrier Safety Regulations
ICR Information Collection Request
ITDM Insulin-Treated Diabetes Mellitus
LFC Licencia Federal de Conductor
ME Certified Medical Examiner
MEC Medical Examiner's Certificate
MRB Medical Review Board
NPRM Notice of Proposed Rulemaking
OMB Office of Management and Budget
PIA Privacy Impact Assessment
PRA Paper Reduction Act
RFA Regulatory Flexibility Act
RIA Regulatory Impact Analysis
SAFETEA–LU Safe, Accountable, Flexible, Efficient Transportation Equity Act: A Legacy for Users
SORN System of Records Notice
TEA–21 Transportation Equity Act for the 21st Century
TC Treating Clinician

IV. Legal Basis for the Rulemaking

FMCSA has authority under 49 U.S.C. 31136(a) and 31502(b)—delegated to the Agency by 49 CFR 1.87(f) and (i), respectively—to establish minimum qualifications, including medical and physical qualifications, for CMV drivers operating in interstate commerce. Section 31136(a)(3) requires that the Agency's safety regulations ensure that the physical conditions of CMV drivers enable them to operate their vehicles safely, and that MEs trained in physical and medical examination standards perform the physical examinations required of such operators.

In 2005, Congress authorized the creation of the Medical Review Board (MRB) composed of experts ''in a variety of medical specialties relevant to the driver fitness requirements'' to provide advice and recommendations on qualification standards [49 U.S.C. 31149(a)]. The position of Chief Medical Officer was authorized at the same time [49 U.S.C. 31149(b)]. Under section 31149(c)(1), the Agency, with the advice of the MRB and Chief Medical Officer, is directed to ''establish, review and revise . . . medical standards for operators of commercial motor vehicles that will ensure that the physical condition of operators of commercial motor vehicles is adequate to enable them to operate the vehicles safely.'' As discussed below in this proposed rule, the Agency, in conjunction with the Chief Medical Officer, asked the MRB to review and report on the current diabetes standard. The Board's recommendations and the Agency's responses are described elsewhere in this NPRM.

In addition to the statutory requirements specific to the physical qualifications of CMV drivers [49 U.S.C. 31136(a)(3)], FMCSA's regulations must also ensure that CMVs are maintained, equipped, loaded and operated safely [49 U.S.C. 31136(a)(1)]; that the responsibilities imposed on CMV drivers do not impair their ability to operate the vehicles safely [49 U.S.C. 31136(a)(2)]; that the operation of CMVs does not have a deleterious effect on the physical condition of the drivers [49 U.S.C. 31136(a)(4)]; and that drivers are not coerced by motor carriers, shippers, receivers, or transportation intermediaries to operate a vehicle in violation of a regulation promulgated under 49 U.S.C. 31136 (which is the basis for much of the FMCSRs), 49 U.S.C. chapter 51 (which authorizes the hazardous materials regulations) or 49 U.S.C. chapter 313 (the authority for the Commercial Driver's License (CDL) regulations and the related drug and alcohol testing requirements) [49 U.S.C. 31136(a)(5)].

This proposed rule is based on 49 U.S.C. 31136(a)(3) and 31149(c), but does not deal with 49 U.S.C. 31136(a)(1), (2), or (4). FMCSA believes that coercion of drivers with ITDM to violate the current rule preventing them from operating in interstate commerce—which is prohibited by 49 U.S.C. 31136(a)(5)—does not and will not occur. On the contrary, motor carriers have generally been reluctant to employ such drivers at all. The Federal Highway Administration's (FHWA) original exemption program in the 1990s and FMCSA's subsequent program under 49 U.S.C. 31315(b) allowed selected individuals with ITDM to drive legally for the first time, while also generating data showing that their safety records were at least as good as those of non-ITDM drivers.

Section 4129 of the Safe, Accountable, Flexible, Efficient Transportation Equity Act: A Legacy for Users (SAFETEA–LU) [Pub. L. 109–59, 119 Stat. 1144, 1742, Aug. 10, 2005], in paragraphs (a) through (c), directed the Agency to relax certain requirements of its exemption program for drivers with ITDM.[2] The last paragraph of section 4129 provides that insulin-treated individuals may not be held by the Secretary to a higher standard of physical qualification in order to operate a commercial motor vehicle in interstate commerce than other individuals applying to operate, or operating, a commercial motor vehicle in interstate commerce; except to the extent that limited operating, monitoring, and medical requirements are deemed medically necessary under regulations issued by the Secretary.[3]

FMCSA believes that this proposed rule would satisfy the purposes of section 4129(d), by imposing appropriate requirements on such drivers as contemplated by that provision and maintaining current levels of highway safety.

Finally, prior to prescribing any regulations, FMCSA must consider their ''costs and benefits'' [49 U.S.C. 31136(c)(2)(A) and 31502(d)]. Those factors are discussed in the Rulemaking Analyses and Notices section of this NPRM.

V. Background

A. Diabetes

Diabetes is a disorder of metabolism—the way the body uses digested food for growth and energy.[4] The body breaks down most food into glucose. After digestion, glucose passes into the bloodstream, where cells use it for growth and energy. For glucose to enter cells, insulin, a hormone produced by the pancreas, must be present. Normally, the pancreas produces the right amount of insulin automatically to move glucose from blood into the cells. In people with diabetes, however, either the pancreas produces little or no insulin or the cells do not respond appropriately to the insulin that is produced. Glucose builds up in the blood, overflows into the urine, and passes out of the body in the urine. Thus, the body loses its main source of fuel although the blood contains large

[2] The exemption requirements were changed in a notice issued November 8, 2005 (70 FR 67777).

[3] See *http://www.gpo.gov/fdsys/pkg/STATUTE-119/pdf/STATUTE-119-Pg1144.pdf* (pages 599–600 of the 835 page PDF).

[4] See the source document for this discussion at *http://diabetes.niddk.nih.gov/dm/pubs/overview/DiabetesOverview_508.pdf.*

amounts of glucose. The excess glucose in the blood (called hyperglycemia) plays an important role in disease-related complications.

Type 1 diabetes is an autoimmune disease in which the immune system attacks and destroys the insulin-producing cells in the pancreas. The pancreas then produces little or no insulin. A person who has Type 1 diabetes must take insulin daily to live. Type 1 diabetes accounts for about 5 percent of all diagnosed cases of diabetes in the United States and is usually diagnosed in children and young adults.

In Type 2 diabetes, the pancreas is usually producing enough insulin, but the body cannot use the insulin effectively, a condition called insulin resistance. After several years, insulin production decreases. The result is the same as for Type 1 diabetes—glucose builds up in the blood and the body cannot make efficient use of its main source of fuel. Type 2 diabetes can be treated through diet, with insulin, or with medications other than insulin. The prevalence of Type 2 diabetes increases with age. Type 2 diabetes accounts for about 95 percent of diagnosed diabetes in adults in the United States.

Over time, people with the disease have a heightened potential of developing other problematic medical conditions. These conditions include proliferative diabetic retinopathy,[5] cataracts and glaucoma, high blood pressure and other cardiovascular problems, kidney disease, and circulation issues for the extremities, which can cause numbness and decreased functionality, particularly with feet and legs.

Of particular concern for drivers, however, are the immediate symptoms of severe hypoglycemia—a condition where insulin treatment may cause blood glucose to drop to a dangerously low concentration.[6] A person experiencing hypoglycemia may have one or more of the following symptoms: Double vision or blurry vision; shaking or trembling; tiredness or weakness; unclear thinking; fainting; seizures; or coma.[7] If any of these symptoms of severe hypoglycemia occurs while someone is driving, there is the potential for a crash.

Some people with blood glucose readings at concentrations below optimal levels perceive no symptoms and no early warning signs of low blood glucose—a condition called hypoglycemia unawareness. This condition occurs most often in people with Type 1 diabetes, but it can occur in people with Type 2 diabetes. Note, however, that impairments associated with diabetes mellitus can be abated through proper disease management and monitoring to stabilize and control the condition.

B. Brief History of Physical Qualification Standards for CMV Drivers With ITDM[8]

From 1940 until 1971, one of FMCSA's predecessors recommended that CMV drivers have urine glucose tests as part of medical examinations for determining whether persons are physically qualified to drive CMVs in interstate or foreign commerce (4 FR 2294, June 7, 1939, effective date January 1, 1940). In 1971, FHWA, FMCSA's predecessor agency, established the current standard for drivers with ITDM (35 FR 6458, April 22, 1970, effective date January 1, 1971), which includes testing urine for glucose. That standard states that a ''person is physically qualified to drive a commercial motor vehicle if that person has no established medical history or clinical diagnosis of diabetes mellitus currently requiring insulin for control.'' 49 CFR 391.41(b)(3). However, beginning in 1993, CMV drivers with ITDM had the opportunity to apply to FHWA for a waiver until a 1994 Federal court decision invalidated the waiver program.

In 1998, section 4018 of the Transportation Equity Act for the 21st Century, Public Law 105–178, 112 Stat. 413–4 (TEA–21) (set out as a note to 49 U.S.C. 31305) directed the Secretary to determine the feasibility of developing ''a practicable and cost-effective screening, operating and monitoring protocol'' for allowing drivers with ITDM to operate CMVs in interstate commerce. This protocol ''would ensure a level of safety equal to or greater than that achieved with the current prohibition on individuals with insulin treated diabetes mellitus driving such vehicles.''

As directed by section 4018, FHWA compiled and evaluated the available research and information. It assembled a panel of medical experts in the treatment of diabetes to investigate and report about the issues concerned with the treatment, medical screening, and monitoring of ITDM individuals in the context of operating CMVs. In July 2000, FMCSA[9] submitted a report to Congress titled, ''A Report to Congress on the Feasibility of a Program to Qualify Individuals with Insulin Treated Diabetes Mellitus to Operate Commercial Motor Vehicles in Interstate Commerce as Directed by the Transportation Equity Act for the 21st Century'' (TEA–21 Report to Congress).[10] This Report to Congress concluded that it was feasible to establish a safe and practicable protocol containing three components allowing some drivers with ITDM to operate CMVs. The three components were: (1) Screening of qualified ITDM commercial drivers, (2) establishing operational requirements to ensure proper disease management by such drivers, and (3) monitoring safe driving behavior and proper disease management.

On July 31, 2001, because of the conclusions found in the TEA–21 Report to Congress, FMCSA published a notice proposing to issue exemptions from the FMCSRs allowing drivers with ITDM to operate CMVs in interstate commerce. 66 FR 39548. After receiving and considering comments, FMCSA issued a Notice of Final Disposition (''2003 Notice'') establishing the procedures and protocols for implementing the exemptions for drivers with ITDM. 68 FR 52441 (Sept. 3, 2003). So beginning again in 2003, CMV drivers with ITDM could apply to FMCSA for an exemption from this prohibition.

To obtain an exemption, a CMV driver with ITDM had to meet the specific conditions and comply with the requirements set out in the final disposition. The driver had to follow the application process set out in 49 CFR part 381, subpart C, and FMCSA could not grant an exemption unless a level of safety equivalent to, or greater than, the level achieved without the exemption

[5] Between 40 and 45 percent of Americans diagnosed with diabetes have some stage of diabetic retinopathy. The four stages of diabetic retinopathy, from mild, non-proliferative to proliferative, are described by the National Eye Institute, National Institutes of Health at: *http://www.nei.nih.gov/health/diabetic/retinopathy.asp.* Web site accessed on March 20, 2015.

[6] According to the ADA Web site, ''Hypoglycemia is a condition characterized by abnormally low blood glucose (blood sugar) levels, usually less than 70 mg/dl.'' *http://www.diabetes.org/living-with-diabetes/treatment-and-care/blood-glucose-control/hypoglycemia-low-blood.html.* Web site accessed on March 20, 2015.

[7] *http://www.nlm.nih.gov/medlineplus/ency/article/000386.htm.* Web site accessed on March 20, 2015.

[8] A more complete history of the Federal regulation of drivers with ITDM is available in the ANPRM published March 17, 2006 (71 FR 13802), which readers can find in the docket for this rulemaking.

[9] The motor carrier regulatory functions of the FHWA were transferred to FMCSA in the Motor Carrier Safety Improvement Act of 1999, Public Law 106–159, 113 Stat. 1748, Dec. 9, 1999.

[10] The TEA–21 Report to Congress can be accessed in the docket for this rulemaking. For a detailed discussion of the report's findings and conclusions, see 66 FR 39548 (July 31, 2001).

would be maintained. 49 U.S.C. 31315 and 49 CFR 381.305(a).

In conformity with the conclusions of the TEA–21 Report to Congress, the 2003 Notice implemented the three protocol components recommended in the report, with a few modifications.

C. Current Exemption Program

FMCSA administers an exemption program for individuals with ITDM who wish to become qualified or maintain their physical qualifications as CMV drivers. The Agency administers this exemption program under 49 CFR part 381 subpart C according to directives in notices of disposition published in 2003 (68 FR 52441, Sept. 3, 2003) and 2005 (70 FR 67777, Nov. 8, 2005).

To apply for an exemption under the current program administered by FMCSA, the driver must submit a letter application with medical documentation showing the following: [11]

(1) The driver has been examined by a board-certified or board-eligible endocrinologist who has conducted a comprehensive evaluation including (i) one measure of glycosylated hemoglobin within a range of ≥7 percent and ≤10 percent, and (ii) a signed statement regarding the doctor's determinations;

(2) The driver has obtained a signed statement from an ophthalmologist or optometrist that the driver has been examined, has no unstable proliferative diabetic retinopathy, and meets the vision standard in § 391.41(b)(10); and

(3) The driver has obtained a signed copy of an ME's Medical Evaluation Report and of a Medical Examiner's Certificate issued showing that the driver meets all other standards in § 391.41(b).

FMCSA does not conduct exams of any of the drivers in the exemption program. We accept the paperwork from the MEs and the TCs and make our decision based on the paperwork. To maintain the exemption, the driver must meet certain conditions, which include the following:

(1) Yearly medical re-certification by an ME;

(2) Quarterly reports submitted by an endocrinologist to FMCSA including blood glucose logs, insulin regimen changes and hypoglycemic events, if any, that the driver has experienced;

(3) Annual comprehensive medical evaluation by an endocrinologist;

(4) An annual vision evaluation confirming no evidence of unstable proliferative diabetic retinopathy and meeting the vision standard for CMV drivers;

(5) Maintaining appropriate medical supplies for glucose management, including a monitor, insulin, and an amount of rapidly absorbable glucose in the vehicle to be used as necessary;

(6) Following a protocol to monitor and maintain blood glucose levels; and

(7) Reporting all episodes of severe hypoglycemia, significant complications, or inability to manage diabetes, and any involvement in a crash or adverse event to the Agency.

According to the annual report for the diabetes exemption program, FMCSA received 858 applications in 2012, continuing the growth trend of the preceding six years.[12] Before granting a request for an exemption, FMCSA must publish a notice in the **Federal Register** for each exemption requested, explaining that the request has been filed, and providing the public an opportunity to inspect the safety analysis and any other relevant information known to the Agency and to comment on the request. The notice also must identify the person or class of persons who will receive the exemption, the provisions from which the person will be exempt, the effective period, and all terms and conditions of the exemption. In addition, the Agency must monitor the implementation of each exemption to ensure compliance with its terms and conditions.

After the comment period, as part of the approval process, FMCSA must publish a notice of its decision to approve or deny the request. A driver must reapply for an exemption every 2 years. However, FMCSA may revoke an exemption immediately under standards set out in § 381.330.

Should this proposal become a final rule, CMV drivers with ITDM could meet physical qualification standards under the new rule without applying for or receiving exemptions.

VI. Reasons for the Proposed Changes

This section of the preamble is divided into two major subsections. The first section discusses data reflected in evidence reports and American Diabetes Association (ADA) studies examining risks associated with diabetes and driving in general, and the association between hypoglycemia and ITDM in particular. It also discusses MRB findings and conclusions based on evidence reports. The second section explains why FMCSA is proposing to eliminate the exemption program and establish a medical qualification standard for drivers with ITDM, including relating the proposed rule elements to the current exemption program, MRB recommendations, and findings from the ADA studies.

A. Expert Guidance and Studies

Medical Review Board Guidance

FMCSA uses an evidence-based systematic review process and consultation with the MRB and the Chief Medical Officer to revise or develop medical standards and guidelines for commercial drivers. In its deliberations concerning commercial drivers with ITDM, the MRB reviewed the analysis of a 2006 evidence-based report and a 2010 update of that report.[13] Both reports focused primarily on the risks to driver safety from the acute risks associated with diabetes mellitus (*e.g.,* hypoglycemia), but did not address driver safety issues related to chronic complications of diabetes (*e.g.,* diabetic nephropathy, neuropathy, retinopathy, and/or cardiovascular conditions resulting from the long-term complications of diabetes). Both the evidence reports and ADA studies, discussed in the next section, show that hypoglycemia is the chief safety concern for drivers with the disease. Further, the 2010 Update studies show use of insulin, a long duration on insulin, and impaired hypoglycemic awareness as among the factors ''repeatedly shown to be associated with an increased incidence of severe hypoglycemia.'' [14]

After considering the findings in the evidence-based reports, the MRB members agreed unanimously that hypoglycemia among individuals with diabetes mellitus is an important risk factor for motor vehicle crashes and approved a set of recommendations to FMCSA for CMV drivers with diabetes mellitus intended to reduce the likelihood of their operating when impaired by hypoglycemic conditions. The MRB recommended that FMCSA allow individuals with ITDM to drive CMVs if they are free of severe hypoglycemic reactions, have no altered mental status or unawareness of hypoglycemia, and manage their diabetes mellitus properly to keep blood sugar levels in the appropriate ranges. The MRB also recommended that all

[11] This list of requirements to apply for and maintain an ITDM exemption is not inclusive.

[12] Annual Report for the FMCSA Diabetes Exemption Program, December 31, 2012.

[13] The 2006 ITDM evidence report is Tregear, SJ, Rizzo M, Tiller M, et al., ''Evidence Report: Diabetes and Commercial Motor Vehicle Driver Safety,'' September 8, 2006. Accessed on May 20, 2015, at: *http://ntl.bts.gov/lib/30000/30100/30117/Final_Diabetes_Evidence_Report.pdf.* The 2010 update report is Bieber-Tregear, M.; Funmilayo, D; Amana, A.; Connor, D; Tregear, S.; and Tiller, M., ''Evidence Report: 2010 Update: Diabetes and Commercial Motor Vehicle Driver Safety,'' May 27, 2011. Accessed on May 20, 2015, at *http://ntl.bts.gov/lib/39000/39400/39416/2010_Diabetes_Update_Final_May_27_2011.pdf,* (2010 Update).

[14] 2010 Update Page 10.

drivers diagnosed with diabetes mellitus be required to obtain at least annual recertification by a ME who is a licensed physician, regardless of whether they are insulin-treated. However, the MRB recommended maintaining a restriction on medical qualification of drivers with ITDM from passenger and hazardous materials transportation.

American Diabetes Association Position Paper

In a 2012 peer-reviewed position paper titled, ''Diabetes and Driving,'' the ADA provided ''an overview of existing (drivers) licensing rules for people with diabetes, address[ing] the factors that impact driving for this population, and identify[ing] general guidelines for assessing driver fitness and determining appropriate licensing restrictions.'' [15] At the end of the paper, ADA set out recommendations for identifying and evaluating diabetes in drivers.[16] Although the ADA addressed these issues in discussing fitness for non-CMV drivers with diabetes, the same disease-related conditions that present driving concerns in the non-CMV driving population create those same concerns in the CMV driving population. ADA begins by stating, ''[M]ost people with diabetes safely operate motor vehicles without creating any meaningful risk of injury to themselves or others.'' [17] Summarizing several studies on understanding diabetes and driving, the paper notes inconsistent findings relative to which drivers with diabetes are at higher risk of crashes. However, the paper notes that according to the studies, ''The single most significant factor associated with driving collisions for drivers with diabetes appears to be a recent history of severe hypoglycemia,[18] regardless of the type of diabetes or the treatment used.'' [19] The paper further references studies finding that even moderate hypoglycemia ''significantly and consistently impairs driving safely and judgment as to whether to continue to drive or self-treat under such metabolic conditions.'' [20]

In evaluating fitness for drivers with diabetes, the ADA paper underscores the importance of individualized assessments ''based not solely on diagnosis of diabetes but rather on concrete evidence of actual risk.'' [21] According to the ADA paper, such an assessment ''must include an assessment by the treating physician or other diabetes specialist who can review recent diabetes history'' as these health care providers are ''the best source of information concerning the driver's diabetes management and history.'' [22] Among other things, the ADA paper recommends physicians provide the following information to licensing authorities: (1) The driver's risk of severe hypoglycemia; (2) the driver's ability to recognize imminent hypoglycemia and take appropriate corrective action; and (3) the driver's ability to provide evidence of sufficient self-monitoring of blood glucose. Appropriate screening inquiries related to driver fitness include ''whether the driver has, within the past 12 months, lost consciousness due to hypoglycemia, experienced hypoglycemia that required intervention from another person to treat or that interfered with driving, or experienced hypoglycemia that developed without warning.'' [23]

The ADA's summary of findings concerning the risks of driving and diabetes concludes that, ''[M]ost people with diabetes safely operate motor vehicles without creating any meaningful risk of injury to themselves or others.'' [24] This statement also reflects FMCSA's conclusion based on the available evidence.

B. What FMCSA is Proposing and Why

In accordance with section 4129(d) of SAFETEA–LU referenced earlier in the Legal Basis section of the preamble, FMCSA may not adopt higher physical qualification standards for drivers with ITDM ''except to the extent that limited operating, monitoring, and medical requirements are deemed medically necessary.'' As noted above, CMV drivers with diabetes whose condition is stable and well-controlled do not pose an unreasonable risk to their health or to public safety. Also, as noted, studies indicate that hypoglycemia is the chief safety concern for drivers with diabetes, and the evidence reports show a connection between insulin use and the risk of hypoglycemia. FMCSA has determined that the inconvenience and expense for drivers, and the administrative burden of an exemption program are no longer necessary to address concerns of hypoglycemia and meet the statutory requirement that drivers with ITDM maintain a physical condition that ''is adequate to enable them to operate (CMVs) safely.'' 49 U.S.C. 31136(a)(3). The principal reason for codifying medical qualification standards for ITDM drivers is to eliminate the prohibition on physically qualifying these drivers, thereby promoting their ability to earn a living without the inconvenience and added costs of obtaining and maintaining an exemption. As stated above, evidence indicates that these drivers are reasonably safe to drive if their diabetes is stable and well-controlled.

In this proposed rule, FMCSA would address hypoglycemia as a driver health and operational safety risk by establishing a regulatory protocol to ensure proper disease monitoring and management for drivers using insulin. The Agency is proposing to allow drivers with ITDM to be medically qualified. As a result, the exemption program established in the 2003 and 2005 notices would be unnecessary, and the notices would be withdrawn when this final rule becomes effective. These actions are consistent with the MRB recommendations. Further, this rulemaking would allow healthcare professionals familiar with a driver's physical condition to communicate directly with each other, appropriately ensuring that the MEs have the information necessary to complete the certificate attesting to the driver's medical qualifications. The practice of medical certification through MEs is more efficient and is reflective of congressional intent to have MEs on the National Registry make an individualized assessment of a particular driver's health status and ability to operate a CMV safely.

Contrary to the MRB recommendations, the Agency is not proposing to prohibit drivers with ITDM from being medically qualified to operate CMVs carrying passengers and hazardous materials. The risk posed by a driver with stable, well-controlled ITDM is very low in general. Further, there is no available evidence to support such a prohibition, and, as noted, under section 4129 of SAFETEA–LU, FMCSA may not hold drivers with ITDM ''to a higher standard of physical qualification . . . than other individuals . . . except to the extent that limited operating, monitoring, and medical requirements are deemed medically necessary under

[15] ADA, ''Diabetes and Driving,'' *Diabetes Care,* vol. 35, supplement 1, January 2012, pp. S81–S85, at S81. Accessed March 20, 2015, from: *http://care.diabetesjournals.org/content/35/Supplement_1/S81.full.pdf+html.*

[16] Id. at S83-S85.

[17] Id. at S81.

[18] Id. at S82 (''The American Diabetes Association Workgroup on Hypoglycemia defined severe hypoglycemia as low blood glucose resulting in neuroglycopenia that disrupts cognitive motor function and requires the assistance of another to actively administer carbohydrate, glucagon, or other resuscitative actions.'').'' Reference omitted.

[19] Id. At page 84, the paper states, ''[R]ecurrent episodes of severe hypoglycemia, defined as two or more episodes in a year, may indicate that a person is not able to safely operate a motor vehicle.''

[20] Id. References omitted.

[21] Id. at S83.

[22] Id.

[23] Id.

[24] Id. at S81.

regulations.'' In addition, the current exemption program permits these drivers to qualify for passenger carrying and hazardous materials transportation. The Agency requests public comment specifically on this point, however.

In addition, FMCSA is not proposing to adopt the MRB recommendation to require annual or more frequent medical recertification for all drivers with diabetes mellitus. The proposed requirements apply only to drivers with ITDM. Current regulations do not prohibit any drivers with non-insulin treated diabetes mellitus from being qualified medically to operate CMVs. Finding no medical necessity for such a prohibition, the Agency is not proposing such a change. Furthermore, although the MRB recommended evaluation by a licensed physician, the Agency believes the TC working in conjunction with the ME, who is certified by the National Registry and working within the regulatory framework under part 391, meets the statutory requirement under 49 U.S.C. 31136(a)(3) for periodic physical examinations of drivers. The Agency seeks comment on these issues.

Today's proposed rule would amend 49 CFR part 391 by revising §§ 391.41 and 391.45 and by adding new § 391.46 to address driver health and public safety concerns associated with hypoglycemia related to diabetes and its control through insulin. The elements of the proposed rule are limited and medically necessary under section 4129(d) of SAFETEA–LU, ensure that the physical condition of drivers with ITDM is adequate to enable them to operate CMVs safely as required by 49 U.S.C. 31136(a)(3), and align with current best medical practice standards for monitoring and managing ITDM. In brief, the Agency proposes the following elements:

A driver with ITDM must have an annual or more frequent evaluation by a TC prior to a DOT medical examination by a certified ME. This proposed requirement is consistent with the MRB recommendations, except that the MRB recommended application to all drivers with diabetes mellitus. For the reason stated above, FMCSA is proposing this requirement only for drivers with ITDM.

The driver must keep blood glucose records as determined by the TC and submit those records to his or her TC at the evaluation. This proposed requirement is consistent with the MRB recommendation that drivers with ITDM monitor blood glucose levels and submit logs as part of their annual evaluation.

The ME must obtain written notification from the driver's TC, who has determined whether, in the preceding 12 months, the driver had a severe hypoglycemic reaction or demonstrated hypoglycemic unawareness and monitored and managed the condition properly as evidenced by blood glucose records. This proposed requirement is consistent with the MRB recommendation that drivers with ITDM be free of severe hypoglycemia and hypoglycemia unawareness, and that these drivers properly monitor and manage the condition.

At least annually, an ME, listed on the National Registry, must examine and certify that the driver is free of complications that would impair the driver's ability to operate a CMV safely and only renew the medical certificate for up to 1 year. This proposed requirement is consistent with the MRB recommendation for annual or more frequent recertification. For the reason stated above, FMCSA is proposing this requirement only for drivers with ITDM.

In contrast with the current exemption program, the proposed rule would require an annual evaluation by a TC instead of an evaluation by an endocrinologist and an annual or more frequent DOT medical examination by a certified ME to determine if medical certification is warranted. Evaluation by a TC allows for the individualized assessment of drivers with ITDM, which is consistent with the recommendations of the ADA and other organizations concerned with diagnosis and treatment of the disease. Most importantly, under section 4129(a) of SAFETEA–LU, Congress expressly directed FMCSA to modify the exemption program to ''provide for the individual assessment of applicants who use insulin to treat their diabetes and who are, except for their use of insulin, otherwise qualified under the [FMCSRs].'' FMCSA believes that a similar provision for an individual assessment is also appropriate in this rule. Further, although the ADA, the U.S. National Institutes of Health, and other organizations urge yearly assessments for individuals with diabetes by a physician or health care professional knowledgeable about the disease, none of these groups calls for yearly evaluations by endocrinologists. The National Institute of Diabetes and Digestive and Kidney Diseases notes that most people with diabetes receive care from a primary care physician—generally an internist or family practice doctor. Indeed, a requirement to be evaluated by an endocrinologist now seems impracticable for most drivers with ITDM. According to the American Board of Internal Medicine, there are only about 5,300 board-certified endocrinologists in the United States, approximately 1,300 of which do not provide clinical care.[25]

Reasonable persons with ITDM have every incentive to manage their condition so that the disease is stable and well-controlled, because the failure to take care of themselves not only would affect the quality of life, but also would significantly increase the risk of a hypoglycemic event. For a CMV driver, this situation would result in the inability to renew the required medical certificate and to earn an income through driving a CMV.

If a driver who has not used insulin previously begins using insulin for control of diabetes mellitus, the driver would be required to have an examination by a TC prior to the required DOT medical examination by a certified ME . The ME would use medical information from the TC in conjunction with the medical certification examination to determine whether a driver new to insulin treatment qualifies for medical certification. Essentially, in issuing a MEC under FMCSA regulations, the ME will reflect his or her evaluation that such drivers are free of complications that might impair the ability to operate a CMV safely in interstate commerce.

For all drivers with ITDM, the annual visit with the TC would ensure that a driver is complying with an appropriate standard of care for individuals with that condition, and it would allow the TC to monitor any of the other progressive conditions associated with diabetes. Although the proposed rule has no requirement for hypoglycemia awareness training, the annual or more frequent ME certification exam provides an opportunity for intervention should the TC evaluation, and the ME's own examination, provide evidence of hypoglycemia unawareness that impairs safe driving. The ME will request that the TC provide written notification regarding the ITDM driver's disease management prior to the examination of the driver.

The annual or more frequent requirement for a new MEC aligns with the current interval specified under the directives in the notices of final disposition and with the interval specified for drivers with ITDM by the Canadian Council of Motor Transport Administrators. The determination of whether a driver with ITDM is eligible to receive a MEC would rest with the ME who, working under part 391 with information provided by the TC, is

[25] *http://thyroid.about.com/od/findlearnfromdoctors/a/endo-shortage.htm.* Accessed on March 20, 2015.

authorized by statute to conduct DOT medical examinations.

The proposed rule would not change the requirement under 49 CFR 392.3 for every CMV driver, including those with ITDM, to refrain from operating a CMV while the driver's ability or alertness is impaired in a way that would compromise safety. The driver's knowledge of the issues surrounding ITDM, appropriate monitoring protocols, and equipment and supplies are still very important. The proposed rule would not allow drivers with ITDM with licenses issued in Canada or Mexico to operate a CMV in the United States. Drivers from Mexico with a Licencia Federal de Conductor (LFC) generally may operate in the United States. 49 CFR 383.23(b), n. 1 and 391.41(a)(1)(i). But Mexico does not issue an LFC to any driver with diabetes. Under the terms of the 1998 reciprocity agreement with Canada, a Canadian driver with ITDM holding a license issued by a Canadian province is not authorized to operate a CMV in the United States.

In 1994, at the termination of the ITDM waiver program described in the Background section of this NPRM, FHWA allowed drivers holding waivers to continue to operate CMVs in interstate commerce under the grandfather provisions of 49 CFR 391.64. The requirements in proposed § 391.46 reflect limited and necessary diabetes monitoring and management practices based on the results of the ADA studies and the evidence reports. On the other hand, under the current requirements in § 391.64, a driver with ITDM must continue to receive an annual endocrinologist examination, carry an absorbable source of glucose, and meet other requirements that FMCSA has determined are impracticable or unenforceable. If the requirements proposed today are adopted, the Agency believes that grandfathering provisions may be redundant because the individuals with waivers would comply already with the necessary elements of § 391.64 (*e.g.,* otherwise qualifying under § 391.41 and annual examination by an ME), or would be able to meet a less restrictive requirement (*e.g.,* annual examination by a TC rather than a board-certified endocrinologist). However, FMCSA seeks comments regarding whether removing these grandfathering provisions would adversely affect any driver that is operating currently under § 391.64.

The current exemption program requires drivers with ITDM to obtain a signed statement from an ophthalmologist or optometrist that the applicant has been examined, meets the vision standard in § 391.41(b) or has an exemption, and does not have diabetic retinopathy. If the applicant has diabetic retinopathy, he or she must be tested by an ophthalmologist to determine whether the condition is unstable and proliferative. Following that exam, the applicant must submit a separate signed statement from the ophthalmologist certifying that the applicant's diabetic retinopathy is not unstable or proliferative.

The proposed rule would not require drivers with ITDM to be examined or obtain a signed statement from an ophthalmologist or optometrist to meet the vision standard or a separate examination for diabetic retinopathy. As stated above, FMCSA believes that reasonable persons with ITDM have every incentive to manage their condition so that the disease is stable and well-controlled, because the failure to care for themselves would affect their quality of life. This includes examinations by an optometrist or ophthalmologist to assess the individual's long term visual health. The regulatory concern for any driver is whether he or she can meet the standards in § 391.41(b)(10). FMCSA believes that meeting the vision acuity standard as part of the annual exam by an ME listed in the National Registry of Certified Medical Examiners provides reasonable certainty of discovering and mitigating risks associated with any safety-related condition that would interfere with meeting the standard, including diabetic retinopathy. This approach also would be less costly for drivers who would incur the cost of seeing a vision specialist only if there are signs of a degenerative condition, in contrast to the exemption program requirement that these drivers must see an optometrist or ophthalmologist to meet visual acuity requirements under § 391.41(b). The Agency requests comment on the need for a person with ITDM to be examined by an optometrist or ophthalmologist as a condition of passing the physical exam.

VII. Section-By-Section Analysis

This NPRM addresses the physical qualification standards for interstate CMV drivers treating their diabetes mellitus with insulin. This section-by-section analysis describes the proposed provisions in numerical order.

Section 391.41 Physical Qualifications for Drivers

Section 391.41 would be amended to allow drivers treating diabetes mellitus with insulin to operate commercial motor vehicles in interstate commerce provided they meet the conditions specified in the new § 391.46. Paragraph (b)(3) would be revised to allow a person to meet the physical qualification standards to operate a commercial motor vehicle either by (1) having no medical history or diagnosis of diabetes mellitus requiring insulin for control or (2) meeting the requirements in new § 391.46.

Section 391.45 Persons Who Must Be Medically Examined and Certified

Section 391.45 would be revised to renumber the section for clarity. Existing paragraph (b)(1) would become new paragraph (b), requiring any driver who has not been medically examined and certified as qualified to operate a CMV during the preceding 24 months, unless the driver is required to be examined and certified in accordance with paragraphs (c), (d), (e) or (f) of this section. Existing paragraph (b)(2) would be divided into new paragraphs (c) and (d). Existing paragraph (c) would become new paragraph (f). New paragraph (e) would require any driver who has diabetes mellitus requiring insulin for control and who has been qualified for a MEC under the standards in § 391.46 to be medically examined and certified as qualified to drive at least every 12 months.

Section 391.46 Physical Qualification Standards for a Person With Insulin-Treated Diabetes Mellitus

A new § 391.46 would be added containing the requirements that a person who has diabetes mellitus currently requiring insulin for control must meet to be physically qualified to drive a CMV in accordance with specific standards for such drivers.

Proposed paragraph (a) would require that a person with diabetes mellitus requiring insulin for control is physically qualified to operate a CMV in interstate commerce if he or she otherwise meets the standards in § 391.41 and also meets the requirements in paragraphs (b) and (c) of proposed § 391.46.

Paragraph (b) would require the person with diabetes mellitus currently requiring insulin for control to have an evaluation by his or her TC who would determine that the driver had not experienced a recent severe hypoglycemic reaction and was properly managing the disease. A definition of TC would be added to the provision. Paragraph (b) also would require a person with diabetes mellitus requiring insulin for control to be medically examined and certified under § 391.43 by an ME. These examinations would occur at least annually. The ME

must obtain and review written notification from the TC that the person is properly managing the diabetes mellitus. Paragraph (c) would require that the medically certified driver with ITDM maintain his or her blood glucose records per the guidance of the TC for the period of certification and submit those records to the TC at the time of the evaluation.

VIII. Rulemaking Analyses and Notices

A. Regulatory Planning and Review (Executive Order (E.O.) 12866) and DOT Regulatory Policies and Procedures

Under E.O. 12866, ''Regulatory Planning and Review'' (issued September 30, 1993, published October 4 at 58 FR 51735, as supplemented by E.O. 13563 and DOT policies and procedures, FMCSA must determine whether a regulatory action is ''significant'' and therefore subject to Office of Management and Budget (OMB) review. E.O. 12866 defines ''significant regulatory action'' as one likely to result in a rule that may:

(1) Have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or Tribal government or communities.

(2) Create a serious inconsistency or otherwise interfere with an action taken or planned by another Agency.

(3) Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof.

(4) Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the E.O.

FMCSA determined this proposed rule is not a ''significant regulatory action'' under Executive Order 12866, Regulatory Planning and Review, and not significant under DOT regulatory policies and procedures. The Agency estimates that the economic impact of this proposed rule will not exceed the annual $100 million threshold for economic significance.

This Regulatory Impact Analysis (RIA) provides an assessment of the costs and benefits of the Qualifications of Drivers: Diabetes NPRM. FMCSA proposes to allow the operation of CMVs in interstate commerce by drivers with well-controlled ITDM whose physical condition allows them to operate safely. Under current medical qualifications requirements an insulin-dependent driver does not meet the qualifications of § 391.41(b)(3) to receive a MEC to operate CMVs in interstate commerce. However, FMCSA may grant the driver with stable, well-controlled ITDM an exemption to drive in interstate commerce under the procedures in 49 CFR part 381 and the protocols in the 2003 Notice of Final Disposition as updated in 2005.[26]

The proposed rule would change the physical qualification standards to allow the ME to qualify drivers with stable, well-controlled ITDM to operate CMVs in interstate commerce. FMCSA has evaluated the costs and benefits of the proposed rule using the current exemption program as a baseline for comparison. The proposed rule and the exemption program differ on key provisions that affect costs, which are summarized below.

TABLE 2—COMPARISON OF CURRENT EXEMPTION PROGRAM AND PROPOSED RULE

Current exemption program	Proposed rule
Annual exam by ME	Annual exam by ME.
Renewable exemption granted by FMCSA for up to every 2 years	No exemption needed.
Annual exam by eye specialist for evidence of diabetic retinopathy	No annual exam by eye specialist required in regulations.
Annual evaluation by board-certified endocrinologist	Annual evaluation by TC.
Submit quarterly reports from board-certified endocrinologist	No report required.

The majority of CMV drivers receive MECs that are valid for two years. The proposed rule would require drivers with ITDM to obtain MECs at least annually as currently required by the exemption program. However these drivers would no longer be required to obtain an exemption from FMCSA. A driver with stable, well-controlled ITDM who meets the requirements of the proposed rule could obtain a MEC and continue to earn income operating CMVs in interstate commerce without the additional expense and delay of applying for an exemption.

Not all drivers who seek to be medically certified under the standards described in this proposed rule would be medically qualified to operate a CMV, however estimating the number of drivers who would join the driver population is difficult. As a result the Agency has performed a threshold analysis using various percentages of ITDM-medically qualified drivers to determine possible costs of the rule annually in millions of dollars. Further information on this analysis may be found in the RIA in the docket.

In this analysis, we provide cost estimates if the estimated rates of ITDM-qualified driver populations are: 33.3%, 66.7%, and 100%. The Agency has no estimate of the actual rate of ITDM-qualified drivers certified under the qualifications proposed here and feels that 33.3%, 66.7%, and 100% acceptance rates allow the reader to understand the range of possible impacts of the rule. This has no impact on the rule's cost per driver which will be discussed shortly.

The proposed rule is less onerous for both drivers with ITDM and for the Agency. The Agency would change the requirement from an annual evaluation by a board-certified endocrinologist to one with a TC because the treating licensed healthcare professional is capable of determining whether the driver's condition is well-controlled. The revised requirement also would eliminate quarterly reports from the board-certified endocrinologist, the sharing of information between the ME on the National Registry and the TC would ensure that only drivers who are controlling their ITDM would receive a 1-year medical certificate. The Agency would no longer review applications for exemptions, further reducing administrative costs for FMCSA. The rule would eliminate an annual eye exam, because a qualified ME on the Agency's National Registry could determine whether the driver meets the vision standard. For these reasons, the per-driver cost would be significantly lower under the proposed rule than under the current exemption program.

The table below compares costs of the current exemption program with projected costs of the proposed rule. As the Agency lacks sufficient data to project the affected population changes

[26] 68 FR 52441 and 70 FR 67777.

in subsequent years, the analysis projects this rule's total annual costs to remain constant in real terms during each of the ten years from the initial compliance date. A separate discussion of the *annualized* costs at the 7% discount rate for this rule is therefore unnecessary, as the annualized costs are identical to the corresponding discounted annual costs. The Agency seeks comments on the use and appropriateness of these ranges in the absence of additional data on the prevalence of ITDM-qualified drivers and their likelihood of participating in the proposal's certification program.

TABLE 3—TOTAL ANNUAL COSTS

[In millions of $]

	Current exemption program	Proposed rule (100% IDTM-qualified drivers [27]—209,664 drivers)	Proposed rule (66.7% ITDM-qualified drivers—139,846 drivers)	Proposed rule (33.3% ITDM-qualified drivers—69,818 drivers)
Cost of Endocrinology Visits ($m)	$0.26	$0.00	$0.00	$0.00
Cost of Annual Exam of Eye Specialist ($m)	0.40	0.00	0.00	0.00
Cost of Issuing Annual Medical Certificates ($m)	0.13	16.35	10.91	5.45
Cost of Applying for Exemption ($m)	0.03	0.00	0.00	0.00
Driver Time Costs of Medical Exams ($m)	0.0	7.55	5.03	2.51
Cost to Government ($m)	0.91	0.00	0.00	0.00
Total Costs ($m)	1.79	23.90	15.94	7.96

On a per-driver basis, the annual cost impact of this rule is consistent across all ITDM-qualified drivers. These costs include a driver's cost of time related to the DOT medical examination ($31 per hour) and a driver's expense for the out-of-cycle DOT medical examination ($120). Combined, the out-of-pocket cost per ITDM-qualified driver resulting from this proposal is $151 (= $31 + $120). If an ITDM-qualified driver presently participates in the medical exemption program, although he or she will still incur the annual $151 cost of this proposal, this driver will experience a significant cost reduction relative to the cost to participate in the current exemption program, discussed further in the RIA.

In addition to examining published literature on the safety risk of drivers with diabetes, the Agency has also examined the safety performance of drivers holding diabetes exemptions.

TABLE 4—DIABETES EXEMPTION ANALYSIS RESULTS

	Fatal crashes	Fatalities	Injury crashes	Injuries	Tow away crashes	Total crashes
Pre-Exemption Period	16	24	108	171	193	317
Exemption-Period	0	0	22	31	52	74
Post-Exemption Period	3	4	16	22	22	41
Total	19	28	146	224	267	432

Source: December 14, 2012 MCMIS snapshot.

The table above titled ''Diabetes Exemption Analysis Results'' summarizes the crash performance of 1,730 drivers in the Diabetes Exemption Program. Crash statistics for the pre-exemption career and (if any) post-exemption career [28] of the drivers are presented, but the primary periods of interest are the months and years during which a driver was granted an exemption. As can be seen, as a whole, drivers in the exemption program were involved in 74 crashes, none of them fatal.

This record of crash history can be compared against the crash performance of drivers as a whole. Because one can examine MCMIS reported crashes only for drivers in the exemption program, the analysis of the safety performance of drivers as a whole is restricted to MCMIS reported crashes. The Agency lacks data on vehicle miles traveled for drivers in the exemption program, however, and the best indication of exposure is therefore years of driving.

The exemption program provides data on when an exemption was granted, renewed, rescinded, or terminated. These data allow one to determine, for each exemption holder, approximately how many months and years each driver operated a CMV while holding an exemption. FMCSA was able to analyze data for 1,730 drivers involved in 74 crashes. Some drivers could not be analyzed because of missing data. (They had a termination date but no acceptance date, they could not be matched to a driver's license record, or some other data problem made it impossible to calculate the number of years they had been driving or to match their exemption to a crash record.) The 1,730 drivers had an average of 3.293 years of driving experience in the exemption program. On a per-driver, per-year basis, the crash rate for drivers with ITDM in the exemption program was 0.013 (0.0130 = 74 crashes ÷ 1,730 drivers ÷ 3.293 years).

[27] ''ITDM-qualified drivers'' are those the Agency believes would qualify under this proposed rule to receive medical certificates enabling them to operate CMVs in interstate commerce were they to undergo a DOT medical examination. The derivation of the estimated number of ITDM-qualified drivers at the three participation rates evaluated is shown in section 2.4.1 of the regulatory evaluation.

[28] Some drivers continued driving CMVs after their exemption was rescinded or terminated. It is unlikely that these drivers stopped taking insulin. Instead, it is most likely that these drivers ignored the prohibition on driving while being treated with insulin unless the driver holds an exemption.

Data indicate that the safety performance for CMV drivers with ITDM who hold exemptions is as good as that of the general population of CMV drivers. The table below shows crashes reported to MCMIS for all FMCSA-regulated CMV drivers from 2005 to 2011. Over this period, there was an average of 134,191 crashes reported to MCMIS each year. FMCSA estimates that there are currently 3.5 million active CMV drivers in FMCSA-regulated operations. Consequently, the average number of crashes per year per active CMV driver is about 0.038 (134,191 ÷ 3,500,000).

TABLE 5—MCMIS CRASHES (ANY SEVERITY) INVOLVING LARGE TRUCKS, 2005–2012

Year	2005	2006	2007	2008	2009	2010	2011	Average
Crashes	149,878	148,221	148,733	134,666	111,502	122,851	123,483	134,191

Source: December 2013, MCMIS snapshot.

The proposed rule would eliminate the blanket prohibition against drivers with ITDM so that the exemption program would no longer represent the sole means of physically qualifying to operate CMVs. The Agency believes that the benefits of the proposed rule to ITDM individuals are significant. These individuals may pursue interstate driving careers after demonstrating to a ME that their condition is well-controlled and that their ability to operate CMVs safely is not compromised by their medical condition. Although the annual costs will be higher because of the increased number of drivers with stable, well-controlled ITDM who could be eligible for medical certification under the new rule, the Agency expects that drivers with ITDM will benefit from greater employment opportunities, and will realize benefits to their health through improved monitoring of their ITDM.

B. Regulatory Flexibility Act

The Regulatory Flexibility Act of 1980 (5 U.S.C. 601 *et seq.*) (RFA) requires Federal agencies to consider the effects of the regulatory action on small business and other small entities and to minimize any significant economic impact. ''Small entities'' consist of small businesses and not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with a population of less than 50,000.[29]

Accordingly, DOT policy requires an analysis of the impact of all regulations on small entities and mandates that agencies strive to lessen any adverse effects on these businesses. Under the standards of the RFA, as amended by the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121, 110 Stat. 857) (SBREFA), the proposed rule does not impose a significant economic impact on a substantial number of small entities (SEISNOSE) because the medical standards apply to individuals seeking to operate a CMV in interstate commerce; they are qualifications for an occupation rather than for small entities. Although there are individual drivers who are self-employed, qualifications for an occupation are not considered a small business issue.

Consequently, I certify that the proposed action will not have a significant economic impact on a substantial number of small entities. FMCSA invites comment from members of the public who believe there will be a significant impact either on small businesses or on governmental jurisdictions with a population of less than 50,000.

C. Assistance for Small Entities

Under section 213(a) of SBREFA, FMCSA wants to assist small entities in understanding this proposed rule so that they can better evaluate its effects on themselves and participate in the rulemaking initiative. If the proposed rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please consult the FMCSA point of contact, Ms. Linda Phillips, using the contact information in the **FOR FURTHER INFORMATION CONTACT** section of this proposed rule.

D. Unfunded Mandates Reform Act of 1995

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, taken together, or by the private sector of $151 million (which is the value in 2012 after adjusting for inflation $100 million from 1995) or more in any 1 year. FMCSA's assessment is that this proposed rule would not result in such an expenditure.

E. National Environmental Policy Act and Clean Air Act

FMCSA analyzed this proposed rulemaking for the purpose of the National Environmental Policy Act of 1969 (42 U.S.C. 4321 *et seq.*) and determined under our environmental procedures Order 5610.1, published March 1, 2004, (69 FR 9680) that this NPRM does not have any significant impact on the environment. In addition, the actions in this rulemaking are categorically excluded from further analysis and documentation per paragraph 6(b) and 6(s)(7) of Appendix 2 of FMCSA's Order 5610.1. A Categorical Exclusion determination is available for inspection or copying in the *www.regulations.gov* Web site listed under **ADDRESSES**.

FMCSA analyzed this proposed rule under the Clean Air Act, as amended (CAA), section 176(c) (42 U.S.C. 7401 *et seq.*), and implementing regulations promulgated by the Environmental Protection Agency. The Agency has determined that this proposed rule is exempt from the CAA's general conformity requirement since the action results in no increase in emissions.

F. Environmental Justice (E.O. 12898)

Under E.O. 12898, each Federal agency must identify and address, as appropriate, ''disproportionately high and adverse human health or environmental effects of its programs, policies, and activities on minority populations and low-income populations'' in the United States, its possessions, and territories. FMCSA evaluated the environmental justice effects of this proposed rule in accordance with the E.O., and has determined that no environmental justice issue is associated with this proposed rule, nor is there any collective environmental impact that would result from its promulgation.

G. Paperwork Reduction Act

Under the Paperwork Reduction Act of 1995, a Federal agency must obtain approval from the OMB for each

[29] Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*), see National Archives at *http://www.archives.gov/federal-register/laws/regulaotry-flexibility/601.html.*

collection of information it conducts, sponsors, or requires through regulations. 44 U.S.C. 3501–3520. Current exemption program applicants provide personal, employee health, and driving information during the application process. In the currently drafted supporting statement for the Information Collection Request (ICR), ''Medical Qualifications of Drivers'' (OMB control number 2126–0006), FMCSA attributes 2,219 annual burden hours to the applications made by CMV drivers to the current exemption program, and this proposed rule would eliminate this entire burden. However it would add fewer burden hours for the information collection of the TC who prepares written notification for the ME on the driver health, the completion of the ME report and results, and the ME's submission of the exam data and Medical Certificates to FMCSA. The supporting statement for this ICR is on display in the docket for your review and comment.

H. Governmental Actions and Interference With Constitutionally Protected Property Rights (E.O. 12630)

E.O. 12630 requires Federal agencies to consider the potential takings implications of their proposed actions, decisions, or regulations on constitutionally protected property rights, and document takings implications in all significant rulemaking documents that must be submitted to the OMB. FMCSA has determined that this proposed rule would not effect a taking of private property or otherwise have taking implications under E.O. 12630.

I. Civil Justice Reform (E.O. 12988)

This proposed rule meets applicable standards in sections 3(a) (regarding the general duty to review regulations) and 3(b)(2) (addressing important issues affecting clarity and general draftsmanship) of E.O. 12988, Civil Justice Reform, to minimize litigation, eliminate ambiguity, and reduce burden.

J. Protection of Children (E.O. 13045)

E.O. 13045, ''Protection of Children from Environmental Health Risks and Safety Risks,'' requires that agencies issuing economically significant rules, which concern an environmental health or safety risk that an Agency has reason to believe may disproportionately affect children, must include an evaluation of the environmental health and safety effects of the regulation on children. 62 FR 19885 (Apr. 23, 1997). Section 5 of E.O. 13045 directs an agency to submit for a covered regulatory action an evaluation of its environmental health or safety effects on children. The FMCSA has determined that this proposed rule is not a covered regulatory action as defined under E.O. 13045, because this proposal would not constitute an environmental health risk or safety risk that would disproportionately affect children.

K. Federalism (E.O. 13132)

Under E.O. 13132, a rule has implications for federalism if it has a substantial direct effect on State or local governments and would either preempt State law or impose a substantial direct cost of compliance on States or localities. FMCSA has analyzed this proposed rule under that E.O. and has determined that it does not have implications for federalism. Nothing in this proposed rule would preempt State law or regulation or impose substantial direct compliance costs on these governmental entities.

L. Intergovernmental Review (E.O. 12372)

The regulations implementing E.O. 12372 regarding intergovernmental consultation on Federal programs and activities do not apply to this program.

M. Consultation and Coordination With Indian Tribal Governments (E.O. 13175)

FMCSA analyzed this proposed rule in accordance with the principles and criteria in E.O. 13175, Consultation and Coordination with Indian Tribal Governments. This rulemaking does not significantly or uniquely affect Indian tribal governments or impose substantial direct compliance costs on tribal governments. Thus, the funding and consultation requirements of E.O. 13175 do not apply, and no tribal summary impact statement is required.

N. Energy Supply, Distribution, or Use (E.O. 13211)

FMCSA has analyzed this proposed rule under E.O. 13211, ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use.'' This proposal is not a significant energy action within the meaning of section 4(b) of the E.O. This proposal is not economically significant and would not have a significant adverse effect on the supply, distribution, or use of energy.

O. Privacy Impact Analysis

Section 522 of title I of division H of the Consolidated Appropriations Act, 2005, enacted December 8, 2004 (Pub. L. 108–447, 118 Stat. 2809, 3268, 5 U.S.C. 552a note), requires the Agency to conduct a privacy impact assessment (PIA) of a regulation that will affect the privacy of individuals. In accordance with this Act, a privacy impact analysis is warranted to address any privacy implications contemplated in the proposed rulemaking. The Agency submitted a Privacy Threshold Assessment analyzing the privacy implications to the Department of Transportation, Office of the Secretary's Privacy Office to determine whether a PIA is required. The DOT Chief Privacy Officer has evaluated the risks and effects that this rulemaking might have on collecting, storing, and sharing Personally Identifying Information and has examined protections and alternative information handling processes in developing the proposal in order to mitigate potential privacy risks. The privacy risks and effects associated with this proposed rule are not unique and have previously been addressed by the medical examination/certification requirements in the National Registry of Certified Medical Examiners (National Registry) and the Medical Examiner's Certification Integration PIA published on the DOT Privacy Web site and the DOT/FMCSA 009—National Registry of Certified Medical Examiners System of Records Notice (SORN) (77 FR 24247) published on April 23, 2012. An additional PIA and SORN for this rulemaking is not required.

P. National Technology Transfer and Advancement Act (Technical Standards)

The National Technology Transfer and Advancement Act (15 U.S.C. 272 note) directs agencies to use voluntary consensus standards in their regulatory activities unless the agency provides Congress, through OMB, with an explanation of why using these standards would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards (*e.g.,* specifications of materials, performance, design, or operation; test methods; sampling procedures; and related management systems practices) are standards that are developed or adopted by voluntary consensus standards bodies. This proposed rule does not use technical standards. Therefore, we did not consider the use of voluntary consensus standards.

Q. E-Government Act of 2002

The E-Government Act of 2002, Public Law 107–347, sec. 208, 116 Stat. 2899, 2921 (Dec. 17, 2002), requires Federal agencies to conduct a PIA for new or substantially changed technology that collects, maintains, or disseminates information in an identifiable form. FMCSA has

determined that this proposed rulemaking does not involve new or substantially changed technology.

List of Subjects in 49 CFR Part 391

Alcohol abuse, Diabetes, Drug abuse, Drug testing, Highway safety, Medical, Motor carriers, Physical qualifications, Reporting and recordkeeping requirements, Safety, Transportation.

For the reasons set forth in the preamble, FMCSA proposes to amend 49 CFR part 391 as follows:

PART 391—QUALIFICATIONS OF DRIVERS AND LONGER COMBINATION VEHICLE (LCV) DRIVER INSTRUCTORS

■ 1. The authority citation for part 391 continues to read as follows:

Authority: 49 U.S.C. 504, 508, 31133, 31136, and 31502; sec. 4007(b) of Pub. L. 102–240, 105 Stat. 1914, 2152; sec. 114 of Pub. L. 103–311, 108 Stat. 1673, 1677; sec. 215 of Pub. L. 106–159, 113 Stat. 1748, 1767; sec. 32934 of Pub. L. 112–141, 126 Stat. 405, 830; and 49 CFR 1.87.

■ 2. Revise § 391.41(b)(3) to read as follows:

§ 391.41 Physical qualifications for drivers.

* * * * *

(b) * * *

(3) Has no established medical history or clinical diagnosis of diabetes mellitus currently requiring insulin for control, unless the person meets the requirements in § 391.46;

* * * * *

■ 3. Revise § 391.45 to read as follows:

§ 391.45 Persons who must be medically examined and certified.

Except as provided in § 391.67, the following persons must be medically examined and certified in accordance with § 391.43 as physically qualified to operate a commercial motor vehicle:

(a) Any person who has not been medically examined and certified as physically qualified to operate a commercial motor vehicle;

(b) Any driver who has not been medically examined and certified as qualified to operate a commercial motor vehicle during the preceding 24 months, unless the driver is required to be examined and certified in accordance with paragraphs (c), (d), (e) or (f) of this section;

(c) Any driver authorized to operate a commercial motor vehicle only within an exempt intra-city zone pursuant to § 391.62, if such driver has not been medically examined and certified as qualified to drive in such zone during the preceding 12 months;

(d) Any driver authorized to operate a commercial motor vehicle only by operation of the exemption in § 391.64, if such driver has not been medically examined and certified as qualified to drive during the preceding 12 months;

(e) Any driver who has diabetes mellitus requiring insulin for control and who qualifies for a medical certificate under the standards in § 391.46, if such a person has not been medically examined and certified as qualified to drive during the preceding 12 months;

(f) Any driver whose ability to perform his or her normal duties has been impaired by a physical or mental injury or disease.

■ 4. Add new § 391.46 to read as follows:

§ 391.46 Physical qualification standards for a person with insulin-treated diabetes mellitus.

(a) *Diabetes mellitus requiring insulin.* A person with diabetes mellitus requiring insulin for control is physically qualified to operate a commercial motor vehicle in interstate commerce provided:

(1) The person otherwise meets the physical qualification standards in § 391.41 or has the exemption or skill performance evaluation certificate, if required; and

(2) The person has the medical evaluations required by paragraph (b) of this section and meets the monitoring requirements in paragraph (c) of this section.

(b) *Medical evaluations.* A person with diabetes mellitus requiring insulin for control must have the following medical examinations.

(1) *Evaluation by the treating clinician.* Prior to the annual or more frequent examination required by § 391.45, the person must be evaluated by the treating clinician. For purposes of this paragraph, ''treating clinician'' means a physician or health care professional who manages and prescribes insulin for the treatment of individuals with diabetes mellitus. The treating clinician must determine that within the previous 12 months the person has—

(i) Had no severe hypoglycemic reaction resulting in a loss of consciousness or seizure, or requiring the assistance of another person, or resulting in impaired cognitive function; and

(ii) Properly managed his or her diabetes.

(2) *Medical examiner's examination.* (i) At least annually, the person must be medically examined and certified as physically qualified in accordance with § 391.43 and free of complications that might impair his or her ability to operate a commercial motor vehicle.

(ii) The medical examiner must obtain written notification from the person's treating clinician that the person's diabetes is being properly managed and must evaluate whether the person is physically qualified to operate a commercial motor vehicle.

(c) *Blood glucose records.* During the period of medical certification, the driver with insulin-treated diabetes mellitus must monitor and maintain blood glucose records as determined by the treating clinician and submit those blood glucose records to the treating clinician at the time of the evaluation required in paragraph (b)(1) of this section.

Issued under the authority of delegation in 49 CFR 1.87.

Dated: April 22, 2015.

T.F. Scott Darling, III,

Chief Counsel.

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DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Parts 223 and 224

RIN 0648–XD680

Endangered and Threatened Wildlife; 90-Day Finding on a Petition to List the Common Thresher Shark as Threatened or Endangered Under the Endangered Species Act

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Extension of public comment period.

SUMMARY: We, NMFS, announce the extension of the public comment period on our March 03, 2015, 90-day finding on a petition to list the Common Thresher Shark (*Alopias vulpinus*) as endangered or threatened under the ESA, or, in the alternative, delineate six distinct population segments (DPSs) of the common thresher shark, as described in the petition, and list them as endangered or threatened. As part of that finding, we solicited scientific and commercial information about the status of this species and announced a 60-day comment period to end on May 04, 2015. Today, we extend the public comment period by 60 days to July 6, 2015. Comments previously submitted