



DEPARTMENT OF TRANSPORTATION

[4910-EX-P]

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: Final rule.

SUMMARY: FMCSA revises its regulations to permit individuals with a stable insulin regimen and properly controlled insulin-treated diabetes mellitus (ITDM) to be qualified to operate commercial motor vehicles (CMVs) in interstate commerce. Previously, ITDM individuals were prohibited from driving CMVs in interstate commerce unless they obtained an exemption from FMCSA. This rule enables a certified medical examiner (ME) to grant an ITDM individual a Medical Examiner’s Certificate (MEC), MCSA-5876, for up to a maximum of 12 months. To do so, the treating clinician (TC), the healthcare professional who manages, and prescribes insulin for, the treatment of the individual’s diabetes, provides the Insulin-Treated Diabetes Mellitus Assessment Form (ITDM Assessment Form), MCSA-5870, to the certified ME indicating that the individual maintains a stable insulin regimen and proper control of his or her diabetes. The certified ME then determines that the individual meets FMCSA’s physical qualification standards and can operate CMVs in interstate commerce.

DATES: This final rule is effective November 19, 2018, except for amendatory instruction 5.b. which is effective November 19, 2019. Comments sent to the Office of

Management and Budget (OMB) on the collection of information must be received by OMB on or before November 19, 2018.

Petitions for Reconsideration of this final rule must be submitted to the FMCSA Administrator no later than October 19, 2018.

FOR FURTHER INFORMATION CONTACT: Ms. Christine A. Hydock, Chief, Medical Programs Division, Federal Motor Carrier Safety Administration, 1200 New Jersey Avenue, SE., Washington, DC 20590-0001, by telephone at (202) 366-4001, or by email at fmcsamedical@dot.gov. If you have questions on viewing or submitting material to the docket, contact Docket Services, telephone (202) 366-9826.

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I. RULEMAKING DOCUMENTS

A. Availability of Rulemaking Documents

For access to docket FMCSA–2005–23151 to read background documents and comments received, go to <http://www.regulations.gov> at any time, or to Docket Services at U.S. Department of Transportation, Room W12-140, 1200 New Jersey Avenue, SE., Washington, DC 20590, between 9 a.m. and 5 p.m. E.T., Monday through Friday, except Federal holidays.

B. Privacy Act

In accordance with 5 U.S.C. 553(c), the Department of Transportation (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.transportation.gov/privacy.

II. EXECUTIVE SUMMARY

A. Purpose of the Amendments

This final rule amends the Federal Motor Carrier Safety Regulations (FMCSRs) to allow individuals with stable insulin regimens and properly controlled ITDM to drive CMVs in interstate commerce if they meet the physical qualification standards in §§ 391.41, 391.45, and 391.46. The final rule eliminates the diabetes grandfather provision under § 391.64(a) 1 year after the effective date of this rule and also eliminates the need for the Federal diabetes exemption program.

B. Summary of Major Provisions

This final rule allows individuals with stable insulin regimens and properly controlled ITDM to drive CMVs in interstate commerce if they have an annual or more

frequent examination by a certified ME who is listed on the National Registry of Certified Medical Examiners (National Registry), are found physically qualified to operate a CMV, and are issued an MEC, MCSA-5876, from a certified ME. Prior to the annual or more frequent examination by the certified ME, the individual must have an evaluation by his or her TC. The final rule defines a TC as the healthcare professional who manages, and prescribes insulin for, the treatment of the individual's diabetes as authorized by the healthcare professional's State licensing authority.

The TC provides information to the certified ME via the ITDM Assessment Form, MCSA-5870, on which the TC attests that the individual maintains a stable insulin regimen and proper control of his or her diabetes. The certified ME must receive the ITDM Assessment Form, MCSA-5870, no later than 45 days after the individual's TC has completed and signed it for each medical examination. Upon receipt of a valid form, the certified ME will perform an examination, consider the information provided by the TC, and determine whether the individual meets FMCSA's physical qualification standards to operate a CMV safely. If so, the certified ME may issue an MEC, MCSA-5876, for up to a maximum of 12 months.

The final rule requires that all ITDM individuals must provide to the TC at least the preceding 3 months of blood glucose self-monitoring records while being treated with insulin to be eligible for up to the maximum 12-month MEC, MCSA-5876. If an individual does not provide the 3 months of records, the certified ME has discretion to grant the individual up to but not more than a 3-month MEC, MCSA-5876, to allow time for the individual to collect the necessary records. Once the individual has 3 months of blood glucose self-monitoring records, the individual is treated the same as an ITDM

individual with 3 months of records. The individual must first go to the TC for evaluation and then to the certified ME, who must exercise independent medical judgment, to determine if the individual is eligible for up to the maximum 12-month MEC, MCSA-5876.

If an ITDM individual has had a severe hypoglycemic episode, the individual is prohibited from operating a CMV and must report the episode to and be evaluated by a TC as soon as is reasonably practicable. The prohibition from operating a CMV continues until the ITDM individual has been evaluated by a TC and the TC determines that the cause of the severe hypoglycemic episode has been addressed and that the individual again has a stable insulin regimen and properly controlled ITDM. Once a TC completes a new ITDM Assessment Form, MCSA-5870, following the episode, the individual may resume operating a CMV. This rule defines a severe hypoglycemic episode as one requiring the assistance of others, or resulting in loss of consciousness, seizure, or coma.

ITDM individuals who have been diagnosed with severe non-proliferative diabetic retinopathy or proliferative diabetic retinopathy are disqualified permanently from operating a CMV in interstate commerce. These advanced stages of diabetic retinopathy present a serious risk to visual function, the safe operation of a CMV, and public safety.

The fewer than 100 ITDM individuals currently certified under the diabetes grandfather provision in § 391.64(a) will have 1 year after the effective date of this final rule to comply with the provisions of this rule. During that year, grandfathered individuals may elect to seek medical certification through the provisions of the final rule or § 391.64. However, 1 year after the effective date of this final rule, all grandfathered

MECs, MCSA-5876, will become void. FMCSA anticipates that individuals certified previously under § 391.64(a) will find it advantageous to transition to certification under this rule as soon as possible because costs potentially may be reduced and the requirements of this rule are no more stringent than those of § 391.64(a).

FMCSA has determined that this rule will ensure that ITDM individuals can operate a CMV safely. This final rule also creates a clearer, equally effective, and more consistent framework to certify ITDM individuals than a program based entirely on granting exemptions under 49 U.S.C. 31315(b).

C. Benefits and Costs

This rule revises the FMCSRs to permit individuals with a stable insulin regimen and properly controlled ITDM to be qualified to operate CMVs in interstate commerce. Previously, ITDM individuals were prohibited from driving CMVs in interstate commerce unless they obtained an exemption from FMCSA. Revising the regulations will reduce the regulatory burden and result in a \$6.21 million cost savings per year – the aggregate of cost savings to ITDM individuals, motor carriers that hire ITDM individuals, and FMCSA.

The notice of proposed rulemaking (NPRM) stage of this rulemaking action predates the January 30, 2017, Executive Order (E.O.) 13771 titled “Reducing Regulation and Controlling Regulatory Costs” (82 FR 9339, Feb. 3, 2017). As such, the analysis of this final rule introduces several changes necessary to clarify that the final rule will result in total costs less than zero. The Agency presents the following comparison of the NRPM and final rule analyses.

The Preliminary Regulatory Impact Analysis (RIA) published with the NPRM estimated that existing exemption holders would realize \$0.76 million in cost savings attributable to the rule.¹ It also estimated there to be 209,664 ITDM individuals operating CMVs in interstate and intrastate commerce – a group that the NPRM estimated would incur costs ranging from \$7.96 million to \$23.90 million depending on the share of that group that would be medically qualified to receive an MEC, MCSA-5876.² That range of costs reflected *gross* compliance costs to those individuals; however, on a *relative* basis, the Agency estimated that compliance costs per individual under the proposed rule would decrease by \$441 versus the cost to comply with the exemption program.

By reducing compliance costs per ITDM individual, the rule is a deregulatory action both as proposed in the NPRM and again with this final rule. The Agency concludes that an ITDM individual not currently participating in the exemption program will bear the compliance costs of the final rule only if he or she considers the cost to comply to be equal to or lesser than his or her perceived cost of non-compliance. As a result, ITDM individuals not currently participating in the exemption program will incur no new net costs from this rule, while existing exemption holders will (in aggregate) receive a savings of \$5.09 million in compliance costs per year. On a per-individual basis, the compliance cost of the final rule is less than the baseline (\$332 versus \$5,585) during the first year an ITDM individual comes into compliance and is 75.4 percent less than the baseline (\$332 versus \$1,350) in each year thereafter.

¹ FMCSA Preliminary Regulatory Evaluation of Qualification of Drivers: Diabetes Standard Notice of Proposed Rulemaking, pp. 11-12, which is available in the docket for this rulemaking.

² *Id.* at 12-13.

The Final RIA estimates a greater amount of cost savings than in the Preliminary RIA as a result of several changes and updates. First, the Final RIA accounts for new ITDM individuals’ opportunity costs of income forgone, as well as corresponding motor carriers’ opportunity costs of labor hours forgone, during the period FMCSA processes an exemption program application. These costs were not considered in the Preliminary RIA; the Agency made these changes during the development of the Final RIA in response to comments received on the NPRM. Second, the final analysis has been adjusted to correct the number of endocrinologist visits per year required by the exemption program, as these visits were not fully accounted for in the Preliminary RIA. Third, the Final RIA updates inputs used to estimate the costs of the rule. Medical fees for the various healthcare professionals’ services, driver wage and benefits values, and the population of drivers were updated using 2016 values.

Table 1 summarizes the key requirements of the exemption program and compares them to the final rule. These requirements are reflected in the cost estimates of the exemption program and the final rule.

Table 1. Requirements of the Exemption Program vs. the Final Rule

Exemption Program (Baseline)	Final Rule
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<ul style="list-style-type: none"> • The average processing time for a new exemption application is 77 days, during which applicants cannot drive CMVs in interstate commerce.³ • Annual examination by a certified ME. • Annual vision examination performed by an optometrist or ophthalmologist for evidence of diabetic retinopathy (if retinopathy is present, an ophthalmologist report on stability of disease). • Annual examination by an endocrinologist and three quarterly visits. 	<ul style="list-style-type: none"> • No exemption needed, therefore no processing wait time. • Annual examination by a certified ME. • No annual vision examination is required. • No annual examination or quarterly evaluations by an endocrinologist are required. • Annual evaluation by the TC who completes an ITDM Assessment Form, MCSA-5870, that is provided to the certified ME.
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As shown in Table 2, the annualized cost of the baseline (the exemption program) is estimated at \$8.02 million, while the annualized cost of the final rule is estimated at \$1.67 million. The annualized cost savings of the rule are therefore \$6.35 million, a 79 percent decrease. These cost savings are distributed among certain groups of ITDM individuals, motor carriers, and FMCSA.

Table 2. Total Costs of the Final Rule (Annualized in Millions of 2016\$)

Entities Potentially Impacted	Baseline Cost	Final Rule Cost	Total Cost
Currently Compliant ITDM Individuals	\$6.75	\$1.66	(\$5.09)
Future Compliant ITDM Individuals	\$0.17	\$0.01	(\$0.16)
Non-Participating ITDM Individuals	\$0.00	\$0.00	\$0.00
Motor Carriers	\$0.07	\$0.00	(\$0.07)
FMCSA	\$1.03	\$0.00	(\$1.03)
Total	\$8.02	\$1.67	(\$6.35)

FMCSA estimates that currently compliant ITDM individuals (that is, individuals that currently have exemptions) will realize \$5.09 million of annualized costs savings

³ The 77 days represents the average processing time for 3,674 exemption applications accepted between 2012 and 2016 in the exemption program database maintained by the contractor that assists FMCSA with the administration of the diabetes exemption program.

because of the rule. These ITDM individuals' costs to comply with the exemption program are estimated at \$6.75 million, versus \$1.66 million to comply with the final rule. This group of ITDM individuals consists of 3,945 FMCSA exemption holders and an estimated 930 ITDM individuals with intrastate commercial driver's licenses (CDLs) issued exemptions in accordance with State exemption programs.

The Agency estimates that the number of future compliant ITDM individuals that would obtain exemptions in the absence of the rule would increase annually by 27. Under the rule, the annualized cost savings realized by these 27 individuals are estimated at \$0.16 million (\$0.17 million to comply with the exemption program versus \$0.01 million to comply with the final rule). The difference between the two cost estimates is due primarily to the elimination of the opportunity costs associated with the wait for FMCSA to process exemption program applications. Motor carriers are estimated to realize \$0.07 million in cost savings due to the elimination of the application processing wait time.

As discussed earlier, ITDM individuals not currently participating in the exemption program (referred to as "Non-Participating ITDM Individuals" in Table 2) incur no new net costs from this rule.

Lastly, the rule will eliminate contractor costs that FMCSA incurs for the administration of the exemption program. The average cost of the remaining 3 option years of the contract is \$1.03 million, which the Agency relies on to estimate FMCSA's annual cost savings resulting from the rule.

III. ABBREVIATIONS AND ACRONYMS

AAFP	American Academy of Family Physicians
AAPA	American Academy of Physician Assistants
AAPA-OM	American Academy of Physician Assistants in Occupational Medicine

ABA	American Bus Association
ACOEM	American College of Occupational and Environmental Medicine
ADA	American Diabetes Association
Advocates	Advocates for Highway and Auto Safety
ANPRM	Advance Notice of Proposed Rulemaking
AOA	American Optometric Association
APN	Advanced Practice Nurse
ATA	American Trucking Associations, Inc.
BLS	Bureau of Labor Statistics
CAA	Clean Air Act
CDC	Centers for Disease Control and Prevention
CDL	Commercial Driver's License
CE	Categorical Exclusion
CFR	Code of Federal Regulations
CMV	Commercial Motor Vehicle
DC	Doctor of Chiropractic
DO	Doctor of Osteopathy
DOT	Department of Transportation
E.O.	Executive Order
FAA	Federal Aviation Administration
FHWA	Federal Highway Administration
FMCSA	Federal Motor Carrier Safety Administration
FMCSRs	Federal Motor Carrier Safety Regulations
FR	Federal Register
HIPAA	Health Insurance Portability and Accountability Act
H&SW	Health and Safety Works, LLC
IBT	International Brotherhood of Teamsters
ICR	Information Collection Request
ITDM	Insulin-Treated Diabetes Mellitus
LFC	Licencia Federal de Conductor
MD	Doctor of Medicine
ME	Medical Examiner
MEC	Medical Examiner's Certificate, MCSA-5876
MRB	Medical Review Board
National Registry	National Registry of Certified Medical Examiners
NEPA	National Environmental Policy Act
NP	Nurse Practitioner
NPRM	Notice of Proposed Rulemaking
NTSB	National Transportation Safety Board
OMB	Office of Management and Budget
OOIDA	Owner-Operator Independent Driver Association
PA	Physician Assistant
PIA	Privacy Impact Assessment
RIA	Regulatory Impact Analysis
RN	Registered Nurse

SAFETEA–LU	Safe, Accountable, Flexible, Efficient Transportation Equity Act: A Legacy for Users
§	Section symbol
SOCO	Southern Company Entities
SORN	System of Records Notice
TC	Treating Clinician
TEA–21	Transportation Equity Act for the 21st Century
TFAC	Truckers for a Cause
TTD	Transportation Trades Department, AFL-CIO
U.S.C.	United States Code
University of Utah	University of Utah School of Medicine
UMA	United Motorcoach Association

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 individuals operating CMVs in interstate commerce. Section 31136(a)(3) requires specifically that the Agency’s safety regulations ensure that the physical conditions of CMV drivers enable them to operate their vehicles safely and that certified MEs trained in physical and medical examination standards perform the physical examinations required of such operators.

Additionally, 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 medical advice and recommendations on qualification standards (49 U.S.C. 31149(a)). The position of Chief Medical Examiner 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 Examiner, 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 in the

NPRM (80 FR 25260, May 4, 2015), the Agency asked the MRB to review and report on the current diabetes standard. More recently, the Agency directed the MRB to review and analyze all comments to the NPRM submitted from medical professionals and associations, and identify factors the Agency should consider in this rulemaking. The MRB's recommendations and the Agency's responses are described elsewhere in this final rule.

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 (which is the authority for the CDL regulations and the related drug and alcohol testing requirements) (49 U.S.C. 31136(a)(5)).

This rule is based primarily on 49 U.S.C. 31136(a)(3) and 31149(c) and does not concern the requirements in 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 been reluctant generally to employ such

drivers at all. The original exemption program developed in the 1990s by the Federal Highway Administration (FHWA) and FMCSA’s subsequent program under 49 U.S.C. 31315(b) allowed selected ITDM individuals to drive legally for the first time, while also generating data showing that their safety records were at least as good as those of all other 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 ITDM individuals. Paragraph (d) of section 4129 provides that ITDM individuals may not be held by the Secretary of Transportation to a higher standard of physical qualification to operate a CMV in interstate commerce than other individuals applying to operate, or operating, a CMV in interstate commerce; except to the extent that limited operating, monitoring, and medical requirements are deemed medically necessary under regulations issued by the Secretary. FMCSA has determined that this final rule satisfies the purposes of section 4129(d) by imposing appropriate requirements on such individuals 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 Regulatory Analyses section of this final rule.

V. BACKGROUND

A. Brief History of Physical Qualification Standards for CMV Drivers with ITDM

In 1939, one of FMCSA's predecessors recommended that CMV drivers have urine glucose tests as part of medical examinations for determining whether they were physically qualified to drive CMVs in interstate or foreign commerce (4 FR 2296, June 7, 1939). That recommendation remained in effect from January 1, 1940, until a replacement standard established by FHWA went into effect on January 1, 1971. In 1970, FHWA established the current standard for ITDM individuals (35 FR 6463, 6464, April 22, 1970), which also includes testing urine for glucose. That standard states that a "person is physically qualified to drive a commercial motor vehicle if that person . . . [h]as no established medical history or clinical diagnosis of diabetes mellitus currently requiring insulin for control" (49 CFR 391.41(b)(3)). Beginning in 1993, however, CMV drivers with ITDM had the opportunity to apply to FHWA for a waiver (57 FR 40690, July 29, 1993), until a 1994 Federal court decision invalidated the waiver program. *See Advocates for Highway and Auto Safety v. FHWA*, 28 F.3d 1288 (D.C. Cir. 1994).

In 1998, section 4018 of the Transportation Equity Act for the 21st Century (TEA-21) (Pub. L. 105-178, 112 Stat. 107, 413, June 9, 1998 (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 ITDM individuals 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" (section 4018(a)).

As also 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 on issues concerned with the treatment, medical

screening, and monitoring of ITDM individuals in the context of operating CMVs. In July 2000, FMCSA 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). This report concluded that it was feasible to establish a safe and practicable protocol containing three components allowing some ITDM individuals to operate CMVs. The three components were as follows: (1) screening of qualified commercial drivers with ITDM; (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, as a result of the conclusions found in the TEA–21 Report to Congress, FMCSA published a notice proposing to issue exemptions from the FMCSRs allowing ITDM individuals 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 ITDM individuals (68 FR 52441, Sept. 3, 2003). 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. Beginning in 2003, ITDM individuals could apply to FMCSA for an exemption from the prohibition of operating CMVs in interstate commerce.

B. Exemption Program

FMCSA administers an exemption program for ITDM individuals 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 the 2003 Notice and a notice of revised final disposition published in 2005 (70 FR 67777, Nov. 8, 2005).

To apply for an exemption under the program administered by FMCSA, the individual must submit a letter application with medical documentation showing the following:⁴

(1) The ITDM individual has been examined by a board-certified or board-eligible endocrinologist who has (i) conducted a comprehensive evaluation including one glycosylated hemoglobin test (HbA1C) with a result within a range of 7 to 10 percent, inclusive,⁵ and (ii) signed a statement regarding his or her determinations;

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

(3) The ITDM individual has obtained a signed copy of both a certified ME's Medical Examination Report Form, MCSA-5875, and an MEC, MCSA-5876, showing that the individual meets all physical qualification standards in § 391.41(b) other than the diabetes standard.

FMCSA does not conduct medical examinations of any individuals in the exemption program. Instead, it makes its decision whether to grant the exemption based on individual applications and supporting documentation from healthcare professionals.

FMCSA cannot grant an exemption unless it is likely that a level of safety would be

⁴ The requirements to apply for and maintain an exemption are not exhaustive.

⁵ FMCSA subsequently removed the requirement to include one HbA1C result on the application itself.

achieved that is equivalent to, or greater than, the level that would be achieved without the exemption (49 U.S.C. 31315(b) and 49 CFR 381.305(a)).

Before granting a request for an exemption, FMCSA must publish a notice in the Federal Register. The notice explains a request has been filed and provides 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 must identify: the individual who will receive the exemption; the provision(s) from which the individual will be exempted; the effective period; and all terms and conditions of the exemption. After the conclusion of the comment period, FMCSA must publish a notice of its decision to approve or deny the request.

Once approved, to maintain an exemption, the driver must:

(1) Have annual medical recertification by a certified ME;

(2) Have quarterly evaluations by an endocrinologist;

(3) Have annual comprehensive medical evaluations by an endocrinologist;

(4) Have annual vision evaluations that confirm there is no evidence of unstable proliferative diabetic retinopathy and the driver meets the vision standard for CMV drivers;

(5) Maintain 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) Follow a protocol to monitor and maintain blood glucose levels; and

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

A driver must reapply for an exemption every 2 years. FMCSA may revoke an exemption immediately under standards established in § 381.330.

C. May 4, 2015, NPRM: Qualifications of Drivers; Diabetes Standard

In the May 2015 NPRM, FMCSA proposed to amend its physical qualification standards in § 391.41 to allow ITDM individuals to operate CMVs (80 FR 25272).

Proposed paragraph (b)(3) provided that an individual was physically qualified to drive a CMV either by having no established medical history or clinical diagnosis of diabetes mellitus currently requiring insulin for control, or by meeting the requirements in new § 391.46.

The NPRM also proposed to reorganize § 391.45, which provides when individuals must be medically examined and certified, and to add a new paragraph (e). That proposed paragraph required any ITDM individual who had been qualified for an MEC, MCSA-5876, under the standards in § 391.46 to be medically examined and certified as qualified to drive at least every 12 months.

Proposed § 391.46 provided that an ITDM individual was physically qualified to operate a CMV if the individual otherwise met the physical qualification standards in § 391.41, or had the exemption or skill performance evaluation certificate, if required, and had the medical evaluations required by § 391.46.

Prior to the annual or more frequent examination by a certified ME, the ITDM individual would have to be evaluated by the TC. The TC was defined in the proposed

rule as a physician or health care professional who manages and prescribes insulin for the treatment of individuals with diabetes mellitus. The TC would have to determine that within the previous 12 months the individual: 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 had properly managed his or her diabetes. During the period of medical certification, the individual was required to monitor and maintain blood glucose records as determined by the TC and submit those blood glucose records to the TC at the time of the evaluation.

At least annually, the ITDM individual would have to be medically examined and certified by a certified ME as physically qualified in accordance with § 391.43 and as free of complications that might impair the individual's ability to operate a CMV. The certified ME would be required to obtain written notification from the individual's TC that the individual's diabetes was being properly managed. The certified ME also would have to evaluate whether the individual was physically qualified to operate a CMV.

Although not part of the proposed regulation, FMCSA requested comments on whether it should prohibit drivers with ITDM from being medically qualified to operate CMVs carrying passengers and hazardous materials, and whether removing the grandfather provision would affect any driver adversely who is operating currently under § 391.64. Finally, the Agency also requested comment on the need for an ITDM individual to be examined by an optometrist or ophthalmologist as a condition of passing the medical examination.

D. September 9, 2016, Notice of Availability; Request for Comments: Medical Review Board Task Report on Insulin-Treated Diabetes Mellitus and Commercial Motor Vehicle Drivers

The NPRM's comment period closed on July 6, 2015. In that same month, FMCSA directed the MRB to review and analyze all comments to the NPRM from medical professionals and associations, and to identify factors the Agency should consider when making decisions about the next steps in the diabetes rulemaking (MRB Task 15-1). In response, the Agency received MRB Task 15-1 Report (2015 MRB report) dated September 1, 2015. FMCSA published a Federal Register notice on September 9, 2016, announcing the availability of the 2015 MRB report and requesting comments on the MRB recommendations (81 FR 62448). The MRB's recommendations are considered in the Discussion of Comments and Responses section below. The full report is available in the docket for this rulemaking, in addition to being available on the Agency's website at <https://www.fmcsa.dot.gov/advisory-committees/mrb/mrb-task-15-01-report>.

E. July 27, 2017, Notice and Request for Comments: Agency Information Collection Activities; Information Collection Revision Request—Medical Qualification Requirements, OMB Control Number 2126–0006 (proposed ITDM Assessment Form)

On July 27, 2017, FMCSA published a 60-day notice announcing that it was considering submitting an Information Collection Request (ICR) to OMB for its review and approval (82 FR 35041). In anticipation of this final rule, the notice invited public comment on a revision to an information collection titled *Medical Qualification Requirements*, covered by OMB Control Number 2126–0006, which is currently due to expire on August 31, 2018. Based on the MRB's 2015 analysis of the comments and its recommendations, as well as public comments to the NPRM, FMCSA announced that it was considering replacing the previously proposed written notification from the TC with the ITDM Assessment Form. The form would be completed by the TC and provided to the certified ME. The 60-day notice, draft supporting statement, and proposed form are

available in the docket for this rulemaking. The comment period closed on September 25, 2017. The comments are addressed in the Discussion of Comments and Responses section below.

VI. DISCUSSION OF COMMENTS AND RESPONSES

A. Comment Overview

In this rule, FMCSA responds to public comments to the following Federal Register documents.

NPRM:

In response to the May 2015 NPRM (80 FR 25260), FMCSA received 1,281 submissions between May 4, 2015, and February 16, 2016.⁶ Based on a review of those submissions, 114 submissions were identified as non-germane and four submissions were duplicates. Almost all commenters expressed general support for the proposed rule, though many asked for more detail about the proposal. These commenters include CMV drivers, individuals diagnosed with diabetes, relatives of individuals diagnosed with diabetes, diabetes educators, health care professionals, and medical associations. General opposition to the proposed rule cited a risk to public safety as the basis for opposition contending that insulin-controlled diabetes is not a condition well-suited to the demands of operating CMVs. These commenters included two individuals diagnosed with diabetes, a physician, and a diabetes educator. Of the generally-supportive submissions, 561 were form letters. The common reasons cited for general support of the proposal include the following: it would treat ITDM individuals fairly by assessing how diabetes

⁶ FMCSA stated in the NPRM, at 80 FR 25261, that it would not respond to comments made in response to the March 17, 2006, advance notice of proposed rulemaking (ANPRM) (71 FR 13801). The Agency requested that commenters reference any previous relevant comments in their comments to the NPRM. Therefore, this final rule does not respond to the comments submitted in response to the ANPRM.

affects each individual rather than focusing on the diagnosis of diabetes or use of insulin alone; it would simplify the qualification procedures for ITDM CMV drivers and focus on their operational safety by requiring that they be evaluated by healthcare professionals; it would improve safety by encouraging ITDM CMV drivers to properly manage their condition rather than to hide it in an effort to keep their jobs; and this action would enable CMV drivers newly diagnosed with ITDM to keep their jobs and encourage more individuals to enter the workforce, thereby reducing the driver shortage.

Approximately a dozen commenters expressed general opposition to the proposed diabetes standard. Most of these commenters cited the risk to public safety for their opposition to the proposed rule and contended that insulin-controlled diabetes is not a condition well-suited to the demands of operating CMVs.

2015 MRB Report:

In response to the September 2016 notice of availability and request for comments on the 2015 MRB report (81 FR 62448), FMCSA received 41 comments, one of which was a duplicate. Commenters focused on specific recommendations within the 2015 MRB report.

ITDM Assessment Form:

In response to the request for comments on the ICR and the ITDM Assessment Form (82 FR 35041), FMCSA received 44 comments. Rather than providing substantive comments on the content or structure of the ITDM Assessment Form, 39 commenters discussed the issue of allowing ITDM individuals to operate CMVs. None of these commenters presented new issues that were not raised in the comments submitted in response to the NPRM or the 2015 MRB report. Five substantive comments related to the

ITDM Assessment Form are discussed in the appropriate section below (TC Written Notification (ITDM Assessment Form)).

B. Qualifications of a Certified ME to Examine an ITDM Individual

NPRM:

FMCSA proposed that ITDM individuals be medically examined and certified by a certified ME listed on the National Registry as provided in § 391.43.⁷

Comments on the Qualifications of a Certified ME to Examine an ITDM Individual:

Both the American Academy of Physician Assistants (AAPA) and the American Academy of Physician Assistants in Occupational Medicine (AAPA-OM) supported FMCSA's proposal and noted that PAs are qualified to examine and certify any individual who operates a CMV. These commenters stated that the certified ME does not need to be a specialist to examine an individual.

The National Transportation Safety Board (NTSB) noted that some certified MEs have no experience prescribing medications or managing the effects of insulin; thus, they would have to accept the TC's assessment without further evaluation. The American College of Occupational and Environmental Medicine (ACOEM) stated the certified ME should be an MD or DO experienced with the treatment and evaluation of diabetes and diabetes treated with insulin to medically qualify individuals using insulin; therefore, there should be designated certified MEs who review and medically qualify individuals

⁷ The Agency notes that the categories of healthcare professionals eligible to be listed on the National Registry are advanced practice nurses (APNs), doctors of chiropractic (DCs), doctors of medicine (MDs), doctors of osteopathy (DOs), physician assistants (PAs), and other healthcare professionals authorized by applicable State laws and regulations to perform physical examinations (49 CFR 390.103). APNs, also referred to as advanced practice registered nurses (APRNs), are registered nurses (RNs) educated at the masters or post masters level who have passed a national certification test in a specific role and patient population. The types of APNs are certified nurse practitioners (CNPs or NPs), clinical nurse specialists (CNSs), certified registered nurse anesthetists (CRNAs), and certified nurse-midwives (CNMs). See <https://www.ncsbn.org/aprn.htm> (Accessed May 25, 2018).

using insulin. The ACOEM stated further that some certified MEs are making certification determinations pertaining to individuals with medical conditions that they are unable to independently diagnose or treat.

A number of commenters stated that the certified ME should be a physician (either an MD or DO) or have other professional qualifications. For example, individuals who identified themselves as the first five members appointed to the MRB (herein after “former MRB members”)⁸ wrote in their comment that there are now thousands of certified MEs who have no significant medical training. These former MRB members also stated that the primary care and tertiary care providers for individuals with diabetes often do not understand the specific demands on CMV drivers. Based on these considerations, the former MRB members wrote that FMCSA cannot meet the statutory requirement under 49 U.S.C. 31136(a)(3) for periodic physical examinations of individuals by having the TC work in conjunction with the certified ME.

Unless TCs are required to have appropriate additional training, experience, and certification, Truckers for a Cause (TFAC) suggested that FMCSA require that ITDM individuals get their MECs, MCSA-5876, from a certified ME who is an MD, DO, NP, or PA. TFAC was concerned that not all certified MEs, e.g., DCs, will have the medical expertise to evaluate the information from a TC. TFAC wrote that in some States, for example Illinois, it would be a violation of State law for a DC to render an expert medical opinion on an individual meeting a diabetes treatment requirement. An individual commenter wanted to delay a rulemaking until there is assurance that the certified MEs can safely screen ITDM individuals.

⁸ The Agency notes that the comments expressed by the former MRB members in their letter were received in the docket in response to the Agency’s request for public comments.

2015 MRB Report:

The 2015 MRB report did not change the qualifications of certified MEs for conducting medical certification examinations on ITDM individuals.

Comments on the MRB Report Regarding the Qualifications of a Certified ME:

The University of Utah School of Medicine (University of Utah) stated that, unless the form proposed by the MRB clearly specifies what the outcome of a particular response is, the only alternative is to have diabetes examinations done by those with medical backgrounds, which is “particularly mandatory because of the large number of non-medically trained examiners.” An NP who is a certified ME hoped that NPs and PAs certified in primary care and experienced in managing patients with ITDM would not be excluded from certifying ITDM individuals. The NP stated that numerous studies have demonstrated that APNs in primary care settings perform as well as physicians in terms of clinical outcomes and patient satisfaction. The ACOEM stated that the certified ME must have the training and knowledge to evaluate whether the documentation provided is sufficient. Concentra commented that certified MEs who are not licensed to prescribe insulin should not be allowed to certify an individual with ITDM.

FMCSA Response:

In this final rule, the Agency continues to provide that ITDM individuals may be examined and medically certified by any certified ME on the National Registry. As such, the categories of healthcare professionals eligible to become certified MEs remain unchanged from when the National Registry was established (77 FR 24104; April 20, 2012). All certified MEs are required to be licensed, registered, or certified by their States to perform physical examinations. FMCSA will continue to rely on State determinations

regarding which categories of healthcare professionals have sufficient education and training to qualify them to perform physical examinations.

To become a certified ME and be listed on the National Registry, healthcare professionals are required to receive training on the Agency's physical qualification standards and the demands of driving a CMV, complete a certification test, and receive a certificate evidencing that they are qualified to perform medical certification examinations and determine who is qualified to safely operate a CMV. A State has found certified MEs to possess sufficient medical training to perform a physical examination and the Agency has found them to be proficient in the use of the medical protocols necessary to perform the medical certification examination in accordance with the FMCSRs. As such, the Agency's certified MEs have a significant training on performing medical certification examinations. Moreover, the National Registry allows FMCSA to monitor and audit certified MEs and to provide periodic training to its certified MEs.

The current categories of certified MEs have been evaluating individuals with diabetes and have been making qualification determinations based on the existing physical qualification standards in § 391.41(b) for many years. In addition, conditions that may result from complications of diabetes may also result from medical conditions other than diabetes. The Agency has no data that suggests MEs have had difficulty applying the physical qualification standards to individuals with diabetes or to any specific conditions. If a certified ME encounters a condition that is outside his or her scope of practice or requires evaluation by a specialist, FMCSA expects the certified ME to make any appropriate referral and to confer with the specialist as necessary.

FMCSA emphasizes that the role of the certified ME is to conduct a medical certification examination to determine if the individual meets the physical qualification standards and to evaluate the safety impact of any medical conditions; it is not to diagnose or treat individuals. As such, FMCSA has concluded that it is not necessary for a certified ME to be licensed or certified to diagnose and treat every condition that is addressed by the physical qualifications standards. FMCSA has no data that suggests that this longstanding conclusion is flawed.

The Agency has determined that its certified MEs are qualified to examine and medically certify that ITDM individuals are physically qualified to drive a CMV in accordance with § 391.43 and new § 391.46, and are free of complications that may impair an individual's ability to safely operate a CMV. The Agency finds that this medical certification approach through certified MEs is consistent with congressional intent to have certified MEs make an individualized assessment of an individual's health status and ability to safely operate a CMV.

C. Definition and Qualifications of a TC

NPRM:

The NPRM defined a TC as a physician or healthcare professional who manages and prescribes insulin for the treatment of diabetes mellitus.

Comments on the Definition and Qualifications of a TC:

Because of the TC's personal knowledge of the driver's medical history and condition, both the Illinois Office of the Secretary of State and the Owner-Operator Independent Driver Association (OOIDA) stated that the TC would be able to make an accurate determination of a driver's condition. The Illinois Office of the Secretary of

State agreed with FMCSA's proposal to use the TC, working with a certified ME to complete the physical examination of drivers.

Some commenters, including AAPA, AAPA-OM, and TFAC, stated that a TC should be a physician, PA, or NP who manages and prescribes insulin for the treatment of individuals with diabetes mellitus. AAPA and AAPA-OM noted these represent the three types of healthcare professionals in the United States who provide primary medical care. In rural and other medically-underserved communities, a PA may be the only healthcare professional.

The AAPA-OM noted further that PAs are trained in primary care and complete board certification every 10 years in primary care. The AAPA-OM commented that PAs have been treating patients with complicated medical conditions for over 40 years and should be allowed to continue the evaluations of commercial drivers with ITDM.

The American Trucking Associations, Inc. (ATA) requested that FMCSA further define the term TC to reduce ambiguity and ensure the person making the recommendation is properly certified and knowledgeable about ITDM. Health & Safety Works, LLC (H&SW) was concerned FMCSA did not address drivers who receive insulin without a prescription and therefore would not have a TC. This commenter recommended FMCSA should state that "anyone without a prescription or a treating clinician may not be qualified to operate a CMV in interstate commerce."

Some commenters agreed with FMCSA that TCs do not need to be licensed physicians or specialists in diabetes treatment and management, but could be other types of healthcare professionals. Commenters, including the ATA, the American Diabetes Association (ADA), the International Brotherhood of Teamsters (IBT), and TFAC,

supported allowing the certified ME to consult with the TC instead of requiring approval from an endocrinologist, noting that driver access to board-certified endocrinologists may be limited. The IBT wrote that the TC, rather than an endocrinologist, would be a more suitable medical provider to monitor any of the progressive conditions associated with diabetes (e.g., nerve damage to the extremities and diabetic retinopathy).

The American Academy of Family Physicians (AAFP) urged FMCSA to allow applicants to be examined by their family physicians, rather than endocrinologists. This commenter noted that not all applicants have access to an endocrinologist, and the family physician is more than capable of managing and treating patients with diabetes, as well as completing the forms needed by CMV drivers.

Some commenters, including the American Bus Association (ABA), two diabetes educators, a physician, an NP, and the Southern Company Entities (SOCO), disagreed with the proposal and wanted ITDM individuals to continue to be evaluated by endocrinologists. While ABA appreciated the interest in simplifying the process or putting fewer restrictions on the medical professionals available to drivers with ITDM, it could not support this proposed provision because in its opinion endocrinologists are the best qualified individuals to be engaged in the process. SOCO would require a note from the treating physician with a specialty in diabetes, such as an endocrinologist, who is also familiar with the essential job functions of a commercial driver. The note would document that the driver is stable and not experiencing hypoglycemic episodes.

The NP objected to removing an endocrinologist from the process of certifying drivers with ITDM because it significantly limits objective, specialized medical assessment of the disease. This commenter indicated that primary care providers are

sometimes too lenient.

While they did not indicate that evaluation by an endocrinologist is necessary, some commenters stated that the TC should be a licensed physician or other medical professional with appropriate training. In order to address sufficient training in diabetes, the complications of diabetes, and interactions among diabetic medications, the former MRB members stated that an MD or DO should, at a minimum, oversee a mid-level provider and this physician should countersign the forms approving the ITDM driver as safe to drive. An RN stated that drivers should be followed by a primary care physician. A physician commented that a diabetologist—not an endocrinologist—should evaluate patients for safety because they are better equipped to determine whether a patient with type 1 diabetes might be a low-risk driver. Advocates for Highway and Auto Safety (Advocates) stated that the Agency should require the TC to be a physician and establish penalties for both drivers and TCs who submit falsified reports, specifically concerning diabetes management and severe hypoglycemic reactions.

The ADA agreed that requiring a specialist to perform evaluations of drivers with ITDM is unnecessary. It stated that internists or primary care physicians—not endocrinologists—treat many individuals with diabetes and that there are parts of the country where no endocrinologists are available. The ADA commented that the important qualification is that the TC must have knowledge of the disease and treatment regimens in order to assess an individual's diabetes management and determine whether CMV operation is safe and practicable in accordance with the revised standard and accompanying diabetes guidelines.

TFAC agreed that requiring an evaluation by a board-certified endocrinologist

places an undue burden on a driver, due to the lack of these specialists nationwide. However, TFAC did not think that FMCSA's qualifications for a TC specified enough medical training and certification to evaluate properly a CMV operator with ITDM. TFAC recommended that the TC have completed appropriate additional training and have the experience to hold a certification in Advanced Diabetes Care and Management.

A physician wrote that FMCSA is putting the TC, whose duty is to his or her patient, in the position of losing patients who will doctor shop until they find a TC to sign off on their condition.

2015 MRB Report:

The 2015 MRB report recommended that a TC be defined as the MD, DO, NP, or PA who prescribes insulin to the driver and is knowledgeable regarding the treatment of diabetes.

Comments on the MRB's Report on the Definition and Qualifications of a TC:

The AAPA stated that allowing PAs who have clinical experience with diabetes to act as TCs will ensure that drivers who are under the care of a PA can remain in compliance with FMCSA regulations, while continuing to see their current healthcare provider. It commented that this is particularly important in medically-underserved areas, where there may be less access to specialists. The AAPA described the breadth of PA education, testing, and experience, particularly as it applies to diabetes.

OOIDA agreed that letting an MD, DO, NP, or PA who has prescribed insulin to the driver perform the assessment will provide a better way to determine if the driver's condition is well-controlled. It would reduce the costs and treatment delays caused by the requirement for an evaluation by a board-certified or board-eligible endocrinologist.

A certified ME, who is an NP, commented that there is a shortage of MD and DO primary care providers in her region; therefore, the use of NPs and PAs improves access to needed care. She also stated that access to endocrinologists is limited in her area, so most ITDM individuals are managed by their primary care providers.

The ADA stated that an appropriate TC, including endocrinologists, physicians, PAs, NPs, and diabetes educators, is one who is knowledgeable and experienced in the management of diabetes, not necessarily a specialist.

A driver, a certified ME, and SOCO stated that a TC, as defined by the MRB, is not qualified to properly assess drivers with ITDM. These commenters indicated that only an endocrinologist should assess such drivers. The certified ME stated that the rulemaking will increase the burden on the certified ME and affect the certified ME's willingness to accept a "clinician" statement about a driver's control of diabetes mellitus.

H&SW, the University of Utah, AAFP, Concentra, and an individual were not satisfied with the definition and qualifications of a TC in the 2015 MRB report and indicated that the TC should meet additional requirements. Some commenters stated that many TCs are not familiar with the requirements of commercial driving. For example, H&SW noted that the total reliance on the TC to evaluate a driver's management of his or her diabetes was a flaw in the proposal. H&SW pointed out that FMCSA has no authority over the TC. It did not agree that the Agency should assign responsibility to the TC, who is not certified to perform CMV physical examinations.

The University of Utah wanted the TC to have knowledge of at least 3 years of the driver's treatment—either through direct knowledge or from medical records. The commenter added that there also had to be a mechanism to stop drivers with ITDM from

doctor shopping for a favorable opinion. Concentra stated that the TC should have treated the driver for the preceding 12 months, so the TC can attest to the lack of hypoglycemic reactions and to the driver having properly managed the diabetes.

While the AAFP urged FMCSA to allow drivers to be examined by their primary care physicians, rather than to require examination by an endocrinologist, it asked FMCSA to allow only a DO or MD to perform these services. Both Concentra and the individual indicated that the non-physician healthcare professional should qualify as a TC only if under the supervision of an endocrinologist or other physician.

The individual commenter warned that the TC must be held to high standards, and any TC who submitted a falsified or disingenuous report should be penalized. This commenter also wrote that FMCSA should require the TC to notify the Agency if the driver becomes noncompliant or if the driver discharges the TC.

FMCSA Response:

The final rule does not limit the TC to a specific discipline or require the TC to be an endocrinologist. The Agency agrees with commenters who stated that an appropriate TC is one who is knowledgeable and experienced in the management of diabetes and is not necessarily a specialist.

FMCSA defines the TC in the final rule as a healthcare professional who manages, and prescribes insulin for, the treatment of the individual's diabetes mellitus as authorized by the healthcare professional's State licensing authority. The final rule establishes that the ITDM individual must have a prescription from his or her TC for treatment with insulin. FMCSA adds this requirement because prescriptive authority for some healthcare disciplines may be limited by the State's scope of practice. This

requirement ensures that the healthcare professional who routinely treats the ITDM individual is the one who prescribes the individual's insulin for treatment.

The Agency declines to specify disciplines that may serve as the TC for purposes of this rulemaking due to the differences in scopes of practice among States. Some areas of the country may be underserved in some disciplines and have greater access to other disciplines. FMCSA finds that identifying specific disciplines disadvantages individuals who may not have access to those healthcare professionals. The Agency's definition allows for maximum flexibility in addressing issues related to shortages in various categories of licensed healthcare professionals in all States.

FMCSA agrees with the commenters who stated that requiring evaluation by an endocrinologist is burdensome to ITDM individuals seeking certification because of the scarcity of endocrinologists in many regions of our country. A June 2014 Endocrine Society white paper states that there were approximately 4,841 adult endocrinologists engaged in clinical practice in 2011, and it projected a shortage of 1,484 adult endocrinologists by 2015.⁹ The paper also shows that 85 percent of office visits for diabetes were with physicians other than endocrinologists.¹⁰ As stated in the NPRM, a requirement to be evaluated by an endocrinologist seems impracticable for most drivers with ITDM (80 FR 25266). The frequent monitoring by a specialist as required by the exemption program was a financial burden for many individuals, many of whom have primary care providers who are capable of prescribing and managing insulin treatment for their patients. The Agency has concluded that the higher cost of an endocrinologist

⁹ "Endocrine Clinical Workforce: Supply and Demand Projections" prepared for the Endocrine Society by the Lewin Group, 2014, pp. 1-2. Available at <https://www.endocrine.org/~media/endosociety/files/advocacy-and-outreach/important-documents/white-paper--endocrinology-workforce-final-white-paper.pdf> (May 25, 2018).

¹⁰ *Id.* at 40.

evaluation is not justified given that a TC can determine that the individual has a stable insulin regimen and properly controlled ITDM.

The requirement that the TC must be the healthcare professional who manages, and prescribes insulin for, the treatment of the individual who is being evaluated makes it likely that the TC will be the individual's primary care provider. As the commenters indicate, primary care providers are well trained and experienced in managing diabetes and provide most care for diabetes in many areas. As such, FMCSA is not requiring that a qualified TC hold any specific certification or have any specialized training with respect to diabetes. The Agency agrees with commenters that TCs who have personal knowledge of an individual's medical history and treatment regimens will be able to make an accurate determination as to whether an individual maintains a stable insulin regimen and proper control of his or her ITDM. As such TCs managing, and prescribing insulin for, the treatment of ITDM individuals are well-suited to monitor for complications related to diabetes. FMCSA is confident that when necessary, TCs will refer the ITDM individual to appropriate specialists for any additional medical evaluations for diabetes-related co-morbid conditions requiring specialized diagnosis and treatment.

FMCSA anticipates that the TC would have an ongoing relationship with the individual being evaluated, but is not requiring that the TC treat the individual for any specific period. If the TC is newly establishing a relationship with an individual seeking evaluation, the TC may exercise his or her independent medical judgment with respect to the need to obtain and review prior medical records and whether the TC has sufficient information to complete the ITDM Assessment Form, MCSA-5870, and to attest the information provided is true and correct to the best of the TC's knowledge. Similarly,

FMCSA declines to require the TC to notify the Agency if a driver becomes noncompliant or discharges the TC. The need to obtain the required information from a TC who is prescribing insulin for the treatment of the individual's ITDM should discourage noncompliance and doctor shopping for a favorable attestation.

FMCSA emphasizes that it is not relying on the TCs to make the medical qualification determination. FMCSA is implementing the ITDM Assessment Form, MCSA-5870, as recommended by the 2015 MRB report, that asks specific questions of the TC and provides information needed for medical certification determinations by the certified ME. Evaluation by the TC in this collaborative manner is consistent with current certified ME practice during the medical certification process. Certified MEs confer routinely with and obtain the treating providers' opinions concerning the stability of individuals' underlying medical conditions and how the medical conditions may impact safety. This process minimizes the concern that TCs who are primary care providers may be lenient because certified MEs make the determination regarding physical qualification.

D. Role and Relationship of the TC and Certified ME

NPRM:

FMCSA proposed that, prior to the annual or more frequent examination by the certified ME, the ITDM individual would have to be evaluated by the TC. The TC would determine that within the previous 12 months the individual had no severe hypoglycemic reaction and had properly managed his or her diabetes. The certified ME had to obtain written notification from the individual's TC that the individual's diabetes was being properly managed and had to evaluate whether the individual was physically qualified to operate a CMV.

Comments on the Role and Relationship of the TC and Certified ME:

The IBT supported the Agency's proposal. It stated that, although the TC may not be thoroughly familiar with FMCSA regulations or tasks performed by a CMV driver, subsequent evaluation by a certified ME would complement the role of the TC in the certification process. The ADA noted that the NPRM had not made completely clear the role of the certified ME in evaluating the applicant's diabetes. However, the ADA supported a two-step certification process where the TC certifies that the individual with ITDM meets the revised diabetes standard and the certified ME completes the certification process with regard to all other aspects not related to diabetes. If the certified ME had concerns about an individual's diabetes, the ADA recommended that the certified ME should consult the TC or an independent diabetes healthcare professional for verification.

A number of commenters wanted certified MEs and TCs to work directly together. For example, given that certified MEs are ultimately responsible for certifying individuals, the Transportation Trades Department, AFL-CIO (TTD) and the Amalgamated Transit Union wanted FMCSA to encourage certified MEs and TCs to work closely together so that fit individuals may work.

The ACOEM added that allowing the certified ME, who has the training and understanding of the role of the CMV operator, to obtain and review additional medical information would increase the margin of safety in the determination, while lessening the certified ME's liability in relying on a TC who might not fully understand the safety concern. The ACOEM commented that FMCSA should require the TC to sign a statement saying that the ITDM individual can manage his or her health condition.

A physician/certified ME, who is also board-certified in occupational medicine, questioned the value of having certified MEs for ITDM individuals, if the certified MEs simply defer to the TC. This commenter wanted FMCSA to clarify that a certified ME can request whatever medical information is necessary to make a sound determination. He also stated that the increased cost and responsibility for the certified ME would be reflected in higher fees.

The NTSB noted that FMCSA allows healthcare professionals who are not licensed to prescribe medication to medically-certify individuals who operate CMVs. Because these certified MEs have no experience prescribing medications or managing the effects of insulin or other diabetic medications, the NTSB indicated that these certified MEs must accept a TC's assurance of "proper management" without further evaluation. The NTSB commented that a TC's interpretation of proper management, as well as the individual's compliance with recommendations, might vary considerably.

TFAC noted that the certified ME is required to certify the ITDM individual is free of complications, while the written notification from the TC gives the certified ME no information about how the TC made that determination. This commenter proposed that "the statement required from the TC make[s] it clear in the area of diabetes management it is the TC who is rendering the expert medical opinion that the driver is 'safe' therefore relieving the medical examiner from concerns about potential liability."

H&SW disagreed with FMCSA relying solely on the TC for information about the ITDM individual's management of his or her diabetes. It recommended that FMCSA require the collection of documentation by the TC as only one piece of the data gathered by the certified ME. It further suggested that FMCSA should also require the certified

ME to obtain additional test and laboratory results, review glucose logs, and ensure the ITDM individual has received hypoglycemic awareness training. If documentation from a TC is the only tool the certified ME has, H&SW indicated the Agency is permitting the TC to make the medical certification decision even though he or she is not listed on the National Registry. A physician questioned how the certified MEs will protect themselves from discrimination lawsuits when they do not approve every individual recommended by the TCs.

Some commenters were concerned that the NPRM did not provide the certified ME with sufficient specific criteria to determine if the individual's diabetes was properly managed or if he or she was physically qualified to operate a CMV. H&SW indicated that the certified ME needs to see the blood sugar logs and the results of the eye examination; ensure the driver has had hypoglycemic awareness training; and check the blood levels for glucose to make an evidence-based decision regarding whether the driver is physically qualified to operate a CMV.

2015 MRB Report:

The 2015 MRB report recommended that a questionnaire be developed for the TC to complete and send to the certified ME. Based on the responses to the questionnaire, the TC was to indicate whether the individual had stable, well-controlled diabetes and had no severe hypoglycemic episodes over the past year, and to state that neither the individual's diabetes nor diabetes-related medical conditions would impair the ability to operate a CMV safely. The MRB recommended specifically that the final determination as to whether the ITDM individual was physically qualified to drive a CMV was to be made by the certified ME.

Comments on the MRB’s Report on the Role and Relationship of the TC and Certified ME:

In response to this recommendation, OOIDA, Concentra, H&SW, and the ACOEM commented on the appropriate relationship between certified MEs and TCs. Concentra commented that certified MEs should be able to review a TC’s records of an ITDM individual for at least the preceding year. OOIDA had concerns that the certified ME could override the TC’s determinations. It suggested that certified MEs should provide “sound medical evidence” before challenging the TCs findings or requiring individuals to undergo more testing. H&SW added that the certified ME should be given the tools that the TC has and should ask for detailed tests and laboratory reports from the TC, if needed. H&SW also wrote that FMCSA should put the TC in a consultation position, especially because the certified MEs will be held responsible should the ITDM individual have a crash. The ACOEM stated that certified MEs must review at least 3-5 years of medical records so the certified ME can evaluate the individual’s condition independently.

FMCSA Response:

This final rule continues the two-step process for medical certification in which the TC evaluates the individual’s insulin regimen and control of his or her ITDM, then a certified ME performs an examination and determines whether the individual is physically qualified under all medical standards to operate a CMV. FMCSA agrees with commenters that the medical information provided by the TC to the certified ME should be relevant and useful and allow a certified ME to make an appropriate medical certification determination on an ITDM individual. As such, FMCSA is adding a requirement in this final rule that the TC complete an ITDM Assessment Form, MCSA-

5870, rather than simply provide written notification that the individual's diabetes was being properly managed.

As discussed above, the Agency relies on State licensing authorities to make scope of practice determinations and has found that the TCs and certified MEs are qualified to perform their respective roles in this collaborative certification process. The role of the individual's TC, who is experienced in the management of diabetes, is to attest on the ITDM Assessment Form, MCSA-5870, that the individual maintains a stable insulin regimen and proper control of his or her ITDM. The role and responsibility of the certified ME, who is trained in FMCSA's physical qualification standards and the demands of operating a CMV, is to medically certify that the ITDM individual can safely operate a CMV. In making the qualification determination, the certified ME is to consider the attestation and information provided by the TC, but the certified ME does not automatically defer to the TC's attestation or rely solely on it. Consistent with current practice for any medical condition, the certified ME may confer with the TC concerning an individual's medical history and status, make appropriate referrals, or request medical records, all with appropriate consent.

The final rule relies on the TC's knowledge of an individual and understanding of the treatment of ITDM and the certified ME's knowledge of the requirements to operate a CMV and FMCSA regulations. FMCSA agrees with commenters and the MRB, as discussed more fully below, that the certified ME must be provided with more information regarding how the TC made his or her determinations. This rule adopts the ITDM Assessment Form, MCSA-5870, as the way to communicate that information.

The form requests specific information to assist both the TC and the certified ME in evaluating and assessing whether an ITDM individual maintains a stable insulin regimen and proper control of his or her diabetes. The TC will have the relevant and current information on the individual's medical history needed to complete and sign the ITDM Assessment Form, MCSA-5870.

FMCSA notes that, if a certified ME also meets the qualifications to be an individual's TC, the certified ME may perform the TC evaluation and medical certification examination contemporaneously. The certified ME who also acts as the TC must still complete the ITDM Assessment Form, MCSA-5870.

E. TC Written Notification (ITDM Assessment Form)

NPRM:

FMCSA proposed that the certified ME must obtain written notification from the individual's TC that the individual's diabetes is being managed properly.

Comments on TC Written Notification:

Some commenters stated that FMCSA should develop a comprehensive form to organize the certification criteria, thus ensuring that the information was complete and providing the certified ME the information necessary to determine that the individual is physically qualified. The former MRB members suggested a form that includes sections completed by the driver, the TC, and an ophthalmologist or optometrist. Some commenters, like the ADA, OOIDA, the IBT, and the ACOEM, recommended the use of specific forms or checklists that they suggested be adopted. Several commenters had extensive lists of documentation they suggested the TC should provide to the certified ME including: properly-maintained glucose logs; proof of proper diabetes management

and compliance; records related to any hypoglycemic episodes; HbA1C testing results; and proof of yearly preventive care to screen for the long-term side effects of diabetes, such as retinopathy. Some commenters, like the ACOEM, requested a full packet of documentation be submitted to the certified ME.

Many commenters said the requirements of the proposed rule needed clarity or more specific guidance for the TC or certified ME to use to decide whether an ITDM individual may operate a CMV in interstate commerce. Concentra suggested that the Agency review the criteria with leading endocrinologists who specialize in diabetes.

Other commenters suggested adoption of best practices. The NTSB suggested that FMCSA emulate the Federal Aviation Administration (FAA) and the United States Coast Guard, which require operators with ITDM to be evaluated using published or scientifically-based standards. An individual commenter suggested that FMCSA model the requirements after FAA requirements, adjusted to allow ITDM individuals to take insulin by pump or manual injection. H&SW provided specific recommendations, some based on requirements cited by the ADA and Canada's qualifications for ITDM individuals.

TFAC understood FMCSA's reluctance to make very specific medical requirements, as the science of treatment options changes; yet, it noted there is a need for specificity in medical requirements to ensure there is consistency in how certified MEs handle situations. TFAC stated that without clear criteria, normal practice standards would be established by individual certified MEs and litigators, rather than by FMCSA through rulemaking. A physician who had experience with a discrimination lawsuit stated that, unless FMCSA provides specific certification guidance, the TC and the certified ME

will avoid the risk of litigation by allowing individuals who should not be driving to get an MEC, MCSA-5876.

2015 MRB Report:

The 2015 MRB report recommended that FMCSA develop a questionnaire for the TC to provide to the certified ME and provided an outline of specific information to obtain. The TC would complete, sign, and send the form to the certified ME. The form would also be signed by the ITDM individual. The report also recommended specific criteria in several areas including severe hypoglycemic episodes, glucose logs and self-monitoring blood glucose, HbA1C results, eye examinations, and diabetic complications.

Comments on the General MRB Recommendation to Develop a Form:

The AAPA supported using the MRB recommended form as proposed. It stated that the degree of uniformity provided by the form would ensure that all TCs are assessing commercial drivers in the same way and using the same metrics when evaluating a driver's health. Additionally, a certified ME commended inclusion of the TC's signature and stated that the form would facilitate communication between the certified ME and TC. The ADA appreciated the efforts of the MRB to provide instruction to the TC regarding clinical indicators for evaluation but indicated the criteria were medically inappropriate in several places. An endocrinologist provided a sample of an assessment form used by the Pennsylvania DOT in the evaluation of ITDM drivers.

Concentra stated that the MRB-proposed form was lengthy, complex, and lacked specific direction, particularly in identifying serious co-morbid diseases. The University of Utah stated that the form was just an outline and needed exact requirements and consequences. It wanted a place for the ITDM individual to sign to attest to its

truthfulness and to include a penalty for that individual not being truthful. It also stated that the final draft form should be made available to the public for comment. The ADA stated that having an ITDM individual sign the form would be inappropriate because FMCSA does not have the legal authority to require the TC to report any information to a certified ME unless the patient provides express permission for such reporting.

Proposed ITDM Assessment Form:

FMCSA agreed with commenters that a form would enhance communication between the TC and certified ME and provide consistent information to certified MEs. Accordingly, FMCSA prepared a proposed ITDM Assessment Form and published a 60-day notice on July 27, 2017, announcing that it was considering replacing the previously proposed written notification from the TC with the ITDM Assessment Form (82 FR 35041). The Agency sought comment on the form, which is available in the docket for this rulemaking.

Comments on the ITDM Assessment Form:

Five commenters provided substantive comments specific to the ITDM Assessment Form in response to the 60-day notice. An endocrinologist wholeheartedly agreed with the proposed approach of the form. A certified ME supported the use of the form and stated that it should be passed along to the treating primary care physician for completion and then should be reviewed by a certified ME who is knowledgeable about the challenges of driving a CMV. Another certified ME was concerned that the form requests information on severe hypoglycemic events for only the past 3 months. This commenter stated that he “would want to know of any severe hypoglycemic events over the past 5 years, as previous guidance from the FMCSA Examiner’s Handbook for

diabetics not on insulin, was not to certify if there had been a severe hypoglycemic event within the past 12 months, or 2 within the last 5 years.” The commenter also wanted to know the lowest recorded finger-stick blood glucose over the preceding 3 months and all HbA1c results for the preceding year. An MD stated that the form should include questions about co-morbid conditions such as peripheral neuropathy, sleep apnea, uncontrolled hyperlipidemia, or hypertension being treated by the TC.

The ADA was concerned about the requirement that a driver be on a stable insulin regimen for the prior 3 months. The ADA also stated that the Agency requires the driver to have his or her HbA1C measured intermittently over the last 12 months with the most recent measure within the preceding 3 months and noted that newly-diagnosed individuals will not have that data.

FMCSA Response:

The Agency agrees with commenters that more than written notification from the individual’s TC that the individual’s diabetes is being managed properly should be provided by the TC to the certified ME. The final rule requires that the TC complete the ITDM Assessment Form, MCSA-5870, to provide additional information for the certified ME about the ITDM individual’s medical history. The Agency has considered the forms and checklists provided by commenters, and has determined that the ITDM Assessment Form, MCSA-5870, collects the appropriate information to enable the certified ME to make his or her certification determination. Comments on specific criteria are discussed below by substantive area.

With respect to the comment that the form should be completed by the treating primary care physician, FMCSA is not limiting the TC role to physicians. As discussed

above, FMCSA expects that the TC will be the individual's primary care provider for diabetes treatment.

A certified ME determines whether an individual meets FMCSA's physical qualification standards as of the time of the medical certification examination. Therefore, FMCSA has determined that providing information to the certified ME regarding whether an ITDM individual has had a severe hypoglycemic episode in the prior 3 months is generally sufficient. As discussed elsewhere in this preamble, that time frame coincides with the Agency's requirement that an ITDM individual provide the TC with 3 months of blood glucose self-monitoring records to be eligible for up to the maximum 12-month MEC, MCSA-5876. The Agency finds that this is a balanced approach for ITDM individuals that allows time to demonstrate a stable insulin regimen and proper control of ITDM, while providing enough information for the certified ME to determine whether the individual can safely operate a CMV. In any event, an ITDM individual is also required to provide the certified ME with a completed ITDM Assessment Form, MCSA-5870, for any severe hypoglycemic episodes that may have occurred since any previous medical certification examination, so the certified ME will be aware of such episodes. With respect to comments suggesting that the form be consistent with guidelines provided in the Medical Examiner Handbook, FMCSA notes that the Handbook, a tool certified MEs could consider during the medical certification process, has now been withdrawn.

The ITDM Assessment Form, MCSA-5870, already includes questions about co-morbid medical conditions as suggested by a commenter. It also provides an area for additional comments by the TC where other relevant conditions may be referenced.

The final rule requires that, to be eligible for up to the maximum 12-month MEC, MCSA-5876, all ITDM individuals must provide to the TC at least the preceding 3 months of blood glucose self-monitoring records while being treated with insulin. If an individual does not provide the 3 months of records, the certified ME has discretion to grant the individual up to but not more than a 3-month MEC, to allow time for the individual to collect the necessary records. Once the individual has 3 months of blood glucose self-monitoring records, the individual is treated the same as an ITDM individual with 3 months of records. The individual must first go to the TC for evaluation and then to the certified ME, who must exercise independent medical judgment, to determine if the individual is eligible for up to the maximum 12-month MEC.

The form asks has the individual had HbA1C measured intermittently over the last 12 months, with the most recent measure within the preceding 3 months, and, if so, to attach the most recent result. The Agency notes that the lack of HbA1C data does not automatically disqualify an individual from being medically certified.

In the final form, FMCSA made changes to be consistent with the terminology, definitions, and requirements in the final rule. The Agency also made minor changes to improve clarity and organization. More specifically, a sentence was added to specify that the certified ME must receive the form and begin the medical examination no later than 45 days after the date on the signed form; however, FMCSA notes that the medical certification determination does not need to be completed within 45 days. The Agency also added a provision that an ITDM individual who is being evaluated after a severe hypoglycemic episode must retain the form and give it to the certified ME at the next medical certification examination. FMCSA removed the question that asked whether the

individual experienced any severe hypoglycemic episodes in the absence of warning symptoms in the preceding 3 months. The Agency found the question was redundant of the general request for information about severe hypoglycemic episodes. The Agency added a request for the individual's driver's license number and issuing State, but agrees with the ADA that it is not appropriate for the form to require the individual's signature. The Agency also added a request for the TC's medical credential, as well as professional license number and the issuing State, to be able to identify these individuals. Finally, FMCSA modified the TC's attestation on the form.

The Agency notes that the ITDM Assessment Form, MCSA-5870, is available on FMCSA's Medical Programs and National Registry websites. Additionally, once the TC has signed and dated the form as required, the form is provided to the certified ME by either the ITDM individual or the TC.

F. Certified ME Certification and TC Evaluation Frequency

NPRM:

In the NPRM, FMCSA proposed that at least annually, a certified ME listed on the National Registry must examine and certify that the ITDM individual is physically qualified and free of complications that would impair the individual's ability to operate a CMV. Prior to the annual or more frequent certified ME's examination, the individual would have to be evaluated by the TC.

Comments on Certified ME Certification and TC Evaluation Frequency:

While some commenters wanted an interval of 2 years between medical certification of drivers, others stated the ITDM individual should be examined more frequently. For example, the ADA, SOCO, Advocates, and H&SW agreed with the

proposed interval of at least annual examination. The ATA and AAPA-OM suggested a graduated approach whereby certified MEs would issue shorter-term medical certifications initially and longer-term certifications after the initial period during which the ITDM individual demonstrated his or her condition was stable and properly controlled. The ATA recommended that the longest term of certification should not exceed a year. A physician/certified ME wrote that the endocrinologist is responsible for stating that the ITDM individual is well controlled throughout the year; this commenter stated that the NPRM took a step back from the effort to improve medical examinations.

2015 MRB Report:

The 2015 MRB report recommended that a certified ME could certify an ITDM individual as medically qualified for no more than 1 year if the individual had no disqualifying factors. The MRB did not make a specific recommendation regarding the frequency of the TC evaluation. No comments were received concerning the MRB report in this regard.

FMCSA Response:

FMCSA agrees with commenters who stated that ITDM individuals should not be granted medical certification for a period longer than 12 months. Annual or more frequent recertification by the certified ME allows for earlier detection and consideration of any changes or complications that may impact an ITDM individual's ability to safely operate a CMV. If a certified ME determines an individual should not be qualified for the maximum 12 months, the certified ME may certify that individual for a shorter period. FMCSA finds that this approach allows for the application of individualized medical certification determinations based on the certified ME's medical discretion. ITDM

individuals must see their TC prior to every medical certification examination to ensure they maintain a stable insulin regimen and proper control of their ITDM as the rule requires.

G. Annual Certification of Individuals with Diabetes Mellitus Not Treated with Insulin

NPRM:

In the NPRM, the Agency did not propose that individuals with diabetes mellitus not treated with insulin (non-ITDM individuals) be recertified at least annually. However, FMCSA cited the 2007 MRB recommendation to require annual or more frequent medical recertification for *all* individuals with diabetes mellitus, and requested comment on the recommendation.

Comments on Annual Certification of Non-ITDM Individuals:

The IBT, Illinois Office of the Secretary of State, and the ADA said the Agency should not require that non-ITDM individuals obtain recertification at least annually because a change to the current procedure for qualifying these individuals is not warranted. The ADA commented that non-ITDM individuals should be able to hold a medical certificate for up to 24 months like other individuals, unless their healthcare provider or the certified ME determines otherwise. In contrast, Advocates recommended that the Agency should establish more frequent medical certification for all individuals with diabetes.

2015 MRB Report:

The 2015 MRB report did not address the requirement that non-ITDM individuals be recertified at least annually; no comments were received concerning the MRB report in this regard.

FMCSA Response:

FMCSA agrees with commenters that a 2-year recertification period for non-ITDM individuals is appropriate and will not adopt the MRB's 2007 recommendation. FMCSA finds that is not necessary to impose a requirement for annual certification of these individuals because certified MEs have a long history with certification of non-ITDM individuals. Certified MEs have been trained that they may issue short duration MECs, MCSA-5876, for medical conditions that require frequent monitoring or where additional medical information is needed. Moreover, the commenters provided no data that suggests annual medical certification of non-ITDM individuals is warranted.

H. Eye Examinations**NPRM:**

The NPRM did not propose any changes to the existing vision standards. The Agency requested comments on the need for an ITDM individual to be examined by an optometrist or ophthalmologist as a condition of passing the physical examination.

Comments on Eye Examinations:

The ADA commented that it should be left to the judgment of the TC to refer the individual to an optometrist or ophthalmologist, as needed, based on clinical indicators that a screening by an eye specialist is necessary. The ADA's Standards of Medical Care recommend that individuals with type 1 diabetes be screened for retinopathy within 5 years of diagnosis because retinopathy is estimated to take at least 5 years to develop following hyperglycemia. The Standards of Care recommend that patients with type 2 diabetes be screened shortly after diagnosis. The ADA further commented that after one or more normal eye examinations, individuals with well-controlled type 2 diabetes had

essentially no risk of developing significant retinopathy within 3 years of a normal examination. According to the ADA's comments, "[n]ot all individuals with diabetes will develop vision complications, and among those that do, not all will interfere with safe driving ability. As such, only those CMV drivers who pose a high risk—because of the presence of complications that interfere with driving, such as impaired vision—should be further assessed by a specialist to determine if the risk is too high." OOIDA endorsed the comments submitted by the ADA.

The Illinois Office of the Secretary of State agreed with the proposal, provided that the ITDM individual can meet the vision standards in § 391.41(b)(10). It stated that the process will provide a reasonable certainty that any ITDM individual who cannot meet the standards will be discovered by the certified ME during the annual examination and the process will not present any threat to general traffic safety. The IBT also agreed with the proposal and FMCSA that meeting the vision acuity standard provides "reasonable certainty of discovering and mitigating risks associated with any safety-related condition that would interfere with meeting the standard, including diabetic retinopathy."

Some commenters, including H&SW and the ACOEM, stated that FMCSA should require an annual evaluation from an ophthalmologist or optometrist. SOCO suggested that FMCSA should require a note from an ophthalmologist or optometrist stating that the individual is free of diabetic-related retinal disease and vision impairing cataracts and has good field of vision in both eyes. The NTSB stated that diabetic retinopathy can cause loss of areas of vision without affecting acuity; therefore, a dilated retinal eye examination is an annual standard of care for most ITDM individuals. It

indicated that eliminating the annual ophthalmological examination will increase the likelihood of ITDM individuals driving CMVs with significant diabetic retinopathy and degraded visual performance, which will pose a hazard to public safety. A physician/certified ME stated that if the exemption program is eliminated he will continue to expect at least annual assessment from an ophthalmologist.

Several commenters that were in favor of requiring annual eye examinations, including the American Optometric Association (AOA) and the former MRB members, noted that the certified ME may not have the experience and training to perform dilated eye examinations or have the specialized equipment necessary to do so. The former MRB members noted that by the time an ITDM individual experiences reduced visual acuity that is captured by the relatively crude examination performed by a certified ME, it is often too late to avoid complications. Thus, the former MRB members stated there is further need for mandatory, annual eye examinations for retinopathy by ophthalmologists or optometrists.

The AOA noted it is important to understand that the entire range of diabetic retinopathy complications are predominantly asymptomatic and can occur without any deterioration in visual acuity. It stated that a visual acuity test is not a substitute for a dilated eye examination, which is the only appropriate method for evaluating the eye health of ITDM individuals and for predicting with high confidence which individuals will retain adequate visual function in the interim between eye examinations. It was concerned that the current proposal could put drivers and the public at serious risk. The AOA suggested, rather than requiring evaluation by an ophthalmologist, FMCSA could reduce the cost and burden to ITDM individuals, while maintaining quality of evaluation,

by allowing a doctor of optometry to evaluate those applicants.

TFAC suggested FMCSA require a vision examination by a qualified eye specialist when the individual goes on insulin treatment and every 2 years thereafter. It suggested that the eye specialist complete a form acknowledging familiarity with the requirements of 49 CFR and the physical demands of a CMV operator.

2015 MRB Report:

The 2015 MRB report included the recommendation that ITDM individuals receive a complete eye examination by a qualified ophthalmologist or optometrist, including a dilated retinal examination, at least every 2 years. This examination should document the presence or absence of retinopathy and macular edema, and, if present, the degree using the International Classification of Diabetic Retinopathy and Diabetic Macular Edema. The MRB advised increasing the frequency of these examinations based on the ophthalmological findings.

Comments on the MRB's Report on Eye Examinations:

HS&W concurred with the MRB's recommendation. The National Rural Electric Cooperative Association commented that it was not opposed to a comprehensive eye examination¹¹ every 2 years, but having the TC attest that the TC reviewed the results of the report was "duplicative at best and onerous at worst."

The AOA, the ACOEM, and several individuals suggested a comprehensive eye examination should be conducted on an annual basis. The AOA stated that its evidence-based guidelines explain that the clinical signs of diabetic retinopathy can appear early in

¹¹ The AOA commented that "comprehensive eye examination" is the proper terminology to describe the general evaluation of the complete visual system, including a dilated retinal examination, rather than "an ophthalmology or optometry exam."

the disease process; however, individuals many not experience symptoms until relatively late, at which time treatment may be less effective. The AOA noted that “[t]he success of appropriate intervention and management strategies depends upon accurate and timely detection of diabetic eye disease.” The University of Utah stated that individuals with non-proliferative retinopathy should be required to have annual comprehensive eye examinations.

The ADA repeated its prior comments to the NPRM that an annual comprehensive eye examination is not required by its Standards of Care. It again concluded that it should be left to the judgment of the TC to refer the ITDM individual to an ophthalmologist or optometrist as needed.

FMCSA Response:

This rule does not include a mandatory requirement or specify the frequency for comprehensive eye examinations for ITDM individuals. FMCSA finds the Standards of Care and comments presented by the ADA to be persuasive and reasonable. Given that not all individuals with diabetes will develop vision complications, FMCSA has determined that it would be inconsistent with the rule’s emphasis on individualized assessment to impose a required frequency for a separate comprehensive eye examination by an ophthalmologist or optometrist as a condition of passing the medical certification examination for all ITDM individuals. FMCSA also finds that to do so is inconsistent with Congress’ instruction that the Agency may not hold ITDM individuals to a higher standard than other individuals unless it is medically necessary. The Agency’s determination that annual comprehensive eye examinations should not be required also is

supported by the MRB's recommendation that ITDM individuals undergo such examinations every 2 years, unless clinical indicators suggest otherwise.

The Agency finds that the TC is in the best position to determine for each ITDM individual when a comprehensive eye examination is necessary and, when warranted, to make a referral to an ophthalmologist or optometrist. If any eye condition that may impact an ITDM individual's ability to safely operate a CMV is present, it is reasonable for the Agency to expect that the ITDM individual's TC will ensure that proper comprehensive eye examinations are obtained to appropriately monitor any progressive vision impairment. As with all medical certification examinations, with the ITDM individual's consent, the certified ME may confer as needed with the TC or an eye specialist to determine whether additional information or evaluation is necessary prior to the medical certification decision.

The final rule does not change the existing requirement that all individuals must meet the vision standard in § 391.41(b)(10) to operate a CMV. The Agency continues to find that meeting the vision standard provides reasonable certainty of discovering and mitigating risks associated with any safety-related condition that would interfere with meeting the standard. As such, this rule does not include a mandatory requirement or specify the frequency for comprehensive eye examinations for ITDM individuals.

I. Disqualification for Vision Impairment

NPRM:

The NPRM did not propose that any specific visual complications associated with diabetes would disqualify an ITDM individual from being medically qualified.

Comments on Disqualification for Vision Impairment:

Commenters stated that no diabetic retinopathy above stage 1 is acceptable. The risks of progression, which may occur very suddenly, are too high. No laser treatments or intraocular injections for retinopathy should be allowed. Additionally, vision exemptions should not be acceptable in this context.

2015 MRB Report:

If ITDM individuals had stage 3 or 4 of diabetic retinopathy, the MRB recommended that such individuals be disqualified permanently from medical certification.¹²

Comments on the MRB's Report on Disqualification for Vision Impairment:

Commenters agreed that stage 3 or 4 retinopathy should be a permanent disqualification because of the significant risk of sudden vision compromise from bleeding or retinal detachment. In addition, the ADA noted that the standard treatment for this stage is pan-retinal photocoagulation, which cuts down night vision and peripheral vision that are important to CMV operation.

The University of Utah stated that anything beyond non-proliferative retinopathy should be disqualifying because epidemiological studies suggest sudden onset of vision impairment is too common. This commenter also stated that it should be made clear that any laser treatments or intraocular injections for treatment of retinopathy would preclude driving. Additionally, monocular driving in combination with any degree of retinopathy, not just stage 3 or 4 retinopathy, should be clearly disqualifying due to the inability to

¹² The Agency sought clarification from the MRB and was informed that stage 3 diabetic retinopathy could be termed severe non-proliferative diabetic retinopathy and stage 4 diabetic retinopathy could be termed severe proliferative diabetic retinopathy.

have a compensatory eye combined with the potential suddenness of onset of vision impairments.

In contrast, an endocrinologist stated the 2015 MRB recommendation is relatively arbitrary. Proliferative retinopathy, even after laser therapy, affects vision variably. Thus, not all individuals in these categories will have significant vision impairment. The endocrinologist commented that the criterion should be based on function, such as acuity, night vision, and response times to stimuli in the periphery of visual fields. An individual wrote that, if an ITDM individual receives treatment for the diabetic retinopathy and an ophthalmologist states that the individual can operate a CMV safely, the retinopathy should not be a disqualifying factor.

FMCSA Response:

This final rule requires that the certified ME disqualify permanently from medical certification any ITDM individual who is diagnosed with severe non-proliferative diabetic retinopathy or proliferative diabetic retinopathy.

The Agency agrees with the 2015 MRB report and commenters that ITDM individuals with advanced stages of diabetic retinopathy pose a safety risk while operating a CMV. ITDM individuals whose diabetic retinopathy has reached the advanced stages of severe non-proliferative or proliferative diabetic retinopathy are at risk of sudden incapacitation from a detached retina or bleeding. FMCSA agrees, therefore, that ITDM individuals with severe non-proliferative or proliferative diabetic retinopathy should be disqualified permanently from operating a CMV. Given that treatment for advanced diabetic retinopathy impacts night and peripheral vision adversely, which are important for operating a CMV, the Agency has determined that

there is a rational basis to find that ITDM individuals with severe non-proliferative or proliferative diabetic retinopathy should be permanently disqualified from being medically certified, despite treatment.

The Agency declines to incorporate any specific definition of severe non-proliferative or proliferative diabetic retinopathy in either the ITDM Assessment Form, MCSA-5870, or the regulation. Instead, the Agency refers to classification categories created by eye specialists, such as the National Eye Institute¹³ and the International Clinical Diabetic Retinopathy Disease Severity Scale,¹⁴ with which eye specialists are familiar and well versed for the definitions. Adding a specific definition would not assist the trained eyecare specialist in making a clinical determination.

With respect to the disqualification determination process, the ITDM Assessment Form, MCSA-5870, asks the TC whether the ITDM individual has been diagnosed with severe non-proliferative diabetic retinopathy or proliferative diabetic retinopathy. If it is noted on the form that the ITDM individual has been diagnosed as such, the certified ME may rely on that representation and disqualify the individual permanently from medical certification. Alternatively, the certified ME may exercise his or her independent medical judgment and refer the individual for further evaluation prior to making a certification determination.

J. HbA1C Levels

NPRM:

¹³ See <https://nei.nih.gov/diabetes/content/english/know> (Accessed May 25, 2018).

¹⁴ See <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3874488/> (Accessed May 25, 2018).

The NPRM did not propose a standard for HbA1C levels for medical qualification of ITDM individuals.¹⁵

Comments on HbA1C:

The former MRB members wanted FMCSA to state its position on acceptable HbA1C levels, and recommended that driving be allowed when the HbA1C is below 10 percent. A physician indicated that FMCSA needs to establish specific guidance regarding what HbA1C level would enable an individual to operate a CMV safely and asked whether a level of 12 percent is satisfactory. The commenter stated that FMCSA will need to provide a table as it does for blood pressure. An RN stated that ITDM individuals should be required to have an HbA1C test every 3 months. Another commenter stated that an individual should check his or her HbA1C every 6 months.

The ACOEM and TFAC would require the TC to send the certified ME the current HbA1C results. TFAC stated that this should be done within 30 days of certification. TFAC commented further that the HbA1C test provides the best information available on long-term control and cannot be falsified as a daily blood glucose log can. The NTSB suggested that FMCSA could require clinical information, including HbA1C levels, from the TC to demonstrate that the individual meets specified criteria.

The ADA, on the other hand, opposed requiring a specific HbA1C range when licensing ITDM individuals, and recommended that FMCSA not use this “medically unjustified criterion” in any form. The ADA noted that, taken alone, an HbA1C above 7 percent in no way indicates the individual cannot operate a CMV safely. The ADA, along

¹⁵ The A1C blood test is often referred to as the hemoglobin A1C, HbA1C, or glycohemoglobin test. *See* <https://www.niddk.nih.gov/health-information/diabetes/overview/tests-diagnosis/a1c-test#1> (Accessed Sept. 13, 2017).

with the ACOEM, maintained that an HbA1C test is a useful indicator of diabetes management when used in conjunction with other assessment tools to assess an individual's ability to drive safely. The ADA wrote that diabetes management decisions should be made by an individual and his or her physician based on how diabetes affects that person.

2015 MRB Report:

The 2015 MRB report recommended that an ITDM individual with uncontrolled diabetes be disqualified from operating CMVs. The evidence for uncontrolled diabetes would be an HbA1C level greater than 10 percent. The ITDM individual could be reinstated when his or her HbA1C level is less than or equal to 10 percent.

Comments on the MRB's Report on HbA1C:

The ACOEM was the sole commenter who supported this recommendation. It added that the ITDM individual could be reinstated only when the recommended HbA1C level is maintained for at least 3 months.

Some commenters objected to a threshold of 10 percent. An MD commented that this level does not take into consideration individual variability in glycation rate and that the criterion could be tighter. An individual wrote that HbA1C is not clearly defined as a range as it is in Canadian and European regulations nor is the level in the healthy or controlled range.

Other commenters, including H&SW, an MD, the ADA, and the ATA, objected to the use of HbA1C altogether to determine whether an individual is safe to drive. H&SW wrote that the HbA1C test measures average blood sugar over 3 months, and does not give information about hypoglycemic episodes. An MD commented that he is

not aware of any evidence that a high HbA1C renders an individual unfit to drive. The MD added that, while a high HbA1C may result in neuropathy, retinopathy, and other end organ damage that could lead to unsafe driving, these conditions take many years to develop and an HbA1C greater than 10 percent does not mean that an individual has these conditions. Because individuals on oral medications would be allowed to drive with HbA1C levels higher than 10 percent, the MD indicated that this rule would discriminate against ITDM individuals and create a disincentive for individuals to seek appropriate treatment with insulin. The MD recommended either removing this recommendation or increasing the HbA1C threshold to 12 percent.

The ADA and the ATA wrote that the HbA1C test is a useful indicator of poor diabetes management when used with other assessment tools. The ADA highlighted that the HbA1C measure does not predict hypoglycemia. Additionally, a high HbA1C does not impair driving, and evaluation of end organ damage will identify individuals whose diabetes leads to complications that impact safe driving. The ATA stated that disqualifying an individual for an HbA1C level greater than 10 percent may be somewhat arbitrary. This recommendation could create a disparity between individuals who are managing their diabetes with and without insulin. The ATA suggested that the certified ME should work with the TC to determine whether a high HbA1C presents a danger. It recommended further that FMCSA should consider other factors, in addition to a high HbA1C level, for determining whether an individual's diabetes is well-controlled and maintained.

FMCSA Response:

FMCSA agrees with comments that HbA1C values should not be relied upon as a sole measure of an ITDM individual's ability to safely operate a CMV. The final rule allows the TC to evaluate all relevant clinical factors to determine whether an individual maintains proper control of his or her ITDM. HbA1C levels are one factor the TC may consider in making that determination.

FMCSA agrees further that making a medical qualification determination based solely on a specific HbA1C level is inconsistent with the rule's emphasis on individualized assessment. In addition, the National Institute of Diabetes and Digestive and Kidney Disease states that HbA1C test results can be up to 0.5 percent higher or lower than the reported actual percentage; can be unreliable for people of African, Mediterranean, or Southeast Asian heritage; and can be altered by diseases that affect blood or hemoglobin.¹⁶ While a high HbA1C level may suggest that complications from diabetes might develop in the future, it does not mean that an individual presently has complications or is unsafe to drive a CMV.

The ITDM Assessment Form, MCSA-5870, asks the TC to report whether the individual has had HbA1C measured intermittently over the past 12 months, with the most recent measure within the preceding 3 months. If so, a copy of the most recent laboratory result is to be attached to the form so that it is available to the certified ME.

K. Specific Blood Glucose Limits

NPRM:

The NPRM did not propose a specific range for blood glucose readings.

Comments on Establishing Specific Glucose Limits:

¹⁶ See <https://www.niddk.nih.gov/health-information/diabetes/overview/tests-diagnosis/a1c-test#1> (Accessed Sept. 13, 2017)

The NTSB suggested FMCSA require ITDM individuals meet specified criteria to demonstrate that their diabetes is properly managed, including an acceptable range for blood glucose. Some commenters, including a retired FAA safety inspector, the former MRB members, an RN, the ACOEM, and H&SW, recommended specific acceptable blood glucose limits. The retired FAA safety inspector stated that a reading lower than 80 mg/dL should be flagged, which would give the individual time to correct blood glucose. The former MRB members said ITDM individuals should maintain blood glucose levels of at least 100 mg/dL while driving. If a blood glucose value is less than 60 mg/dL, the ACOEM would require the individual to repeat the test at least every 30 minutes until 90 mg/dL is reached. During this time, the individual would have to document that he or she was not driving and provide additional documentation on the low reading. H&SW stated that a blood glucose level within the normal range of 80 to 140 mg/dL would be appropriate.

The ADA wrote that it is appropriate to evaluate blood glucose readings. However, there is no legitimate medical reason to automatically disqualify individuals whose blood glucose logs show some readings below 100 mg/dL or above 400 mg/dL, as stipulated in the current exemption program.

2015 MRB Report:

The MRB recommended that if an ITDM individual had a blood glucose measure of less than 60 mg/dL, as demonstrated in the current glucose logs, the individual would be disqualified for at least 6 months.

Comments on the MRB's Report on Establishing Specific Blood Glucose Limits:

Many commenters objected to the disqualification of an ITDM individual for having a single reading below 60 mg/dL. Several commenters stated that it was not appropriate to set a blood glucose standard for when an individual is not on duty. They, along with the ATA and ADA, discussed that a single reading of a blood glucose level below 60 mg/dL should not be sufficient to disqualify an ITDM individual. They stated that the Agency should consider whether a low blood glucose recording was an isolated incident or part of an overall pattern of poorly-controlled diabetes.

The ADA stated that the recommendation is “an extreme overreaction to the potential risk of hypoglycemia, and does not provide for individualized assessment of a specific driver’s diabetes risk.” It continued that a blood glucose level less than 60 mg/dL is dangerous only if it is not treated. The ADA commented that, instead of disqualifying the individual, it is important to determine the cause of the low blood glucose level. The ADA strongly urged the Agency to eliminate all categorical glucose levels from the list of disqualifying factors.

An endocrinologist stated that all ITDM individuals will have some blood glucose readings below 60 mg/dL, perhaps once a week. In the endocrinologist’s opinion, disqualifying individuals for a blood glucose level any time it was under 60 mg/dL would be “unreasonable/discriminatory.” A different MD stated that disqualification based on a onetime reading of less than 60 mg/dL “seems arbitrary.” The MD continued that “[t]his rare low blood glucose reading does not imply the driver’s diabetes is uncontrolled or that the driver has a problem with hypoglycemic unawareness.”

The ATA noted that there are several factors that can cause blood glucose to drop low, including titration following a new treatment. For this reason, the ATA stated that

the TC and certified ME should review blood glucose logs to determine whether the low blood glucose level was an isolated incident.

The ACOEM stated that a blood glucose level of less than 60 mg/dL is probably too low, as once the blood glucose is at 60 mg/dL the individual is likely to already be having symptoms. If the blood glucose is below 70 mg/dL, the ACOEM recommended that the ITDM individual should not be permitted to drive until all blood glucose logs show levels above 70 mg/dL for at least 6 months, with recurrent episodes triggering progressive duration of out of service periods.

FMCSA Response:

The Agency agrees with commenters that an ITDM individual should not be disqualified for a single blood glucose reading that falls below or above a specific limit. The intent of the final rule is for an individualized assessment of the stability of the individual's insulin regimen and control of his or her ITDM, as determined by the TC, and of whether the individual satisfies the physical qualification standards, as determined by the certified ME. Therefore, FMCSA finds it is appropriate for TCs to set individualized, clinically-based parameters for blood glucose limits for ITDM individuals rather than establishing a regulatory requirement. TCs should look for frequent occurrences of low blood glucose levels and determine the cause. For example, frequent low blood glucose levels may indicate potential improper diabetes management or other underlying medical issues. While the certified ME considers the TC's input on whether the ITDM individual maintains a stable insulin regimen and proper control of his or her ITDM, it is the certified ME's responsibility to consider safety and make a physical qualification determination.

L. Severe Hypoglycemic Episodes

NPRM:

FMCSA proposed to allow ITDM individuals to drive CMVs if they were free of severe hypoglycemic reactions in the 12 months prior to the TC evaluation. A severe hypoglycemic reaction was described as one that results in loss of consciousness or seizure, requires the assistance of another person, or results in impaired cognitive function.

Comments on Severe Hypoglycemic Episodes:

The former MRB members, Concentra, the NTSB, and the ACOEM recommended that FMCSA establish specific, measurable standards to define a severe hypoglycemic episode. Comments included concerns regarding ways of reporting severe hypoglycemic episodes and the length of time between episodes. Advocates supported the proposed rulemaking, but was concerned that the reporting requirement may be too lax and open to potential abuse. SOCO recommended a note from the TC stating that the ITDM individual is stable on current therapy and is not experiencing hypoglycemic episodes. This commenter would require immediate reporting to the certified ME and the TC of new or recurring hypoglycemia. Instead of the proposed 12 months, a diabetes educator stated that ITDM individuals should have to follow-up at least every 6 months with an endocrinologist and diabetes educator to make sure that the individuals are not having multiple episodes of hypoglycemia or hyperglycemia.

The former MRB members, Advocates, the ATA, and AAPA-OM agreed that FMCSA should remove any ITDM individual who has a severe hypoglycemic episode within a year from work for at least 1 year. AAPA-OM stated that there should not be

recurrent (two or more) severe hypoglycemic episodes in the last 5 years. The former MRB members recommended periods of longer than 12 months for not allowing ITDM individuals to operate CMVs if they had more than two episodes in the last 5 years. Concentra commented that the safety risks from acute hypoglycemia are too great not to be defined and that FMCSA should review the criteria with leading endocrinologists who specialize in diabetes. The NTSB was concerned that the NPRM required only that the TC determine that an individual has had no severe hypoglycemic episodes and that the diabetes is properly managed, rather than providing clinical information to demonstrate that the individual meets specified criteria.

2015 MRB Report:

The 2015 MRB report defined a severe hypoglycemic episode as loss of consciousness, seizures or coma, requiring the assistance of others, or needing urgent treatment (glucagon injection or intravenous glucose). If an ITDM individual had an episode of severe hypoglycemia within the previous 6 months, the MRB recommended that the individual be disqualified from operating a CMV for at least 6 months.

Comments on the MRB's Report on Severe Hypoglycemic Episodes:

The ADA, the ACOEM, and the University of Utah stated that the recommended definition needs to be clarified. For example, the ADA stated that urgent treatment is too broad a term and could include self-treatment by an individual who recognizes dropping blood glucose. The University of Utah commented that a glucose level below 60 mg/dL is the same as severe hypoglycemia. This commenter also suggested that there should be a requirement for the ITDM individual who experienced an episode to make some adjustment to prevent another episode from occurring. H&SW recommended that

moderate hypoglycemia should be addressed in the rulemaking because it can pose a serious concern.

Some commenters supported the recommendation that an ITDM individual who experienced a hypoglycemic episode be disqualified for 6 months, while others who disagreed with it, including an endocrinologist, stated the disqualification was unreasonable and discriminatory to ITDM individuals. Commenters who opposed this recommendation, again including the endocrinologist, stated that episodes that occurred off duty should not count against the ITDM individual, as they have no safety implications. They noted that there are many reasons for low blood glucose, such as acute illness, infections, or medication. Commenters, including OOIDA, stated that disqualifying ITDM individuals for 6 months would be financially burdensome on these individuals and may even lead to job losses. Rather than having FMCSA set a specific timeframe for disqualification, commenters, such as the ADA, stated that the TC should determine the length of the disqualification period, or determine that the disqualification has been lifted as a result of corrective measures or lapse in time since the disqualifying event(s). Concentra noted generally that the 6-month disqualification period may be difficult for the certified ME to track and that it is conceivable the individual could be seen by another certified ME who would be unaware of the disqualification.

Some commenters stated that a single episode of severe hypoglycemia should not be disqualifying and that the issue needs to be recurring. For example, the ADA stated that “any policy that disqualifies a driver on the basis of a single episode of severe hypoglycemia is misguided.” Instead, the ADA maintained, the TC should determine the cause of the low blood glucose, whether it was an isolated incident, and the likelihood of

such an episode recurring. In contrast, the University of Utah and the ACOEM stated that the Agency should consider progressively longer periods of disqualification based on the frequency of these episodes. The University of Utah indicated that there must be a limit to the number of severe hypoglycemia episodes.

FMCSA Response:

In the final rule, FMCSA has revised the NPRM and 2015 MRB definitions of a severe hypoglycemic episode to eliminate ambiguity and potential redundancy. FMCSA also has clarified that the scope of the definition is *severe* episodes by eliminating from the definitions that the episode results in impaired cognitive function or requires urgent treatment. The revised definition provides a more objective standard that allows for more consistent determinations regarding what constitutes a severe hypoglycemic episode. A severe hypoglycemic episode is defined as an episode requiring the assistance of others, or resulting in a seizure, coma, or the loss of consciousness.

In view of the potential impact on safety, FMCSA is clarifying in the final rule that an ITDM individual certified as physically qualified to operate a CMV who experiences a severe hypoglycemic episode is prohibited from operating a CMV. The Agency is adding a requirement in the rule that such an individual must report the episode to and be evaluated by a treating clinician as soon as is reasonably practicable.

The driving prohibition continues until the ITDM individual has been evaluated by a TC (who meets the specifications in the rule), and a TC determines that the cause of the severe hypoglycemic episode has been addressed and that the individual again has a stable insulin regimen and properly controlled ITDM. Once a TC completes a new ITDM Assessment Form, MCSA-5870, following the episode, the individual may resume

operating a CMV. The rule requires the ITDM individual to retain the form and to provide it to the certified ME at the individual's next medical certification examination so the certified ME will be aware of the prior episode.

The Agency agrees with commenters that after an ITDM individual experiences a severe hypoglycemic episode the individual must demonstrate that the cause of the episode has been addressed and that a future episode is not likely to recur. However, the Agency also agrees with some commenters that prohibiting an individual from driving for 6 to 12 months after a severe hypoglycemic episode is onerous for both ITDM individuals and employers. In addition, a period of 6 to 12 months is not necessary medically to determine stability in most instances because severe hypoglycemic episodes are often the result of short-term causes. For example, in certain circumstances, the cause of an episode might be able to be addressed while an individual is in an emergency room or other medical facility, and a TC could complete a new ITDM Assessment Form, MCSA-5870, at that time. Moreover, the Agency lacks data that suggest an ITDM individual who has experienced a severe hypoglycemic episode is likely to experience another episode within any specific timeframe, and commenters, as well as the MRB, have not provided any relevant data.

Accordingly, the final rule does not establish a specific timeframe that an ITDM individual is prohibited from operating a CMV following a severe hypoglycemic episode. Rather, the rule defers to a TC to make an individualized assessment as to when the cause of the episode has been addressed and the individual again has a stable insulin regimen and properly controlled ITDM. A TC is in a good position to obtain and take in to account an ITDM individual's medical history. Therefore, a TC is also in a good position

to determine and treat the cause of a severe hypoglycemic episode, assess the response to treatment, determine when the cause has been addressed, and, then, complete an ITDM Assessment Form, MCSA-5870.

FMCSA finds that any regulatory requirement that specifies a timeframe that an ITDM individual is prohibited from operating a CMV is not consistent with the intent of this rule to provide for individualized assessment. The individualized approach the Agency has adopted appropriately balances the safety of the motoring public with encouraging ITDM individuals to seek proper treatment and to comply with the rule's requirements.

The Agency emphasizes that a TC is not determining whether the ITDM individual is qualified to operate a CMV following a severe hypoglycemic episode. Rather, a TC's role continues to be limited to determining whether the ITDM individual has a stable insulin regimen and properly controlled ITDM.

FMCSA has considered the comments to the effect that severe hypoglycemic episodes that occur when an ITDM individual is off duty have no effect on safety. The Agency has revised the definition to clarify that the episodes of hypoglycemia that trigger the prohibition from operating a CMV and the reporting requirement are only those that are *severe*. FMCSA has concluded that it is in the interest of safety to require that ITDM individuals seek treatment after having experienced any severe hypoglycemic episode to ensure that the cause of the episode has been addressed.

FMCSA also declines to establish by regulation that any particular number of severe hypoglycemic episodes automatically disqualifies an ITDM individual from operating a CMV. Such a requirement would be contrary to the individualized assessment

approach adopted in this rule. Instead, TCs will consider prior episodes of severe hypoglycemic episodes in determining whether an individual has a stable insulin regimen and properly controlled ITDM. Additionally, certified MEs will be aware of prior episodes via the ITDM Assessment Form, MCSA-5870, provided at any subsequent medical qualification examination.

FMCSA notes that the existing requirement that a new medical examination and certification must be obtained when an individual has a physical or mental injury or disease that impairs the individual's ability to perform his or her normal duties¹⁷ could, depending on the circumstances, be applicable to the ITDM individual who experiences a severe hypoglycemic episode. Such ITDM individuals would be subject to a new evaluation by the TC, including completion of a new ITDM Assessment Form, MCSA-5870, and subsequent medical examination by the certified ME.

FMCSA declines to define or establish by regulation a moderate hypoglycemic episode as a disqualifying event. FMCSA expects the TC to evaluate a moderate hypoglycemic episode and any other diabetic complications in determining whether the individual maintains a stable insulin regimen and proper control of his or her ITDM.

The Agency developed the ITDM Assessment Form, MCSA-5870, that gathers information about an individual's diabetes and addresses many of the commenters' concerns. The Agency has concluded, through the completion of the form and evaluation of available subjective and objective clinical data, such as interviewing the individual and reviewing blood glucose records for fluctuations over time, that the TC is equipped to provide an appropriate assessment for the certified ME to review.

¹⁷ Now recodified without change in 49 CFR 391.45(f) by this final rule.

M. Hypoglycemia Unawareness

NPRM:

The proposed rule did not address hypoglycemic events occurring without prior warning, also known as hypoglycemia unawareness.

Comments on Hypoglycemia Unawareness and Hypoglycemia Unawareness Training:

The former MRB members commented that, to be qualified to drive, the ITDM individual should not experience hypoglycemia unawareness. The ATA added that the certified ME or TC should evaluate whether the individual has experienced any episodes of hypoglycemia unawareness. In terms of hypoglycemia awareness training, several commenters recommended that FMCSA require this training as a part of the diabetes qualification process to prevent an ITDM individual from experiencing a hypoglycemic episode while operating a CMV. Commenters who supported this requirement include Advocates, H&SW, the ACOEM, and TFAC. Comments on this topic included how often ITDM individuals should attend training sessions and how they should provide documentation to prove their attendance.

2015 MRB Report:

The MRB recommended in its report that an ITDM individual who had hypoglycemia unawareness within the previous 6 months be disqualified from operating a CMV for at least 6 months.

Comments on the MRB's Report on Hypoglycemia Unawareness:

Commenters generally agreed that impaired awareness of hypoglycemia is incompatible with driving and asked FMCSA to clarify the definition of hypoglycemia unawareness. For example, an MD suggested defining hypoglycemia unawareness as

hypoglycemia under 50 mg/dL appearing in the absence of warning symptoms. The MD noted that symptoms of hypoglycemia in many well-controlled ITDM individuals without hypoglycemia unawareness do not arise until the glucose level is under 50, so clinicians may mistakenly label individuals as having hypoglycemia unawareness. The MD agreed, however, that an episode of hypoglycemia unawareness, as he defined it, should result in disqualification for 6 months.

On the other hand, most commenters indicated that a 6-month disqualification period is too long. An endocrinologist stated that the period of 6 months is arbitrary, and, in her opinion, unreasonable and discriminatory. Comments included the view that a single episode of hypoglycemia unawareness should not be disqualifying, and that such episodes need to be recurring or ongoing. The ADA and an endocrinologist indicated that ITDM individuals should be allowed to return to driving once the appropriate measures to avoid hypoglycemia and create awareness have been established.

While some commenters indicated that an ITDM individual should be reinstated once the hypoglycemic unawareness issue is resolved, the University of Utah stated that there should be a minimum, perhaps 6 months, of blood glucose logs and symptom reviews to ascertain that the individual had regained awareness of hypoglycemia. The ACOEM stated that if an ITDM individual with hypoglycemia unawareness is later able to demonstrate hypoglycemia awareness and is certified, but hypoglycemia unawareness recurs, that individual should be permanently disqualified. The ACOEM commented further that, if an ITDM individual is not experiencing awareness of a blood glucose level below 60 mg/dL, the individual should be permanently barred from operating a CMV.

FMCSA Response:

FMCSA has determined that hypoglycemia unawareness on its own should not be considered for medical qualification. Hypoglycemia unawareness would be considered by the TC in determining whether the individual has a stable insulin regimen and proper control of his or her ITDM. Due to the individualized effect of occurrences of hypoglycemia unawareness, the assessment, evaluation, and treatment for this condition should be a component of the TC's individualized management for a stable insulin regimen and proper control of the ITDM individual's diabetes. To assist the TC in educating ITDM individuals regarding hypoglycemic unawareness, FMCSA is planning to develop education and outreach information to promote recognition of hypoglycemia unawareness.

N. Blood Glucose Self-Monitoring

NPRM:

During the period of medical certification, the NPRM required the ITDM individual to monitor and maintain blood glucose records as determined by the TC. The ITDM individual would submit those records to the TC at the time of evaluation. The NPRM did not propose a minimum insulin use period for new or established ITDM individuals to be eligible for medical certification.

Comments on Blood Glucose Self-Monitoring:

Some commenters, including a retired FAA safety inspector, the former MRB members, an RN, the ACOEM, and H&SW, recommended a specific schedule for blood glucose monitoring. Commenters generally suggested testing prior to driving and then every 4 to 6 hours while driving. The retired FAA safety inspector recommended the

most frequent monitoring, with testing 1 hour before driving and at least every 2 hours while driving.

The ACOEM recommended that a log be required consisting of at least 2 weeks of testing four times per day (before meals and at bedtime). It would require the blood glucose log to be downloaded and printed directly from the glucometer—no typed or handwritten logs—and to have a time stamp for each blood glucose value.

Concentra stated that FMCSA should discuss the criteria for self-monitoring blood glucose while driving. A diabetes educator stated that ITDM individuals should follow up at least every 6 months with an endocrinologist who would download their blood glucose readings. SOCO also recommended that a glucose log be maintained for review by the treating doctor.

Advocates was concerned about the lack of definitions for “appropriate ranges” and “management.” To support and document the conclusions of the TC, Advocates recommended that the Agency require ITDM individuals to submit blood glucose records for a specified time prior to the medical evaluation. Advocates indicated that leaving the definition of the appropriate level of reporting to the TC could encourage TC shopping.

The IBT and Concentra asked for clarification on how long insulin must be used before an ITDM individual can be certified to drive. The AAPA-OM commented that an ITDM individual must be on insulin for at least 2 years prior to certification. The ACOEM wrote that FMCSA should require a new insulin user to demonstrate stability, control, and lack of hypoglycemia over a period of time before being medically cleared for driving; this monitoring cycle could be more frequent at the discretion of the TC and the certified ME. The ACOEM commented that the Law Enforcement Officer Medical

Guideline requires 3 months of stable insulin regimen for individuals on insulin for treatment of type 2 diabetes mellitus, and 6 months for individuals on insulin for treatment of type 1 diabetes mellitus. If the individual is on an insulin pump, the ACOEM would require the TC to send the certified ME a summary report on the use of the pump.

2015 MRB Report:

The MRB report recommended that the suggested ITDM form request information on how many times per day the individual is testing blood glucose. It also suggested that ITDM individuals test blood glucose before driving and every 4 hours while driving.

The MRB recommended that the form request information about whether an individual on insulin with type 2 diabetes has been on a stable medication regimen for 3 months prior to evaluation by the TC. For individuals who have been newly diagnosed with type 1 diabetes, the minimum period of insulin use to establish medication regimen stability would be not less than 2 months. For individuals who have type 2 diabetes and are converting to insulin use, the minimum period of insulin use to establish medication regimen stability would be not less than 1 month.

The MRB specified that all ITDM individuals must have documentation of ongoing self-monitoring of blood glucose; however, established insulin users must have records covering a minimum of the most recent 3 months. This monitoring must be done using a finger stick glucose meter that stores every reading and records date and time of the readings, which the user can download. Handwritten blood glucose records would not be acceptable. The MRB recommended that an ITDM individual be disqualified for an inadequate record of self-monitoring blood glucose, “i.e., unreliable or absent capillary

blood glucose measurements.” This disqualification would last until the individual could demonstrate adequate evidence of glucose records, and a minimum of 1 month.

Comments on the MRB’s Report on Blood Glucose Self-Monitoring:

The University of Utah commented that the wording “[i]nadequate record of self-monitoring of blood glucose” was “insufficiently clear.” It recommended that it be specified how many readings can be missing over what period. It suggested considering blood glucose self-monitoring five times per day on days spent driving and four times per day on other days. The ACOEM asked what would be defined as adequate self-monitoring, which may differ based on the treatment. If left to the examiner to determine, the ACOEM commented that the examiner must be someone who can evaluate and treat individuals who use insulin. The ACOEM asked if the monitoring criteria would mirror the exemption program—prior to driving and every 4 hours while driving.

The ADA agreed with the importance of reviewing blood glucose records as part of an individualized assessment of an ITDM individual. It was concerned that the adequacy of records was referenced, but left undefined. The ADA stated that the adequacy of the records should be determined only by the TC. The ADA stated that it is inappropriate for the certified ME or anyone else to determine how often an ITDM individual should be testing blood glucose.

The ADA was the only commenter that discussed the length of time an ITDM individual should be on insulin before being eligible to be medically certified. It noted the discrepancy between requiring an individual with type 2 diabetes treated with insulin to be on a stable medication regimen for 3 months, and the recommendation that an individual with type 2 diabetes converting to insulin use be using insulin for not less than

1 month. The ADA commented that these two standards should be the same and follow the criteria of the existing exemption program, which requires that an individual with type 2 diabetes use insulin for 1 month prior to eligibility for medical certification.

In terms of disqualification for inadequate records, the ADA stated that an ITDM individual should never be disqualified on the assumption that the individual's records of blood glucose monitoring are inadequate. An individual stated that the rule should allow for extenuating circumstances beyond the ITDM individual's control, such as difficulties with the blood glucose monitor. In such circumstances, the commenter felt it would be unfair to penalize the individual.

Some commenters wanted the rule to do more to increase the likelihood that an ITDM individual would keep blood glucose records. The University of Utah wanted a mechanism in the rule to assure ongoing compliance with blood glucose monitoring requirements. Concentra was concerned that an ITDM individual who was certified and became non-compliant would be able to continue to drive without FMCSA's knowledge. It stated that there should be a mechanism in place to require the TC to notify FMCSA if the individual becomes non-compliant or discharges the TC. H&SW wrote that the ITDM individual has "additional impetus to keep blood glucose logs when a regulation requires it." A physician recommended that patients who have type 1 diabetes mellitus for over 5 years use continuous glucose sensors to minimize their risk of driving while hypoglycemic to ensure safety for the others on the road.

FMCSA Response:

FMCSA agrees with the 2015 MRB recommendations and other commenters that a requirement for a period of blood glucose self-monitoring records should be included in

the final rule. The final rule requires that all ITDM individuals must provide at least the preceding 3 months of blood glucose self-monitoring records while being treated with insulin to the TC to be eligible for up to the maximum 12-month MEC, MCSA-5876. If an individual does not provide the 3 months of records, the certified ME has discretion to grant the individual up to but not more than a 3-month MEC, MCSA-5876, to allow time for the individual to collect the necessary records. Once the individual has 3 months of blood glucose self-monitoring records, the individual is treated the same as an ITDM individual with 3 months of records. The individual must first go to the TC for evaluation and then to the certified ME, who must exercise independent medical judgment, to determine if the individual is eligible for up to the maximum 12-month MEC, MCSA-5876.

FMCSA has included the 3-month requirement for blood glucose self-monitoring records while being treated with insulin for all ITDM individuals. FMCSA has determined that there is no basis to differentiate blood glucose self-monitoring record requirements based on whether individuals have been newly diagnosed with type 1 diabetes or have type 2 diabetes and are converting to insulin use because both categories are beginning the use of insulin.

The Agency is requiring 3 months of records because this timeframe provides current blood glucose self-monitoring records to the TC, and is generally consistent with medical practice standards for follow-up visits for ITDM individuals. The Agency finds that this is a balanced approach for ITDM individuals that allows time to demonstrate a stable insulin regimen and proper control of ITDM, while providing enough information for the certified ME to determine whether the individual can safely operate a CMV.

The final rule does not establish the specific frequency of blood glucose monitoring. FMCSA finds that any regulatory requirement that specifies monitoring frequency does not support the intent of the rule for individualized assessment. Rather, the rule provides that ITDM individuals must self-monitor blood glucose in accordance with the specific treatment plan prescribed by the TC.

The TC is most familiar with the ITDM individual's medical history. As such, the TC is in the best position to determine the specific blood glucose monitoring plan, including monitoring requirements while driving a CMV, and whether the submitted blood glucose self-monitoring records are consistent with the plan. The Agency finds that this rule encourages the maintenance of blood glucose records in a manner that is focused on good monitoring practices, as well as maintaining proper control of the individual's diabetes and the overall health of the individual. Because daily testing and recording of results are routine aspects of managing ITDM, the rule's requirements do not impose any additional burden on ITDM individuals.

ITDM individuals must self-monitor blood glucose in accordance with the specific treatment plan prescribed by the TC. They must maintain blood glucose records measured with an electronic glucometer that stores all readings, that records the date and time of readings, and from which data can be electronically downloaded. A printout of the electronic blood glucose records or the glucometer must be provided to the TC at the time of any evaluation. Handwritten blood glucose records are not acceptable. As long as the ITDM individual can satisfy the foregoing requirements, the self-monitoring may be performed by finger stick or continuous glucose sensor.

O. Requirement to Carry Readily-Absorbable Glucose

NPRM:

In the NPRM, FMCSA did not propose that ITDM individuals must carry readily-absorbable glucose, which is required under the existing exemption program.

Comments on the Requirement to Carry Readily-Absorbable Glucose:

H&SW, Concentra, and a certified ME/physician commented that ITDM individuals should have readily-absorbable glucose within reach while driving to mitigate the risk of severe symptoms developing from a hypoglycemic episode. TFAC, on the other hand, stated that the requirement to carry readily-absorbable glucose is overly burdensome and would not improve safety.

2015 MRB Report:

The 2015 MRB report did not address carrying readily-absorbable glucose. No comments were received concerning the MRB report in this regard.

FMCSA Response:

The final rule does not require that ITDM individuals carry a readily-absorbable form of glucose. FMCSA finds that treatment for potential hypoglycemia is more appropriately a component of diabetes management as instructed by the TC rather than a mandate by a regulatory agency.

P. Diabetic Complications and Target Organ Damage

NPRM:

The NPRM proposed that ITDM individuals must meet the physical qualification standards in § 391.41 and be free of complications that might impair their ability to operate a CMV.

Comments on Diabetic Complications and Target Organ Damage:

Several commenters, including SOCO, the ATA, the NTSB, and the ACOEM, indicated that FMCSA should require evaluation of ITDM individuals to make sure that they do not show signs of diabetic complications or target organ damage. Commenters wanted ITDM individuals to be evaluated for complications such as diabetic neuropathy, paresthesia, and proprioception. Commenters also stated that ITDM individuals' kidney function should be evaluated by measuring creatinine. The ACOEM provided that an ITDM individual with kidney function worse than stage 3 should not be qualified. If the ITDM individual had stage 2 kidney function, the individual should be more closely monitored.

The ACOEM added that ITDM individuals have the same cardiovascular risk as someone with established coronary artery disease; thus, cardiovascular risk factors should be evaluated. The ACOEM recommended that ITDM individuals who meet certain Cardiovascular Advisory Panel Guidelines should be subject to the same medical qualifying criteria as those individuals with known coronary heart disease, including an exercise stress test. If there is evidence of ischemia, or the left ventricular ejection fraction is less than 40 percent, then the individual would be deemed ineligible for certification. SOCO also commented that FMCSA should require evaluation and documentation of the presence of coronary atherosclerosis and peripheral or cerebral vascular disease. Concentra commented that the safety risks from long-term comorbidities are too great not to be defined and that FMCSA should review the criteria with leading endocrinologists who specialize in diabetes. The NTSB wrote that many ITDM complications cannot be identified by a routine physical examination.

2015 MRB Report:

The MRB report recommended that, if there were signs of target organ damage, as evidenced by peripheral neuropathy, diabetic nephropathy, or cardiovascular disease, with the risk of impairing the ability to operate a CMV safely, an ITDM individual would be disqualified until the problem was resolved by treatment, if possible.

Comments on the MRB’s Report for Diabetic Complications and Target Organ Damage:

The ACOEM and the ADA supported the MRB recommendation, but the ACOEM added that there should not be a risk of the target organ damage recurring. An individual commented that the only factor should be whether the complication impairs the individual’s ability to safely operate a CMV. An MD commented that the language “signs of target organ damage” is not specific and may not be an appropriate disqualifier. The MD recommended that the query should be whether symptomatic target organ damage is present that could render an ITDM individual unsafe to operate a CMV. If so, the ITDM individual should be disqualified until the matter is resolved by treatment.

The University of Utah stated that the phrase “[d]isqualification until resolved by treatment, if possible” is unclear. It noted that one could not resolve a heart attack by treatment and generally it is impossible to completely resolve neuropathy. This commenter recommended that those with four or more multiple conditions should be precluded from driving. For nephropathy, the prior Renal Medical Expert Panel and MRB recommendations should be applied, including staging of the nephropathy.

Concentra asked for specific direction regarding the diagnostic tests, including their frequency, that should be used to evaluate cardiovascular disease and diabetic nephropathy in ITDM individuals. It also asked that FMCSA clearly define the severity of diabetic nephropathy that would warrant disqualification.

FMCSA Response:

In the final rule, the Agency continues to require that an ITDM individual must meet the physical qualification standards in § 391.41, have an exemption unrelated to diabetes, or have a Skill Performance Evaluation Certificate, if required. With the exception of diabetic retinopathy, the Agency declines to establish specific regulatory requirements pertaining to complications that may arise from diabetes.

The TC for the ITDM individual is best suited to provide information regarding diabetes complications. Moreover, the ITDM Assessment Form, MCSA-5870, adopted in this rule includes specific questions for the TC to identify diabetes complications and possible target organ damage. In making the final medical certification decision, the certified ME will consider the TC's information provided on the form in determining whether the individual meets the physical qualification standards to safely operate a CMV. FMCSA notes that the target organ complications associated with diabetes can result from any number of other medical conditions that certified MEs evaluate. Therefore, certified MEs should be familiar with the medical certification process involving such conditions.

FMCSA agrees with the MRB that an individual who has a complication from diabetes that interferes with safely operating a CMV should not be medically qualified to operate a CMV. The Agency finds, however, that diabetes complications should not automatically preclude medical certification. Such determinations should be based on an individualized assessment and the severity of symptoms. A complication becomes a disqualifying factor only if it impairs the ability to operate a CMV safely. As an alternative to disqualification, a certified ME may determine that an ITDM individual is

unqualified until treatment is received and appropriate intervention mitigates or addresses the problem.

Q. Motor Carrier Responsibility to Enforce the ITDM Standard

NPRM:

FMCSA did not propose any new requirements for motor carriers to enforce the ITDM physical qualification standard.

Comments on Motor Carrier Responsibility to Enforce the ITDM Standard:

The ATA stated that no responsibility for monitoring and submitting compliance information should fall on the motor carrier; instead, it wrote this responsibility most appropriately resides with the certified MEs, TCs, and the ITDM individuals. However, the ATA did want motor carriers to retain access to the health information available on the “medical long form” and other sources to monitor compliance with § 392.3. ABA stated that passenger carriers should not be “placed at the risk of assessing the medical condition of a driver or whether the driver is vigilant in maintaining [his or her] condition.”

2015 MRB Report:

The MRB did not address the issue of motor carriers enforcing the ITDM standard. No comments were received concerning the MRB report in this regard.

FMCSA Response:

The final rule revises the physical qualification standard for ITDM individuals, but does not create any new or additional monitoring or compliance requirements for motor carriers beyond those already set out in general terms in the FMCSRs. *See* 49 CFR 390.11, 391.11(a), and 391.41(a). The provisions of § 392.3 relate only to determining

whether to allow an ill or fatigued individual to operate a CMV. The rule does not require access to any medical records, such as an individual's Medical Examination Report Form, MCSA-5875, to make that determination.

R. ITDM Individuals Operating CMVs Transporting Passengers or Hazardous Materials

NPRM:

FMCSA did not propose to restrict ITDM individuals from being medically qualified to operate CMVs carrying passengers or hazardous materials but indicated that the MRB recommended in 2007 that ITDM individuals be restricted from passenger and hazardous materials transportation. The Agency requested public comment on this issue.

Comments on ITDM Individuals Operating CMVs Transporting Passengers or Hazardous Materials:

The ADA, the IBT, OOIDA, and the Illinois Office of the Secretary of State supported allowing ITDM individuals to continue to operate CMVs carrying passengers or hazardous materials. These commenters agreed with FMCSA that the risk posed by an individual with stable, well-controlled ITDM is very low in general and that there is no medical evidence to support prohibiting ITDM individuals from certain operations. The ADA stated that prohibiting individuals from certain types of operations based on their diagnosis or use of insulin alone is antithetical to the basic premise of individual assessment that Congress required in SAFETEA-LU. OOIDA added that individuals who transport hazardous materials are frequently some of the most experienced and safest operators on our nation's highways and their highway safety performance should be the focus, not an arbitrary condition-based decision.

Commenters that expressed concern about the Agency not restricting ITDM individuals from transporting passengers or hazardous materials include the NTSB, United Motorcoach Association (UMA), ABA, Advocates, and the former MRB members. UMA and ABA, however, supported continuing the current exemption program for drivers transporting passengers.

The NTSB and ABA questioned relying on the ADA study that FMCSA cited in the NPRM¹⁸ to support the Agency's conclusions. For example, the NTSB stated that the ADA report did not address the risks to public safety of ITDM individuals who operate CMVs. The NTSB noted that an individual's risk of becoming impaired from stable, well-controlled ITDM may not be higher among individuals who operate CMVs, but the potential consequences of such an event are significantly greater.

Advocates stated that research has shown individuals with diabetes in the United States have an increased crash risk, as do individuals treated with insulin. Advocates recommended that the Agency restrict ITDM individuals from transporting passengers or hazardous materials for a specified amount of time until they have driven freight under the conditions of the proposed regulations and have a safe driving record.

ABA commented that the 2007 MRB recommendation recognized that drivers of passenger vehicles are not conducting the same operations as cargo carrying CMV drivers, and required a higher medical standard. ABA noted that, although the Agency stated it is impermissible under the law to adopt higher physical standards for ITDM individuals, the law provides for exceptions, as demonstrated by the current exemption process.

¹⁸ ADA, "Diabetes and Driving," Diabetes Care, vol. 35, suppl. 1, Jan. 2012, p. S81, which is available in the docket for this rule.

UMA noted that over-the-road bus operations may not be conducive to maintaining proper blood glucose levels because schedules often vary and are not flexible, testing and snacking opportunities are limited, and passengers may become alarmed when observing a driver injecting insulin or monitoring blood glucose. UMA recommended that FMCSA study crash rates for ITDM individuals operating CMVs under the NPRM for at least 5 years before considering whether to allow ITDM individuals to obtain a passenger endorsement.

2015 MRB Report:

The 2015 MRB report did not mention the 2007 MRB recommendation proposing to restrict ITDM individuals from operating CMVs transporting passengers or hazardous materials cited in the NPRM.

Comment on the MRB's Report on ITDM Individuals Operating CMVs Transporting Passengers or Hazardous Materials:

Advocates noted the omission of the 2007 recommended restriction from the 2015 MRB report. It stated that the Agency is obliged to provide a full and complete discussion of the 2007 MRB recommendation, which it characterized as an important safety precaution. Advocates wrote that the revision of the medical requirements for ITDM individuals should ensure that they do not impose any greater risk of crash involvement than non-ITDM individuals operating CMVs that transport either passengers or hazardous materials.

FMCSA Response:

The Agency continues to conclude that individuals who maintain a stable insulin regimen and proper control of their ITDM can operate any category of CMV safely. No new information or data was provided by commenters that persuades the Agency to

depart from its conclusion. Under section 4129 of SAFETEA-LU, FMCSA may not hold ITDM individuals 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 regulations. The Agency finds that there is no available evidence to support holding ITDM individuals to a higher standard in connection with transporting passengers or hazardous materials. FMCSA addresses the issue of ITDM individuals' ability to safely operate CMVs in a following section.

S. ITDM Individuals with Licenses Issued in Canada or Mexico

NPRM:

The NPRM stated that ITDM individuals with licenses issued in Canada or Mexico would not be allowed to operate CMVs in the United States.

Comments on Not Allowing ITDM Individuals with Licenses Issued in Canada or Mexico to Operate CMVs in the United States:

FMCSA received two comments addressing this issue. The IBT commented that it supports continuing the current policy applicable to ITDM individuals domiciled in Canada and Mexico. A Canadian ITDM individual noted that Canada requires commercial operators to have a medical examination, monitor HbA1C results, and have a retinopathy examination done annually. Because the United States recognizes Canadian medical evaluations, this commenter suggested that FMCSA allow ITDM individuals with licenses issued by Canada to drive in the United States.

2015 MRB Report:

The MRB did not discuss certifying ITDM individuals from Canada or Mexico and no comments were received concerning the MRB report in this regard.

FMCSA Response:

FMCSA retains its position that ITDM individuals with licenses issued in Canada or Mexico are prohibited from operating CMVs in the United States. Individuals from Canada with a license issued in conformity with the Canadian National Safety Code and from Mexico with a Licencia Federal de Conductor (LFC) generally may operate CMVs in the United States (49 CFR 383.23(b) n.1 and 391.41(a)(1)(i)). Nonetheless, under the terms of the 1998 reciprocity agreement with Canada, a Canadian ITDM individual is not authorized to operate a CMV in the United States. Mexico does not issue an LFC to any ITDM individual. FMCSA cannot change its current position unless the underlying reciprocity agreement with Canada is amended or Mexico changes its policy to allow ITDM individuals to be issued LFCs.

T. The Grandfather Provision for Insulin-Treated Diabetes

NPRM:

From 1993 until 1994, ITDM individuals could apply to the FHWA for a waiver that allowed them to drive a CMV in interstate commerce. In 1994, a Federal court decision invalidated the waiver program, but individuals holding waivers were allowed to continue to drive CMVs under the grandfather provision in § 391.64(a). In the NPRM, FMCSA stated that the provisions in § 391.64 might be redundant if the proposed rule was adopted, and asked if removing § 391.64 would affect adversely any individual still operating a CMV under that rule.

Comments on Removing the Grandfather Provision for Insulin-Treated Diabetes:

A physician/certified ME concurred with FMCSA that § 391.64 would be redundant if the proposed rule was adopted. He stated that, with the termination of the diabetes exemption program, § 391.64 should be eliminated. This commenter did not see

how individuals certified under § 391.64 would be affected adversely by eliminating the grandfather provision.

The Illinois Office of the Secretary of State stated that removing the grandfather provision would not adversely affect individuals currently operating CMVs under § 391.64. This commenter noted that there are currently 10 operators in Illinois who are grandfathered under § 391.64. The commenter wrote that holding these individuals to the approach proposed in the NPRM would not impact their safety or the safety of other motorists adversely.

2015 MRB Report:

The 2015 MRB report did not discuss the grandfather provision and no comments were received concerning the MRB report in this regard.

FMCSA Response:

In the final rule, FMCSA eliminates the diabetes grandfather provision in § 391.64(a). FMCSA agrees with the commenter that the grandfather provision is redundant of several requirements in new § 391.46. Individuals currently certified under § 391.64 are either already able to meet the requirements of this rule or could meet a less restrictive requirement. FMCSA finds that discontinuing the grandfather provision has no adverse impact on the less than 100 currently grandfathered individuals or on motor carriers. FMCSA provided a year to transition to the new process to avoid any possible hardships for individuals who would need to be certified just after the rule becomes effective. FMCSA is directly contacting the currently grandfathered individuals to further explain the transition process.

The diabetes grandfather provision in § 391.64(a) will sunset and will be removed 1 year after the effective date of this final rule. During that year, individuals certified under the grandfather provision may choose to be certified under § 391.64(a) or this final rule. Within 1 year after the effective date, however, all individuals previously certified under § 391.64(a) must comply with the provisions outlined in §§ 391.41, 391.45, and 391.46 in the final rule. As such, any individual who chooses to be certified under § 391.64(a) must be certified again under this final rule within a year after the effective date, which would mean that the individual would have to undergo a second evaluation by a TC and a medical qualification examination. FMCSA anticipates that it will be advantageous for individuals certified previously under § 391.64(a) to transition to certification under this rule as soon as possible to avoid duplicative examination costs and to potentially reduce costs by being evaluated by a TC, rather than by an endocrinologist. In any event, any waiver and current MEC, MCSA-5876, issued pursuant to § 391.64(a) will automatically become void 1 year after the effective date of the final rule.

U. Safety of ITDM Individuals

NPRM:

The NPRM proposed to permit individuals with stable, well-controlled ITDM to be medically qualified to operate CMVs and to eliminate the diabetes exemption program. The Agency determined that “[t]he risk posed by a driver with stable, well-controlled ITDM is very low in general” (80 FR 25265). In making this determination, the Agency concurred with a finding of the ADA in its 2012 position statement titled

“Diabetes and Driving” that “[M]ost people with diabetes safely operate motor vehicles without creating any meaningful risk of injury to themselves or others.”¹⁹ *Id.*

Comments on the Safety of ITDM Individuals:

Many commenters agreed specifically that ITDM individuals whose condition is stable and well controlled do not pose an unreasonable safety risk. For example, the National School Transportation Association agreed with this conclusion and expressed support for the proposed rule as it applies to CMV operators driving school buses. Additionally, the Transportation Division of the Sheet Metal, Air, Rail Transportation Union pointed out data in the Preliminary RIA published with the NPRM showed that the 1,730 drivers in the exemption program performed much better than the general CMV population in terms of crash rates. Several commenters noted that the rulemaking alleviates the burden of the exemption process, while maintaining safety. OOIDA concurred that the proposed rule would continue to ensure safe operation of CMVs.

Several commenters, including some medical professionals, the ACOEM, ABA, and the NTSB, stated that changing the exemption program would decrease safety. TFAC supported removing the exemption program but stated that the proposed rule went too far in removing requirements and a compromise group of requirements would be appropriate. H&SW also concurred with the proposal to eliminate the diabetes exemption program, but expressed that it is in the best interest of road safety to maintain some of the important provisions of the exemption program. Advocates acknowledged recent advances in medical information regarding ITDM and expressed support for a change to the medical standards to permit ITDM individuals to operate CMVs. Advocates

¹⁹ ADA, “Diabetes and Driving,” Diabetes Care, vol. 35, supp1. 1, Jan. 2012 p. S81, which is available in the docket for this rulemaking.

maintains, however, that the requirements for ITDM individuals should incorporate the recommendations of the 2007 MRB that were cited in the NPRM.

The former MRB members disputed FMCSA's conclusions on the safety of ITDM individuals. They cited five studies²⁰ and FMCSA's 2006 Diabetes Evidence Report²¹ that they stated show drivers with diabetes have about a 20 percent increased risk of crash and drivers taking insulin have a 40 to 130 percent increased risk of crash. When parsing the data down to insulin use and studies based in the United States, the former MRB members stated that FMCSA's 2010 Evidence Report Update²² found that the risk of crash is likely doubled, even though the result currently lacks statistical significance. They stated that a study shows that efforts to keep HbA1C below 7 percent "is a substantial concern for further increasing crash risk."²³

The former MRB members asserted that an implied purpose of eliminating the diabetes exemption program is to increase the number of ITDM individuals operating CMVs. The former MRB members indicated that it is inappropriate to infer from the diabetes waiver program, the diabetes exemption program, and The Large Truck Causation Study what would happen to a larger pool of ITDM individuals.

The NTSB stated that the Agency's justification for the proposed rule is flawed because the ADA position statement does not address the risks to public safety of CMV

²⁰ Songer TJ, Lave LB, LaPorte RE. Risk Anal. 1993 Jun; 13(3): 319-26.
Songer TJ, Dorsey RR. Annu Proc Assoc Adv Automot Med. 2006; 50: 335-351.
Redelmeier DA, Kenshole AB, Ray JG. PLoS Med. 2009 Dec; 6(12): e1000192.
Kilpatrick ES, Rigby AS, Warren RE, Atkin SL. Diabet Med. 2013 May; 30(5): 616-9.
Orriols L, et al. Accid Anal Prev. 2014 Oct; 71: 137-43.

²¹ "Evidence Report: Diabetes and Commercial Motor Vehicle Drive Safety," Sept. 8, 2006, which is available in the docket for this rulemaking.

²² "Evidence Report: 2010 Update: Diabetes and Commercial Motor Vehicle Driver Safety," May 27, 2011, which is available in the docket for this rulemaking.

²³ Kilpatrick ES, Rigby AS, Warren RE, Atkin SL. Diabet Med. 2013 May; 30(5): 616-9.

drivers with ITDM. H&SW also stated the Agency should not apply the ADA information on driving non-CMV's to driving CMV's. In addition, Advocates disagreed with the Agency's safety conclusions and cited FMCSA's 2010 Evidence Report Update, which it quoted as stating that in the United States there is "approximately a 24 percent increase in crash risk among drivers with diabetes compared with drivers without diabetes," and "a significant increase [175%] in crash risk for individuals treated with insulin compared with drivers treated with oral medication and/or diet alone." Based on this information, Advocates urged the Agency to adopt the 2007 MRB recommendations.

2015 MRB Report:

The 2015 MRB report did not address the safety of ITDM individuals but stated that the baseline for acceptable risk should be the current diabetes exemption program.

Comments on the MRB's Report on Safety of ITDM Individuals:

Few commenters specifically referenced data in connection with evaluating the safety of ITDM individuals. For example, OOIDA commented that, since the implementation of the exemption program in 2003, individuals with a stable history of treating their insulin dependent diabetes have proven to be safe CMV operators. OOIDA was "unaware of any studies that have been conducted or any serious concerns that have been raised concerning those drivers who have completed the current exemption process."

In contrast, the University of Utah stated that FMCSA's 2010 Evidence Report Update notes that the risk of crash among ITDM individuals in the United States is now estimated to be a 2.76-fold increased risk. The commenter stated that this risk is so high that it means there may be a very small minority of ITDM individuals who may be

reasonably safe, and that “[i]t demonstrates that the overwhelming majority of insulin using drivers are unsafe for driving commercial vehicles.” The commenter noted that the United States-based data are naturally the most important to the question of safety, as European countries’ populations have comparatively minor needs to drive motor vehicles. Therefore, European populations are arguably not comparable to the United States.

The University of Utah also stated that DOT’s insulin waiver program, which had stringent criteria and enrolled 139 drivers in the 1990s, had subsequent crash data that suggested there was not an increased risk of crash for those individuals. The commenter noted that the comparison group of general CMV drivers likely included drivers who should not have been driving; thus, it was likely a biased control group. The University of Utah continued that FMCSA has subsequently had a fairly-stringent diabetes exemption program and it should be mandatory to examine the crash risks from that program prior to consideration of this proposal. While the crash data would still have the problem of a biased control population, the commenter stated that it would provide a somewhat reasonable comparison with the prior waiver program and help to determine whether and the extent to which both driver safety and public safety can be assured. Finally, the commenter recommended that there should be a pilot test with monitoring of crash risks before expanding the medical qualification of ITDM individuals.

FMCSA Response:

The Agency continues to conclude that the crash risk posed by ITDM individuals who maintain a stable insulin regimen and proper control of their diabetes is very low in general and that such ITDM individuals do not create any meaningful risk of injury to

themselves or others due to their insulin treatment. Although the Agency acknowledges that there is conflicting data regarding the crash risk posed by ITDM individuals, no new data have been presented by commenters to persuade the Agency to depart from its prior conclusions. Moreover, the Agency has determined that this final rule includes sufficient requirements and safeguards to ensure that only individuals who maintain a stable insulin regimen and proper control of their ITDM will receive medical qualification. Therefore, this final rule has no adverse impact on safety.

The Agency acknowledges that the 2012 ADA position statement focused primarily on non-CMV drivers. FMCSA emphasizes, however, that it is not the only source the Agency has considered in making its determination that the risk posed by ITDM individuals who maintain a stable insulin regimen and proper control of their diabetes is very low. The Agency has considered its Evidence Reports, information presented by commenters, and its own experience with CMV drivers.

As a commenter suggested, because there are few studies that evaluate ITDM individuals who operate CMVs, the Agency's actual experience with such individuals is highly relevant. Considering the long period over which the exemption program has operated, the Agency has determined that there is sufficient data to allow generalized conclusions to be reached. FMCSA's experience with the exemption program has demonstrated that the safety performance of ITDM individuals who hold exemptions is as good as that of the general population of CMV drivers. As set forth in the NPRM, on a per-driver, per-year basis, the crash rate for drivers with an exemption was 0.013, as compared to about 0.038 crashes per year per active CMV driver. As is discussed more fully in the RIA, a November 2016 analysis of the safety performance of ITDM

individuals who held exemptions for the full period of 2011 through 2015 shows the 755 diabetes exemption holders had 58 crashes that resulted in a crash rate of 0.01536 crashes per driver per year. This compares to a crash rate of 0.03115 crashes per driver per year for a national population of 4,599,623 drivers and 143,289 crashes. These results were deemed to be demonstrative that exemption program crash rates were of the same order of magnitude as the national crash rate derived from the Motor Carrier Management Information System data. The analysis proceeded to determine if the 0.02986 crash rate for treatment group drivers was significantly different than the 0.02627 crash rate for the control group drivers, at a 95 percent confidence level. The analysis indicated that there was no statistical difference between the treatment group and control group crash rates at the 95 percent confidence level.²⁴

Although the Agency fully considered FMCSA's 2006 Diabetes Evidence Report and the 2010 Evidence Report Update at the time of the NPRM, the Agency will briefly address the 2010 Evidence Report Update due to comments regarding the crash risks provided in the report. The report found that the overall quality of the crash risk studies reviewed was low to moderate. Because only a single study compared crash risk among CMV drivers with diabetes against comparable CMV drivers without diabetes, an evidence-based conclusion regarding possible increased crash risk for CMV drivers with diabetes could not be drawn. The strength of evidence for the overall finding that drivers with diabetes are at an increased risk for a crash when compared with comparable drivers who do not have diabetes was determined to be weak. It could not be determined whether

²⁴ "Safety Performance of Drivers with Medical Exemptions: How safe are drivers in a medical exemption program compared to those who are not?" Nov. 2016, which is available at <https://rosap.ntl.bts.gov/view/dot/31521> (June 1, 2018).

drivers with type 1 or type 2 diabetes or ITDM drivers were overrepresented in populations of drivers who have experienced a motor vehicle crash. As such, the report's findings are inconclusive at best.

The report noted that studies conducted in the United States showed approximately a 24 percent increase in crash risk among drivers with diabetes compared with drivers without diabetes. This finding, however, was based on six studies that were published in 1965, 1968, 1973, 1988, 1991, and 2003. The Agency agrees with Advocates that knowledge and treatment of diabetes has increased significantly in recent years. Because the studies reviewed most likely do not reflect current treatment practices and protocols, the Agency has determined that they are of little probative value with respect to the present issue. The report noted that in the United States there was a significant increase in crash risk (2.753) for individuals treated with insulin when compared with drivers treated with oral medication and/or diet alone. It continued that a firm conclusion could not be made with respect to this finding because there were only two studies to review. In addition, those studies, which were published in 1988 and 2003, are too old to provide probative evidence. FMCSA finds that its more recent data that relates directly to ITDM individuals who operate CMVs are more relevant in assessing crash risk in such individuals.

The Agency has reviewed the five journal articles referenced by the former MRB members. Three of the articles examine the relationship between diabetes and crash risk for drivers in foreign countries. Because of potential differences in the experience and training of drivers, driving regulations, and the treatment of diabetes, drivers in foreign countries may not be comparable to those in the United States. The Agency agrees,

therefore, with the University of Utah that United States-based data are the most important to assessing the safety risk at issue. One of these articles was cited by the former MRB members for the proposition that increased crash risk is associated with efforts to maintain tight blood glucose control with HbA1C below 7 percent. In as much as this rule has not prescribed a specific HbA1C level that must be achieved to be medically qualified, the rule does not provide an incentive to maintain HbA1C levels below 7 percent. This was the only one of the three articles that included CMV operators; however, it also included non-CMV drivers and did not differentiate between the two types of drivers in the statistical analysis.

A fourth article examined the extent to which there is an age-related component to crash risk among individuals with type 1 diabetes. The article concluded that reported crashes decline with age in all persons, but the crash risk remained higher for persons with diabetes throughout the age span. There was no relationship between crashes and diabetes complications, blood glucose control, and diabetes treatment patterns. Severe hypoglycemia was consistently and strongly related to crashes at all ages.²⁵ However, the authors found that the link between reported hypoglycemia history and reported crashes was indirect, and it was not possible to determine the extent to which hypoglycemia actually contributed to the reported crashes. Additionally, the number of crashes identified was low; therefore, the article concluded further study was necessary to establish the relationship between hypoglycemia and crashes.²⁶ The article does not identify whether it included CMV operators. It also included drivers under the age of 21, who generally would not qualify to obtain an interstate CDL. Finally, the article included

²⁵ Songer TJ, Dorsey RR. Annu Proc Assoc Adv Automot Med. 2006; 50: 348.

²⁶ *Id.* at 349.

individuals with retinopathy who may not be eligible under this rule to be medically qualified to operate a CMV.

The fifth study presents the results of an analysis in which the number of crashes are estimated for a hypothetical group of ITDM truck drivers with an estimated incidence of mild and severe hypoglycemia, an estimated number of reactions while driving, and an estimated likelihood of a crash during a mild or severe hypoglycemic reaction, as compared to a second hypothetical group of truck drivers who are not insulin dependent. Because the article was not based on actual data and was published in 1993, FMCSA finds that this article is unreliable and is no longer relevant.

For the reasons discussed above, the Agency finds that the five articles cited by the former MRB members are not as persuasive as FMCSA's actual experience with crash risk for ITDM individuals who drive CMVs.

The Agency conducted a review of the literature regarding safety of ITDM individuals to identify studies performed after the 2010 Evidence Report Update. The Agency did not find any literature pertaining to the safety risk of ITDM individuals operating CMVs other than its own studies.

FMCSA declines to pursue a pilot period prior to implementing this rule, as a commenter has suggested. FMCSA finds that the current exemption program has demonstrated that ITDM individuals can drive a CMV in a manner as safe or safer than other CMV drivers.

V. Costs and Benefits of the Proposed Rule

NPRM:

The NPRM stated that this rulemaking would not have a significant economic impact. Compared to other CMV drivers, ITDM individuals would incur costs for an additional medical examination of \$150 annually; however, they would have the ability to earn a living without the inconvenience and added costs of obtaining and maintaining an exemption.

Comments on Costs and Benefits of the Proposed Rule:

FMCSA received comments discussing the costs and benefits associated with the proposed rule. Two commenters provided information about potential cost savings. TFAC noted that FMCSA did not account for cost savings to existing drivers with type 2 diabetes who are trying to avoid insulin treatment. TFAC indicated that enabling ITDM individuals to be qualified to operate CMVs would remove the incentive to avoid insulin treatment and would allow medical professionals to treat their CMV-driver patients with type 2 diabetes in the most appropriate, cost-effective manner. An ITDM individual estimated his costs would decrease by at least \$600 annually from eliminating three of his four annual visits to the endocrinologist. The IBT, TTD, and OOIDA commented that the exemption program is a time consuming and financially burdensome process that can result in lost income and possibly job loss while waiting for FMCSA to grant an exemption.

Two commenters said FMCSA underestimated the cost of the proposed rule. A certified ME, who is a physician, stated that because the rule transfers the “function and responsibilities” for medically qualifying an ITDM individual from the Agency to the certified ME, as a physician, he would continue to require at least annual assessments from an ophthalmologist and endocrinologist, and increase his charges to compensate for

the increased time and risk involved in certifying ITDM individuals. This commenter also indicated that the costs saved by FMCSA will be transferred as costs to ITDM individuals and certified MEs.

A different physician asserted that the Agency did not account for several costs associated with the elimination of the exemption program. The physician stated that “to avoid hypoglycemia, the CMV driver will not be able to maintain tight control which will accelerate the progression for the [insulin-treated CMV driver] to develop eye, nerve, and kidney complications.” The physician suggested that FMCSA did not address the increased cost on the medical system of ITDM individuals avoiding hypoglycemia or consider the impact of the proposed rule on the organ systems and lifespan of ITDM individuals. The commenter noted that “[i]n, 2011, about 282,000 emergency room visits for adults aged 18 years or older had hypoglycemia as the first-listed diagnosis and diabetes as another diagnosis.” Additionally, in 2011, about 175,000 emergency room visits for people of all ages had hyperglycemic crisis as the first-listed diagnosis.

2015 MRB Report:

The 2015 MRB report did not address the costs and benefits of the proposed rule.

Comments on the Costs and Benefits of the MRB’s recommendations:

A few commenters discussed the costs and benefits of the 2015 MRB recommendations. For example, OOIDA supported most of the MRB recommendations and noted that the recommendations provide a more efficient and progressive approach than the current exemption process, which is costly and burdensome. OOIDA stated that the exemption process can take 180 days or more, plus a 30-day public comment period, and the costly time off-the-road can put an owner-operator out of business. In addition,

the cost of seeing an endocrinologist can easily reach \$200 a visit. An individual, however, stated that the 2015 MRB recommendations would increase the burden on the ITDM individual, creating twice the amount of work and expense for the individual and a high risk of suspension or loss of license.

FMCSA Response:

The RIA published with this final rule does account for cost savings from replacing four endocrinologist visits with one visit to a TC. FMCSA estimated the average cost of an office visit with an endocrinologist at \$280, including \$60 for the opportunity cost of an assumed 2 hours for the ITDM individual's time to complete the appointment, versus \$223, inclusive of the ITDM individual's time, for a TC evaluation. The annual evaluation and quarterly visits under the exemption program are estimated at \$1,120, which compares to the \$223 annual cost for the TC evaluation.

The Agency does not have sufficient data, nor did TFAC provide any substantive data, to confirm TFAC's assertion that the rule will provide cost savings because type 2 non-ITDM drivers will no longer have the incentive to continue using oral medication to avoid insulin.

In response to OOIDA, the TTD, and the IBT comments, the Agency finds that it is appropriate to estimate the income forgone by an existing CMV operator who begins treatment with insulin. Thus, in the RIA, the Agency included in the exemption program baseline a nonrecurring cost of \$4,235 per ITDM individual for existing CMV operators who begin treatment with insulin.

The Agency disagrees with the certified ME's assertion that the final rule shifts risk to certified MEs and ultimately to individuals in the form of higher fees. FMCSA

does not regulate the fees the certified ME charges, but continues to believe fees are established by market forces that will not be altered by this rule. In addition, the final rule does not prevent a certified ME from mitigating the perceived risk of performing medical examinations on ITDM individuals by restricting the certified ME's practice to non-ITDM individuals.

FMCSA disagrees with the commenter who stated that the Agency did not consider that tight control to avoid hypoglycemia will accelerate the progression of diabetic complications. The Agency did not specify ranges for either HbA1C or blood glucose that would apply to all ITDM individuals. By not specifying such ranges, the Agency provides the TC with the flexibility to establish and adjust an ITDM individual's insulin regimen that will minimize the emergence of complications and the occurrence of hypoglycemic episodes. The commenter did not offer sufficient data to support the assertions that in 2011 the number of emergency room visits for hypoglycemia and hyperglycemia demonstrates that FMCSA failed to recognize such costs. Moreover, the data cited was for a subset of individuals with coexisting diabetic complications. Finally, FMCSA does not maintain data on the lifespan of ITDM individuals. Factors other than the impact of diabetes on target organs affect an ITDM individual's lifespan. It is beyond the scope of this rule to determine the cause of death of ITDM individuals that may occur years after they operate a CMV.

W. Privacy Issues

NPRM:

In the NPRM, the Agency determined that the privacy risks and effects associated with the proposed rule were not unique and had been addressed in other rules.

Comments Related to Privacy Issues:

The IBT expressed its concern about privacy issues related to releasing medical information. According to the IBT, in many instances the certified ME is a “company doctor” who requests the entire medical file for individuals as a prerequisite to performing a certification examination. To obtain that information, the certified ME requires individuals to sign a “blanket authorization,” which allows the certified ME to release the individual’s medical file to insurance companies, the employer, and various other entities. The IBT stated that motor carriers should not be allowed to improperly use the regulations in 49 CFR part 391 as justification to obtain and release to third parties information that is not relevant to determining whether an individual is qualified to operate a CMV.

2015 MRB Report:

The 2015 MRB report did not discuss privacy issues and no comments were received concerning the MRB report in this regard.

FMCSA Response:

This final rule does not change the laws and regulations applicable to the use or disclosure of an individual’s medical information. As such, comments regarding the release of medical information to employers are outside the scope of this rulemaking. Nonetheless, FMCSA notes that TCs and certified MEs are bound by the privacy protections outlined under the Health Insurance Portability and Accountability Act (HIPAA), which establishes national standards to protect individuals’ medical records and other personal health information. HIPAA requires appropriate safeguards to protect the privacy of personal health information and sets limits and conditions on the uses and

disclosures of such information that may be made without authorization by an individual. Therefore, an individual would have to provide his or her consent for a TC or certified ME to share medical information with other entities, including the motor carrier. More information on HIPAA and its requirements can be found on the Department of Health and Human Services' website at <https://www.hhs.gov/hipaa/for-professionals/privacy/index.html>.

X. Other Comments

Comments on Procedural and Other Issues in the NPRM:

Some commenters expressed concerns about procedural or documentation matters related to the proposed rule. For example, Advocates stated that the Expert Panel Opinion resulting from the MRB review of the 2010 Evidence Update Report had not been published on FMCSA's website or added to the docket for this rulemaking.

H&SW suggested adding a checkbox to the MEC, MCSA-5876, that states the individual is physically qualified to operate a CMV when managing his or her condition so the roadside inspector would know the individual has ITDM. H&SW noted that roadside inspectors are not clinicians; therefore, the requirements must set a blood glucose limit to help them determine whether an ITDM individual should operate a CMV. In contrast, TFAC strongly opposed any requirements that would make information on an individual's ITDM status available to roadside enforcement.

Comments on the Other Issues in the MRB Report:

In terms of procedural issues in response to the 2015 MRB report, Advocates stated that the MRB report was sent to the Agency on September 1, 2015, but the Agency took until September 9, 2016, before publishing the report for comment.

FMCSA Response:

As explained elsewhere in this final rule, FMCSA is not specifying any blood glucose level that would prevent an ITDM individual from operating a CMV; therefore, there is no need for involvement of enforcement personnel. The final rule does not provide any changes to the MEC, MCSA-5876. As with any other medical condition, if a driver possesses a valid MEC, MCSA-5876, the certified ME has determined that the ITDM individual has met FMCSA's physical qualification requirements. Therefore, adding a separate designation on the MEC, MCSA-5876, would serve no purpose for enforcement personnel.

In response to the two comments from Advocates, the Agency notes that there is no expert panel commentary in response to the 2010 Evidence Update Report. The Meeting Summary for the June 30, 2011, MRB meeting shows that FMCSA's contractor presented a summary of the results of the 2010 Evidence Update Report to the MRB, and the MRB decided not to request another expert panel following the report.²⁷ To clarify, the MRB recommendations referenced in the NPRM were those provided at the MRB's July 26, 2007, meeting.²⁸ The 2015 MRB report was available for public viewing on FMCSA's website on September 3, 2015, just 2 days after the date of the report. Although the notice of availability was not published until September 9, 2016, the public was provided a meaningful opportunity to comment on the report. Comments received in response to the 2015 MRB report are addressed in this final rule.

Y. Outside the Scope

Comments Outside the Scope of the NPRM:

²⁷ See <https://www.fmcsa.dot.gov/summary-june-30-2011-medical-review-board-public-meeting>.

²⁸ See <https://www.fmcsa.dot.gov/summary-july-26-2007-medical-review-board-public-meeting>.

Several commenters suggested adjustments to the proposed rule such as technological initiatives that are outside the scope of this rule; therefore, a response is not required. For example, one commenter stressed the importance of individuals with diabetes controlling their blood sugar levels, noting both low and high blood glucose index values can impede thinking, and recommended developing technology that would continually monitor the blood glucose index to alert the ITDM individual to highs or lows.

Comments Outside the Scope of the MRB Report:

The following commenters offered some observations that fall outside the scope of the recommendations of the 2015 MRB report. An individual recommended Bydureon as an alternative treatment to placing individuals on insulin. An owner-operator commented on being unable to obtain a CDL since he was prescribed insulin. He stated that, even though his diabetes is under control and he does not haul long distance, the current rule disqualifies him from operating CMVs. He requested that the Agency provide an exemption for individuals with controlled diabetes who haul short distances.

VII. SECTION-BY-SECTION ANALYSIS

This section includes a summary of the regulatory changes in 49 CFR part 391 organized by section number.

§ 391.41 Physical Qualifications for Drivers

In § 391.41, paragraphs (a), (b)(1), and (b)(2) are not altered.

Paragraph (b)(3) adds an exception at the end of the sentence to indicate that there are requirements provided in § 391.46 for individuals who have diabetes mellitus treated with insulin for control.

Paragraphs (b)(4) through (b)(13) are not modified.

§ 391.45 Persons Who Must be Medically Examined and Certified

Other than deleting “of this subpart” from the existing introductory paragraph, the introductory paragraph and paragraph (a) are not altered.

The content from paragraph (b)(1) becomes new paragraph (b) and adds an exception with a reference to the newly created paragraphs (c), (d), (e), (f), and (g) of this section.

Existing paragraph (b)(2) is separated to form new paragraphs (c) and (d) of this section. These new paragraphs are slightly modified for clarity and readability.

New paragraph (e) is inserted to require compliance with new § 391.46.

Content from existing paragraph (c) is moved to new paragraph (f).

Content from existing paragraph (d) is moved to new paragraph (g).

§ 391.46 Physical Qualification Standards for an Individual with Diabetes Mellitus Treated with Insulin for Control

This final rule codifies a new § 391.46.

Paragraph (a), *Diabetes mellitus treated with insulin*, states that ITDM individuals may be physically qualified if they meet certain criteria. Paragraph (a)(1) states that ITDM individuals are required to meet the physical qualification standards or hold an exemption. Paragraph (a)(2) explains that ITDM individuals must have the evaluation and medical examination, as required by paragraphs (b) and (c).

Paragraph (b), *Evaluation by the treating clinician*, states that the ITDM individual must have a TC evaluation completed before any medical examination by the certified ME and defines a TC. Paragraph (b)(1) requires the TC to complete the ITDM

Assessment Form, MCSA-5870. Paragraph (b)(2) requires TCs to sign and date the form, and provide their business contact information on the form.

Paragraph (c), *Medical examiner's examination*, sets forth the requirements for the certified ME's examination, including that the examination must begin no later than 45 days after the individual's TC evaluation. Paragraph (c)(1) states that the certified ME must have an ITDM Assessment Form, MCSA-5870, for each examination. Paragraph (c)(2) provides that the certified ME is to make a medical qualification determination by considering the information in the ITDM Assessment Form, MCSA-5870, and, using independent medical judgement, by applying the medical qualification standards in the paragraph. The standards provide that an individual must maintain a stable insulin regimen and proper control of his or her diabetes, and cannot have severe non-proliferative diabetic retinopathy or proliferative diabetic retinopathy. The standards also establish the requirements for blood glucose self-monitoring for ITDM individuals.

New paragraph (d), *Blood glucose self-monitoring records*, discusses the blood glucose record-keeping requirements, including submitting those records to the TC during the evaluation.

New paragraph (e), *Severe hypoglycemic episodes*, provides that an ITDM individual who experiences a severe hypoglycemic episode, which is defined in the paragraph, is prohibited from operating a CMV and must report the episode to and be evaluated by a TC as soon as is reasonably practicable. The prohibition from operating a CMV continues until the ITDM individual has been evaluated by a TC, and the TC determines that the cause of the severe hypoglycemic episode has been addressed and that the individual again has a stable insulin regimen and properly controlled ITDM.

Once a TC completes a new ITDM Assessment Form, MCSA-5870, following the episode, the individual may resume operating a CMV. The ITDM individual must retain and provide the form to the certified ME at the individual's next medical certification examination.

§ 391.64 Grandfathering for Certain Drivers Participating in Vision and Diabetes Waiver Study Programs

FMCSA inserts new language at the beginning of existing paragraph (a) that provides this rule will not apply to individuals certified pursuant to § 391.64(a) until 1 year after the effective date of the rule. During that year, individuals certified under the grandfather provision may choose to be certified under § 391.64(a) or this final rule.

FMCSA adds new paragraph (a)(3) to remove and void all of paragraph (a) 1 year after the effective date of this rule; thus, eliminating certification under § 391.64(a). FMCSA also adds an amendatory instruction for the deletion of paragraphs (a) through (a)(3) 1 year after the effective date of this rule. On this date, this language will be stricken from the regulation and paragraph (a) will be reserved.

Updates to Appendix A to Part 391 - Medical Advisory Criteria

FMCSA removes paragraph II.C., *Diabetes § 391.41(b)(3)*, in its entirety. That paragraph outlines advisory guidelines for the diabetes standard. These guidelines are no longer necessary because this final rule creates a new standard for ITDM individuals.

Updates to Guidance Q&A for § 391.41, Question 3

FMCSA also revises guidance for § 391.41, Question 3. In the answer to Question 3, FMCSA will remove "four" and replace it with "three" to update and reflect the correct number of medical conditions that are not subject to the certified ME's judgement, and

remove “insulin-using diabetes” from the list of conditions for which the certified ME has no discretion.

The answer to Question 3 of the guidance for § 391.41 will now read as follows: “The qualification standards cover 13 areas that directly relate to the driving functions. All but three of the standards require a judgement by the medical examiner. A person’s qualification to drive is determined by a medical examiner who is knowledgeable about the driver’s functions and whether a particular condition would interfere with the driver’s ability to operate a CMV safely. In the case of vision, hearing, and epilepsy, the current standards are absolute, providing no discretion to the medical examiner.”

VIII. INTERNATIONAL IMPACTS

The FMCSRs, and any exceptions to the FMCSRs, apply only within the United States (and, in some cases, United States territories). Motor carriers and drivers are subject to the laws and regulations of the countries in which they operate, unless an international agreement states otherwise. Drivers and carriers should be aware of the regulatory differences among nations. As stated previously, ITDM individuals with licenses issued in Canada or Mexico will not be allowed to operate CMVs in the United States.

IX. REGULATORY ANALYSES

A. E.O. 12866 (Regulatory Planning and Review), E.O. 13563 (Improving Regulation and Regulatory Review), and DOT Regulatory Policies and Procedures

FMCSA determined that this final rule is not a significant regulatory action under section 3(f) of E.O. 12866 (58 FR 51735, Oct. 4, 1993), Regulatory Planning and Review, as supplemented by E.O. 13563 (76 FR 3821, Jan. 21, 2011), Improving Regulation and Regulatory Review, and does not require an assessment of potential costs

and benefits under section 6(a)(3) of that Order. Accordingly, OMB has not reviewed it under that Order. It is also not significant within the meaning of DOT regulatory policies and procedures (DOT Order 2100.5 dated May 22, 1980; 44 FR 11034, Feb. 26, 1979). The Agency, however, has considered the total costs and benefits of this final rule and determined they are less than \$100 million annually.

The objective of the final rule is to replace the exemption program with a less time consuming and less costly process that continues to ensure that ITDM individuals can operate CMVs safely. The final rule also provides a clearer, equally effective, and more consistent framework than a program based entirely on exemptions. In the following sections, the Agency describes the impacts of the rule to the entities listed in Table 2 (above).

Costs to ITDM Individuals Currently Compliant with the Exemption Program

The Agency estimates that there are presently 5,000 ITDM individuals that have exemptions (4,879 = 3,945 FMCSA exemption holders + estimated 930 State exemption holders rounded to the nearest thousand).²⁹ As the compliance costs of the exemption program are greater than those of the final rule, the Agency assumes that these ITDM individuals will comply with the final rule. Because these ITDM individuals have already obtained an MEC, MCSA-5876, and an exemption, the baseline costs for this group consist of annual recurring medical and associated expenses for examinations necessary to maintain their exemption.

²⁹ See RIA Section 2.5.2 for the detailed development of the estimated number of State exemption holders.

To gauge the final rule's cost impact to these ITDM individuals, it is necessary to compare their compliance costs pre- and post-rule. The Agency estimates the recurring costs in the baseline for an ITDM individual to maintain an exemption as follows:

- The opportunity cost of 1 hour of time to prepare a renewal application: \$30;³⁰
- The cost of four endocrinologist office visits, consisting of one annual complete medical examination plus three quarterly office visits. The cost of each endocrinologist office visit is \$280 (inclusive of the ITDM individual's time to complete the examination).³¹ Therefore, these ITDM individuals would each incur \$1,120 ($\$1,120 = \280×4) per year in compliance costs related to this component of the exemption program;
- The cost for an annual comprehensive eye examination: \$260 (inclusive of the opportunity cost of the ITDM individual's time to complete the examination).³² However, Centers for Disease Control and Prevention (CDC) data indicate that approximately 65 percent of individuals with diabetes receive annual dilated vision examinations.³³ Therefore, FMCSA assumes that only 35 percent of the \$260 comprehensive eye examination cost is a cost attributable to the exemption

³⁰ The opportunity cost of drivers' time is estimated in RIA Section 2.6.1.

³¹ This cost is estimated in RIA Section 2.6.3.

³² *Id.*

³³ CDC, Division of Diabetes Translation, *Diabetes Report Card 2014*, p. 9. This percentage represents the individuals 18 years and older that have diabetes and who reported receiving an annual dilated eye examination. The *Diabetes Report Card* is published biennially by the CDC. The report provides current information on the status of diabetes in the United States. It includes information and data about diabetes mellitus, gestational diabetes, prediabetes, preventive care practices, risk factors, quality of care, diabetes outcomes, and National and State trends. The data are from the CDC Behavioral Risk Factor Surveillance System, which is a health-related telephone (landline and cellphone) survey that collects State-level data about health-related risk behaviors, chronic health conditions, and use of preventive services. The survey questions include 11 questions related to diabetes preventative medicine covering the frequency of physicals, dilated vision examinations, blood glucose and HbA1C monitoring, and diabetes education. See <https://www.cdc.gov/diabetes/pdfs/library/diabetesreportcard2014.pdf> (Accessed May 25, 2018).

program. Thus, the effective average comprehensive eye examination cost is reduced to \$91 for this analysis ($\$91 = \$260 \times (1 - 65 \text{ percent})$); and

- The cost of an out-of-period medical qualification examination: \$218 (inclusive of the opportunity cost of the ITDM individual's time).³⁴ However, the out-of-period examination occurs only every other year and therefore is halved to \$109 for this analysis.

Altogether, the recurring costs for ITDM individuals to renew and maintain their exemptions total \$1,350 each. This is the sum of the costs noted above, specifically the \$30 cost of time to prepare a renewal application, the \$1,120 endocrinologist examination cost, the \$91 vision examination cost, and the \$109 out-of-period medical qualification examination cost.³⁵ The continuation of the exemption program would cost this group of ITDM individuals \$6,750,000 ($\$6,750,000 = 5,000 \text{ ITDM individuals} \times \$1,350 \text{ per ITDM individual}$) per year.

Because of the final rule, the exemption program will be eliminated. The compliance cost under the final rule for each of these 5,000 ITDM individuals to obtain their MEC, MCSA-5876, is estimated as follows:

- The cost of an annual evaluation by a TC: \$223 (inclusive of the opportunity cost of the ITDM individual's time),³⁶ and
- The cost of an out-of-period medical qualification examination: \$218 (inclusive of the opportunity cost of the ITDM individual's time). However, the out-of-period

³⁴ This cost is estimated in RIA Section 2.6.3.

³⁵ The Agency assumes that the cost for an ITDM individual to obtain a State exemption or an FMCSA exemption is the same.

³⁶ This cost is estimated in RIA Section 2.6.3.

examination occurs only every other year and therefore is halved to \$109 for this analysis.

The annual cost each of these 5,000 ITDM individuals will bear per year to comply with the final rule is therefore \$332 ($\$332 = \$223 + \109), a 75.4 percent decrease relative to the \$1,350 compliance cost of the exemption program. In total, these 5,000 ITDM individuals will bear a cost of \$1,660,000 under the final rule ($\$1,660,000 = 5,000 \text{ ITDM individuals} \times \$332 \text{ per ITDM individual}$), which is \$5.09 million less than the cost they would bear under the exemption program ($\$5.09 \text{ million} = (\$6,750,000 - \$1,660,000) / \$1,000,000$), and which constitutes the largest share of the total cost savings that will result from the final rule.

Costs to Future Compliant ITDM Individuals

In accordance with 49 CFR 391.41(b)(3), an individual subject to FMCSA's physical qualification requirements who begins treatment with insulin for diabetes mellitus cannot be medically qualified to operate a CMV. Consequently, an ITDM individual in this situation is likely to lose income until FMCSA issues an exemption. Motor carriers that would employ these ITDM individuals will also lose income from the productivity that would have resulted from the labor hours forgone. The Agency estimates that 27 ITDM individuals and the carriers that would employ them would continue to bear the burden of obtaining an exemption in the baseline.³⁷

FMCSA does not have data on the average length of time it takes for an individual beginning treatment with insulin to complete the daily blood glucose measurements and medical examinations necessary prior to submitting an initial

³⁷ The estimate of 27 new ITDM individuals seeking exemptions in the baseline is developed in RIA Section 2.5.2.

exemption application.³⁸ However, after receiving an initial exemption application, it takes FMCSA on average 77 days to review a complete application before granting an exemption. This may be a conservative estimate of the length of time that both drivers and their potential employers incur opportunity costs, because the clock for determining the 77-day average waiting period does not start until the application is deemed complete by FMCSA. For these reasons, FMCSA finds that the 77-day estimate of the average waiting period during which drivers beginning treatment with insulin and the motor carriers that employ them incur opportunity costs may be conservatively low.

The Agency assumes that new ITDM drivers will obtain alternative employment while waiting for FMCSA to grant an exemption, and that the alternative employment will produce income (wage and benefits combined) equal to \$25 per hour.³⁹ Based on the \$30 per hour average wage and benefits per driver,⁴⁰ a driver idled while waiting for an exemption to be granted would forgo \$5 of income per hour he or she is prohibited from driving. Given the 77-day average wait time for FMCSA to issue an exemption and an

³⁸ The exemption program requires individuals newly diagnosed with diabetes mellitus who are beginning treatment with insulin to provide 60 days of daily blood glucose measurements while being treated with insulin to the endocrinologist. Drivers transitioning from oral medication to insulin are required to provide 30 days of daily blood glucose measurements while being treated with insulin. FMCSA does not have data to determine how many ITDM individuals might fall under either of these reporting requirements. Were such data available, it would likely increase the Agency's estimate of the length of time an ITDM individual would not be able to operate a CMV. The daily blood glucose monitoring requirements are specified in Section 13A of the endocrinologist checklist that is included in the diabetes exemption program application package. *See* <https://www.fmcsa.dot.gov/medical/driver-medical-requirements/diabetes-exemption-application> (Accessed May 25, 2018).

³⁹ The \$25 per hour wage is an average of the hourly wage for several occupations within North American Industrial Classification System (NAICS) industry 488400 (Support Services Road Transportation). The 2016 average hourly wage for Laborers and Freight, Stock and Materials Movers is \$13.85 and is \$16.73 for Tank Car, Truck and Shop Loaders. This results in an average wage of \$15.29 ($\$15.29 = (\$13.85 + \$16.73) \div 2$) to which is added \$9.54 for average hourly benefits (discussed in further detail in the RIA). The Agency used these labor categories because they are representative of non-driving positions that may be available with motor carriers for a driver who begins treatment with insulin until an exemption is granted. The Agency believes that this is a conservative assumption because a motor carrier could terminate the employee, which would increase the opportunity cost to the driver. The Bureau of Labor Statistics (BLS) wage data are available at https://www.bls.gov/oes/current/naics4_488400.htm#53-0000 (Accessed May 25, 2018).

⁴⁰ *See* RIA Section 2.6.1.

11-hour driving day, a driver filing an initial exemption application would forgo \$4,235 ($\$4,235 = \$5 \text{ per hour} \times 11 \text{ hours per day} \times 77 \text{ days}$) of income. The final rule eliminates this cost, resulting in an annual cost savings of \$114,345 ($\$114,345 = \$4,235 \text{ opportunity cost per new exemption program applicant} \times 27 \text{ new exemption program applicants per year}$).

The Agency also monetizes the opportunity cost to motor carriers resulting from the loss of available labor inputs during the 77-day average application waiting period. The Agency estimates motor carriers' opportunity cost at \$3.20 per hour.⁴¹ At that rate, the opportunity cost to motor carriers per exemption program applicant is estimated at \$2,710 ($\$2,710 = \$3.20 \text{ per hour} \times 11 \text{ hours per day} \times 77 \text{ days}$). The final rule will eliminate this cost, resulting in an annual cost savings of \$73,170 ($\$73,170 = \$2,710 \text{ motor carrier opportunity cost per new exemption program applicant} \times 27 \text{ new exemption program applicants per year}$).

Together, the driver and motor carrier opportunity costs per new exemption program applicant sum to \$6,945 ($\$6,945 = \$4,235 \text{ driver opportunity cost} + \$2,710 \text{ carrier opportunity cost}$). Aggregated over the projected 27 new exemption program applicants per year, this cost totals \$187,515 ($\$187,515 = 27 \text{ applicants} \times \$6,945 \text{ per applicant}$), of which \$114,345 is borne by new ITDM individuals and \$73,170 by motor carriers. In addition to the \$114,345 in opportunity costs, ITDM individuals incur \$36,450 of annual medical-related compliance costs ($\$36,450 = \$1,350 \text{ medical expenses per individual} \times 27 \text{ individuals}$). In total, the baseline annual cost of the exemption

⁴¹ See RIA Section 2.6.2.

program with respect to new exemption holders and the motor carriers that would employ them is \$223,965 ($\$223,965 = \$187,515 + \$36,450$).

The final rule eliminates the \$187,515 opportunity cost of the exemption program's 77-day waiting period. The remaining \$36,450 of baseline compliance costs for the 27 new ITDM individuals will be reduced by the final rule to \$8,964 per year (that is, \$332 per individual per year under the final rule versus \$1,350 per individual per year in the baseline). On an annual basis, the cost savings to these individuals and to motor carriers totals \$215,001 ($\$215,001 = \$187,515 + \$36,450 - \$8,964$).

Costs to Non-Participating ITDM Individuals

There is good reason to assume that ITDM individuals compliant with the requirements of the exemption program will comply with the less burdensome requirements of the final rule. It is not as simple to estimate the degree to which the estimated ITDM individuals without exemptions (among both CDL and non-CDL interstate drivers as well as intrastate CDL drivers), or intrastate non-CDL holders – also without exemptions – may alter their behavior in response to the final rule.

In the RIA published at the NPRM stage, FMCSA demonstrated a range of *gross* compliance costs that would be incurred by medically qualified ITDM individuals by considering costs as a function of the share of medically qualified ITDM individuals. As the Agency does not know what share of ITDM individuals would be medically qualified, the NPRM analysis assumed three possible representative values: 100 percent, 66.7 percent, and 33.3 percent. The Agency reconsidered and ultimately discontinued the use of this approach for the analysis of the final rule. The Agency concludes that a focus on gross compliance costs fails to properly characterize the deregulatory nature and cost

savings of the rule. Therefore, it reassessed its analytical approach from a microeconomic perspective for this analysis of the final rule. Under the revised approach the Agency first divided the group of “non-participating” ITDM individuals into three subgroups, then considered each subgroup’s pre- and post-rule behavior using rational choice theory.

The first subgroup consists of an estimated 189,363 ITDM individuals operating CMVs in interstate commerce either with or without a CDL, plus those with intrastate CDLs.⁴² By definition, these individuals should already be in compliance with the exemption program due to the fact that they either have a CDL, operate a CMV in interstate commerce, or both. The Agency assumes that these individuals have chosen not to participate in either FMCSA or State exemption programs because they perceive the cost of non-compliance to be less than the cost of compliance – making non-compliance their most rational choice in the baseline. The final rule may or may not change their behavior. Each individual will choose between the lesser of the reduced cost of compliance (that is, a \$332 final rule compliance cost, as the final rule eliminates nearly all of the \$5,585 baseline compliance cost) and his or her perceived cost of non-compliance, which is unaffected by the final rule. Regardless of the individual’s chosen behavior under the final rule, he or she will not incur any new net costs, and potentially will incur a cost savings if the \$332 compliance cost of the final rule is less than his or her perceived cost of non-compliance. Therefore, this rule imposes no costs to this subgroup.

⁴² See RIA Section 2.5.2 for the Agency’s derivation of the size of this subgroup’s population.

The second and third subgroups together are composed of ITDM individuals operating as intrastate non-CDL drivers.⁴³ Subgroup two consists of individuals operating in States that have medical requirements applicable to non-CDL individuals. The Agency assumes that this final rule will indirectly apply to these individuals through State adoption of compatible regulations in order to maintain eligibility for Motor Carrier Safety Assistance Program grants. Therefore, by definition, these individuals should already be in compliance with State exemption programs, but are not. Following the same logic as discussed with respect to subgroup one, these individuals will bear no new net costs under the final rule and could potentially incur a cost savings.

The third subgroup is the complement to the second subgroup but is specific to ITDM individuals operating in States that do not have medical requirements applicable to non-CDL individuals. The Agency assumes that these States will not change their regulations as a result of the final rule; therefore, individuals in this subgroup will be unaffected and will bear no costs.

Costs to the Agency

FMCSA relies on a contractor to assist it to administer the diabetes exemption program. The average annual cost for the 3 remaining option years of the contract is \$1,025,474. The final rule eliminates the need for this service, and will therefore produce an annual cost savings of \$1,025,474.

Total Annual Costs of the Rule

⁴³ In Section 2.5.2 of the RIA, the Agency estimates that subgroups two and three together contain a total of 54,000 ITDM individuals, but lacks data to estimate the ratio of the size of subgroup two to subgroup three.

Table 3 shows the total costs estimated for the final rule. The Agency based the costs on a representative year approach (using exemption program participation data from December 31, 2016). The relative costs between the baseline and the final rule do not change in future years (save for slight changes due to growth in the baseline of the exemption holder population that are not accounted for as they are minimal). Therefore, this analysis does not present a separate discussion of the annualized costs at either a 3 percent or 7 percent discount rate, as those costs would be nearly identical to the costs shown in Table 3, which the Agency characterizes as annualized costs. The total costs of the final rule are estimated at -\$6,347,241, representing a cost savings of \$6.35 million annually.

Table 3. Total Cost of Final Rule (Annualized in 2016\$)

Category	Baseline Cost	Final Rule Cost	Total Cost/(Savings)
Current Compliant ITDM Individuals	\$6,750,000	\$1,660,000	(\$5,090,000)
Future Compliant ITDM Individuals	\$167,550	\$8,964	(\$158,586)
Non-Participating ITDM Individuals	\$0	\$0	\$0
Motor Carriers	\$73,170	\$0	(\$73,170)
FMCSA	\$1,025,474	\$0	(\$1,025,474)
Total	\$8,016,205	\$1,668,694	(\$6,347,241)

Benefits

The Agency reviewed the literature to identify analyses that quantified health benefits realized by treating diabetes with insulin. These studies quantified the benefits of insulin use; however, none of these analyses were applicable directly to CMV operators. In the absence of such analyses, the Agency did not quantify health benefits associated with the final rule, though considers that the final rule has potential to improve the health

of drivers by encouraging that ITDM individuals manage their health with the help of TCs.

The Agency finds that ITDM individuals do not present a safety risk greater than CMV drivers that either treat their diabetes with oral medication or who have not been diagnosed with diabetes. With respect to ITDM individuals' safety performance, the Agency has released a study examining the safety performance of CMV operators diagnosed with diabetes. The study examined whether the crash rate for ITDM individuals in compliance with the FMCSA exemption program was significantly different than a control group of non-ITDM individuals.

In November 2016, FMCSA released an *Analysis Brief* titled "Safety Performance of Drivers with Medical Exemptions."⁴⁴ This analysis showed that a 0.02986 crash rate for a treatment group consisting of diabetes exemption holders was not significantly different than a 0.02627 crash rate for a control group of drivers at a 95 percent confidence level.

B. E.O. 13771 (Reducing Regulation and Controlling Regulatory Costs)

This final rule is considered to be an E.O. 13771 deregulatory action.⁴⁵ The present value of the cost savings of this rule, measured on an infinite time horizon at a 7 percent discount rate, is \$79.2 million. Expressed on an annualized basis, the cost savings are \$5.5 million. These values are expressed in 2016 dollars.

C. Regulatory Flexibility Act

⁴⁴ The *Analysis Brief* is available at <https://rosap.nhtsa.gov/view/dot/31521> (Accessed May 25, 2018).

⁴⁵ Executive Office of the President. *Executive Order 13771 of January 30, 2017. Reducing Regulation and Controlling Regulatory Costs*. 82 FR 9339-9341. Feb. 3, 2017.

The Regulatory Flexibility Act of 1980 (5 U.S.C. 601 et seq.) 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. The term “small entities” comprises small businesses and not-for-profit organizations that are independently owned and operated and are not dominant in their fields and governmental jurisdictions with populations of less than 50,000.⁴⁶ Accordingly, DOT policy requires an analysis of the impact of all regulations on small entities, and mandates that agencies shall strive to lessen any adverse effects on these businesses.

Under the standards of the Regulatory Flexibility Act, as amended by the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L.104–121, 110 Stat. 857), this final rule does not impose a significant economic impact on a substantial number of small entities because the medical standards apply to individuals seeking to operate a CMV in interstate commerce. Consequently, I certify that the action will not have a significant economic impact on a substantial number of small entities.

D. Assistance for Small Entities

In accordance with section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996, FMCSA wants to assist small entities in understanding this final rule so that they can better evaluate its effects on themselves and participate in the rulemaking initiative. If the final rule will 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. Christine Hydock, listed in the **For Further Information Contact** section of this final rule.

⁴⁶ Regulatory Flexibility Act (5 U.S.C. 601). *See* <http://uscode.house.gov/browse/prelim@title5/part1/chapter6&edition=prelim>.

Small businesses may send comments on the actions of Federal employees who enforce or otherwise determine compliance with Federal regulations to the Small Business Administration's Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards. The Ombudsman evaluates these actions annually and rates each agency's responsiveness to small business. If you wish to comment on actions by employees of FMCSA, call 1-888-REG-FAIR (1-888-734-3247). DOT has a policy regarding the rights of small entities to regulatory enforcement fairness and an explicit policy against retaliation for exercising these rights.

E. 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, in the aggregate, or by the private sector of \$156 million (which is the value equivalent of \$100,000,000 in 1995, adjusted for inflation to 2015 levels) or more in any one year. This final rule imposes no new costs on any regulated entities nor upon State, local, or tribal governments. Therefore, no further examination of unfunded mandates is required.

F. Paperwork Reduction Act (Collection of Information)

This final rule calls for a collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). As defined in 5 CFR 1320.3(c), "collection of information" comprises reporting, recordkeeping, monitoring, posting, labeling, and other similar actions. The substantive comments in response to the 60-day

notice addressing the ITDM Assessment Form are discussed in the TC Written Notification (ITDM Assessment Form) section above. FMCSA did not receive any comments in response to the burden of this information collection.

The title and description of the information collection, a description of those who must collect the information, and an estimate of the total annual burden follow. The estimate covers the time for reviewing instructions, searching existing sources of data, gathering and maintaining the data needed, and completing and reviewing the collection.

TITLE: Medical Qualification Requirements

OMB CONTROL NUMBER: 2126-0006

SUMMARY OF THE COLLECTION OF INFORMATION: The final rule enables an ITDM individual to obtain an MEC, MCSA-5876, from a certified ME at least annually if the TC attests to the certified ME on the ITDM Assessment Form, MCSA-5879, that the individual maintains a stable insulin regimen and proper control of his or her diabetes, and the certified ME determines that the individual meets FMCSA's physical qualification standards. Certified MEs may certify ITDM individuals for up to 12 months.

NEED FOR INFORMATION: This ICR supports the DOT Strategic Goal of Safety by ensuring that CMV drivers are physically qualified to operate trucks and buses on our nation's highways.

USE OF INFORMATION: The TC completes the ITDM Assessment Form, MCSA-5870, and attests that the ITDM individual maintains a stable insulin regimen and proper control of his or her diabetes. Within 45 days after the form has been completed, it is provided to the certified ME, who performs a physical qualification examination,

considers the information provided by the TC, and determines whether the individual meets FMCSA’s physical qualifications standards to safely operate a CMV in interstate commerce.

DESCRIPTION OF THE RESPONDENTS: TCs

NUMBER OF RESPONDENTS: 4,906

FREQUENCY OF RESPONSE: Annually

BURDEN OF RESPONSE: 8 minutes

ESTIMATE OF TOTAL ANNUAL BURDEN: 654 hours

TC Annual Burden Hours and Salary Costs to Complete a Form Evaluating the Health of a CMV Driver with ITDM

Hourly wage of TC ⁴⁷	Number of forms completed	Time to complete form	Annual hours to complete forms	Annual salary costs for TC to complete forms
\$92.38	4,906	8 minutes	654	\$60,417

As described in the table above, the final rule results in 654 annual burden hours and \$60,417 annual salary costs. However, as explained in the supporting statement to the ICR, eliminating the diabetes exemption program results in 2,599 fewer annual burden hours and a \$77,749 reduction in annual salary costs. Therefore, the final rule results in a net decrease of 1,945 annual burden hours and a net decrease of \$17,332 in salary costs.

As required by the Paperwork Reduction Act, FMCSA will submit a copy of this final rule to OMB for its review of the collection of information.

G. E.O. 13132 (Federalism)

⁴⁷ Note that the \$92.38 TC compensation cost used here differs from the \$163.21 value used to represent the cost of an office visit to a TC. For PRA purposes, the \$92.38 value – an estimate derived from BLS data to represent the *hourly* wage and benefits of a TC – is appropriate for estimating cost as a function of time to complete the form.

A rule has implications for federalism under section 1(a) of E. O. 13132 if it has “substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.” FMCSA has determined that this rule would not have substantial direct costs on or for States, nor would it limit the policymaking discretion of States. Nothing in this document preempts any State law or regulation. Therefore, this rule does not have sufficient federalism implications to warrant the preparation of a Federalism Impact Statement.

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

This final rule meets applicable standards in sections 3(a) and 3(b)(2) of E.O. 12988, Civil Justice Reform, to minimize litigation, eliminates ambiguity, and reduce burden.

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

E.O. 13045, Protection of Children from Environmental Health Risks and Safety Risks (62 FR 19885, April 23, 1997), requires agencies issuing “economically significant” rules, if the regulation also concerns an environmental health or safety risk that an agency has reason to believe may disproportionately affect children, to include an evaluation of the regulation’s environmental health and safety effects on children. The Agency determined this final rule is not economically significant. Therefore, no analysis of the impacts on children is required. In any event, the Agency does not anticipate that this regulatory action could in any respect present an environmental or safety risk that could disproportionately affect children.

J. E.O. 12630 (Taking of Private Property)

FMCSA reviewed this final rule in accordance with E.O. 12630, Governmental Actions and Interference with Constitutionally Protected Property Rights, and has determined it will not affect a taking of private property or otherwise have taking implications.

K. Privacy Impact Assessment

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 rulemaking. The Agency submitted a Privacy Threshold Assessment analyzing the privacy implications to the DOT 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 rule are not unique and have previously been addressed by the medical examination/certification requirements in the National Registry of Certified Medical Examiners and the Medical Examiner’s Certification Integration PIA published on the DOT Privacy website 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 are not required.

L. E.O. 12372 (Intergovernmental Review)

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

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

FMCSA has analyzed this final rule under E.O. 13211, Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use. The Agency has determined that it is not a “significant energy action” under that order because it is not a “significant regulatory action” likely to have a significant adverse effect on the supply, distribution, or use of energy. Therefore, it does not require a Statement of Energy Effects under E.O. 13211. The Administrator of the Office of Information and Regulatory Affairs has not designated it as a significant energy action. Therefore, it does not require a Statement of Energy Effects under E.O. 13211.

N. E.O. 13783 (Promoting Energy Independence and Economic Growth)

E.O. 13783 directs executive departments and agencies to review existing regulations that potentially burden the development or use of domestically produced energy resources, and to appropriately suspend, revise, or rescind those that unduly burden the development of domestic energy resources. In accordance with E.O. 13783, DOT prepared and submitted a report to the Director of OMB that provides specific recommendations that, to the extent permitted by law, could alleviate or eliminate aspects of agency action that burden domestic energy production. This rule has not been

identified by DOT under E.O. 13783 as potentially alleviating unnecessary burdens on domestic energy production.

O. E.O. 13175 (Indian Tribal Governments)

This rule does not have tribal implications under E.O. 13175, Consultation and Coordination with Indian Tribal Governments, because it does not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal government and Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes.

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 rule does not use technical standards. Therefore, FMCSA did not consider the use of voluntary consensus standards.

Q. Environment (National Environmental Policy Act of 1969 (NEPA), Clean Air Act (CAA), Environmental Justice)

FMCSA analyzed this rule for the purpose of NEPA (42 U.S.C. 4321 et seq.) and determined this action is categorically excluded from further analysis and documentation in an environmental assessment or environmental impact statement under FMCSA Order

5610.1 (69 FR 9680, March 1, 2004), Appendix 2, in paragraphs 6(b) and 6(s)(7). The content in this rule is covered by the Categorical Exclusions (CEs) in paragraphs 6(b) and 6(s)(7) and the final action does not have any effect on the quality of the environment.

The CE determination is available for review in the docket.

FMCSA also analyzed this rule under section 176(c) of the CAA, as amended (42 U.S.C. 7506(c)), and implementing regulations promulgated by the Environmental Protection Agency. Approval of this action is exempt from the CAA's general conformity requirement because it does not affect direct or indirect emissions of criteria pollutants.

Under E.O. 12898, Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations, 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 rule in accordance with the E.O., and has determined that no environmental justice issue is associated with this final rule, nor is there any collective environmental impact that would result from its promulgation.

List of Subjects in 49 CFR 391

Alcohol abuse, Drug abuse, Drug testing, Highway safety, Motor carriers, Reporting and recordkeeping requirements, Safety, Transportation

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, 31149, 31502; sec. 4007(b), Pub. L. 102–240, 105 Stat. 1914, 2152; sec. 114, Pub. L. 103–311, 108 Stat. 1673, 1677; sec. 215, Pub. L. 106–159, 113 Stat. 1748, 1767; sec. 32934, Pub. L. 112–141, 126 Stat. 405, 830; secs. 5403 and 5524, Pub. L. 114–94, 129 Stat. 1312, 1548, 1560; sec. 2, Pub. L. 115–105, 131 Stat. 2263; 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 treated with 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.

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 paragraph (c), (d), (e), (f), or (g) 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 treated with insulin for control and who has obtained a medical examiner's certificate under the standards in § 391.46, if such driver's most recent medical examination and certification as qualified to drive did not occur 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; and

(g) Beginning June 22, 2021, any person found by a medical examiner not to be physically qualified to operate a commercial motor vehicle under the provisions of paragraph (g)(3) of § 391.43.

4. Add § 391.46 to read as follows:

§ 391.46 Physical qualification standards for an individual with diabetes mellitus treated with insulin for control.

(a) *Diabetes mellitus treated with insulin.* An individual with diabetes mellitus treated with insulin for control is physically qualified to operate a commercial motor vehicle provided:

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

(2) The individual has the evaluation required by paragraph (b) and the medical examination required by paragraph (c) of this section.

(b) *Evaluation by the treating clinician.* Prior to the examination required by § 391.45 or the expiration of a medical examiner's certificate, the individual must be evaluated by his or her "treating clinician." For purposes of this section, "treating clinician" means a healthcare professional who manages, and prescribes insulin for, the treatment of the individual's diabetes mellitus as authorized by the healthcare professional's State licensing authority.

(1) During the evaluation of the individual, the treating clinician must complete the Insulin-Treated Diabetes Mellitus Assessment Form, MCSA-5870.

(2) Upon completion of the Insulin-Treated Diabetes Mellitus Assessment Form, MCSA-5870, the treating clinician must sign and date the Form and provide his or her full name, office address, and telephone number on the Form.

(c) *Medical examiner's examination.* At least annually, but no later than 45 days after the treating clinician signs and dates the Insulin-Treated Diabetes Mellitus Assessment Form, MCSA-5870, an individual with diabetes mellitus treated with insulin for control must be medically examined and certified by a medical examiner as physically qualified in accordance with § 391.43 and as free of complications from diabetes mellitus that might impair his or her ability to operate a commercial motor vehicle safely.

(1) The medical examiner must receive a completed Insulin-Treated Diabetes Mellitus Assessment Form, MCSA-5870, signed and dated by the individual's treating

clinician for each required examination. This Form shall be treated and retained as part of the Medical Examination Report Form, MCSA-5875.

(2) The medical examiner must determine whether the individual meets the physical qualification standards in § 391.41 to operate a commercial motor vehicle. In making that determination, the medical examiner must consider the information in the Insulin-Treated Diabetes Mellitus Assessment Form, MCSA-5870, signed by the treating clinician and, utilizing independent medical judgment, apply the following qualification standards in determining whether the individual with diabetes mellitus treated with insulin for control may be certified as physically qualified to operate a commercial motor vehicle.

(i) The individual is not physically qualified to operate a commercial motor vehicle if he or she is not maintaining a stable insulin regimen and not properly controlling his or her diabetes mellitus.

(ii) The individual is not physically qualified on a permanent basis to operate a commercial motor vehicle if he or she has either severe non-proliferative diabetic retinopathy or proliferative diabetic retinopathy.

(iii) The individual is not physically qualified to operate a commercial motor vehicle up to the maximum 12-month period under § 391.45(e) until he or she provides the treating clinician with at least the preceding 3 months of electronic blood glucose self-monitoring records while being treated with insulin that are generated in accordance with paragraph (d) of this section.

(iv) The individual who does not provide the treating clinician with at least the preceding 3 months of electronic blood glucose self-monitoring records while being

treated with insulin that are generated in accordance with paragraph (d) of this section is not physically qualified to operate a commercial motor vehicle for more than 3 months. If 3 months of compliant electronic blood glucose self-monitoring records are then provided by the individual to the treating clinician and the treating clinician completes a new Insulin-Treated Diabetes Mellitus Assessment Form, MCSA-5870, the medical examiner may issue a medical examiner's certificate that is valid for up to the maximum 12-month period allowed by § 391.45(e) and paragraph (c)(iv) of this section.

(d) *Blood glucose self-monitoring records.* Individuals with diabetes mellitus treated with insulin for control must self-monitor blood glucose in accordance with the specific treatment plan prescribed by the treating clinician. Such individuals must maintain blood glucose records measured with an electronic glucometer that stores all readings, that records the date and time of readings, and from which data can be electronically downloaded. A printout of the electronic blood glucose records or the glucometer must be provided to the treating clinician at the time of any of the evaluations required by this section.

(e) *Severe hypoglycemic episodes.* (1) An individual with diabetes mellitus treated with insulin for control who experiences a severe hypoglycemic episode after being certified as physically qualified to operate a commercial motor vehicle is prohibited from operating a commercial motor vehicle, and must report such occurrence to and be evaluated by a treating clinician as soon as is reasonably practicable. A severe hypoglycemic episode is one that requires the assistance of others, or results in loss of consciousness, seizure, or coma. The prohibition on operating a commercial motor vehicle continues until a treating clinician:

(i) Has determined that the cause of the severe hypoglycemic episode has been addressed;

(ii) Has determined that the individual is maintaining a stable insulin regimen and proper control of his or her diabetes mellitus; and

(iii) Completes a new Insulin-Treated Diabetes Mellitus Assessment Form, MCSA-5870.

(2) The individual must retain the Form and provide it to the medical examiner at the individual's next medical examination.

5. Amend § 391.64 as follows:

a. Revise paragraph (a) introductory text and add paragraph (a)(3); and

b. Effective November 19, 2019, remove and reserve paragraph (a).

The revision and addition read as follows:

§ 391.64 Grandfathering for certain drivers participating in vision and diabetes waiver study programs.

(a) Until November 19, 2019, the provisions of § 391.41(b)(3) do not apply to a driver who was a participant in good standing on March 31, 1996, in a waiver study program concerning the operation of commercial motor vehicles by insulin-controlled diabetic drivers; *provided:*

* * * * *

(3) On November 19, 2019, the provisions of paragraph (a) of this section are removed, and any medical examiner's certificate issued under § 391.43 of this part on the basis that the driver is qualified by operation of the provisions of 49 CFR 391.64(a), related to insulin-controlled diabetic drivers, is void.

* * * * *

Appendix A to Part 391 [Amended]

6. Remove and reserve paragraph II.C. of appendix A to part 391.

Issued under authority delegated in 49 CFR 1.87 on: September 11, 2018

Raymond P. Martinez
Administrator, FMCSA

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