

**Department of Transportation
Federal Motor Carrier Safety Administration**

**Supporting Statement
Non-Insulin-Treated Diabetes Mellitus Assessment Form, MCSA-5872**

SUMMARY

- This is a request for approval of a new information collection request (ICR) that estimates the burden associated with the voluntary use of the newly developed Non-Insulin-Treated Diabetes Mellitus Assessment Form, MCSA-5872.
- The estimated annual burden of the information collection for respondent treating healthcare providers is 32,274 hours with an associated annual salary cost of \$4,234,055.

INTRODUCTION

This is to request the Office of Management and Budget's (OMB) approval of a new ICR titled, Non-Insulin-Treated Diabetes Mellitus Assessment Form, MCSA-5872. This ICR is voluntary and may be utilized by medical examiners (ME), who issue Medical Examiner's Certificates, Form MCSA-5876, to individuals who operate commercial motor vehicles (CMV) in interstate commerce, to communicate with treating healthcare providers responsible for managing the individuals' diagnosed non-insulin-treated diabetes mellitus. The purpose of the Non-Insulin-Treated Diabetes Mellitus Assessment Form, MCSA-5872, is to assist the ME in determining whether an individual diagnosed with non-insulin-treated diabetes mellitus is physically qualified and the individual's physical condition is adequate to enable the individual to operate a CMV safely.

Part A. Justification

1. CIRCUMSTANCES THAT MAKE THE COLLECTION OF INFORMATION NECESSARY

The primary mission of the Federal Motor Carrier Safety Administration (FMCSA) is to reduce crashes, injuries, and fatalities involving CMVs (large trucks and buses). As part of this mission, the Agency's Medical Programs Division works to ensure that individuals who operate CMVs engaged in interstate commerce are physically qualified and able to safely perform their work.

CMVs are longer, heavier, and more difficult to maneuver than automobiles. Not only does it take a skilled driver to operate them safely, it takes a physically and mentally fit driver to do so. Information used to determine and certify driver medical fitness helps to promote and maintain safety on our highways.

FMCSA is the Federal government agency authorized to suggest the collection of this information. FMCSA is required by 49 U.S.C. § 31502 and 31136 to establish minimum

standards for the physical qualifications of individuals who operate CMVs in interstate commerce for non-excepted industries. FMCSA has authority under 49 U.S.C. § 31502(b) to establish qualifications, including physical qualifications, for individuals operating CMVs in interstate commerce. Section 31136(a)(1) requires FMCSA to issue regulations on CMV safety, including regulations to ensure that CMVs are operated safely. Section 31136(a)(3) requires specifically that the Agency's safety regulations ensure that the physical condition of CMV drivers is adequate to 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 drivers.

The regulations applicable to this collection are outlined in the Federal Motor Carrier Safety Regulations (FMCSRs) at 49 CFR part 391, subpart E. The FMCSRs in 49 CFR § 391.41(b)¹ set forth the physical qualification standards that individuals operating CMVs in interstate commerce who are subject to part 391 must meet. The FMCSRs covering the performance of the CMV physical qualification examination of individuals who operate in interstate commerce by an ME and the related recordkeeping requirements are found at 49 CFR § 391.43.² The results of the examination must be recorded in accordance with the requirements set forth in that section; they include preparing and maintaining a Medical Examination Report Form, MCSA-5875, and, if the individual is physically qualified, issuing a Medical Examiner's Certificate, Form MCSA-5876.

The FMCSRs in 49 CFR § 391.41(b)(1) through (13) generally include the physical qualification standards required for medical certification of individuals who operate CMVs in interstate commerce. The physical qualification standards in 49 CFR § 391.46 address the physical qualification requirements for medical certification of individuals who are diagnosed with diabetes mellitus and are treated with insulin. However, the FMCSRs do not specifically address individuals who are diagnosed with diabetes mellitus and are treated with non-insulin therapy. The type of diabetes mellitus that is not treated with insulin (commonly known as Type 2 diabetes) is recognized as a health concern for the general public.

Non-insulin-treated diabetes mellitus that is not properly managed and controlled may lead to diabetes complications and/or target organ damage and may result in the individual's physical condition being inadequate to enable the driver to operate a CMV safely. The physical qualification standards in the FMCSRs broadly address some of the conditions and symptoms that may be attributable to complications from non-insulin-treated diabetes mellitus. Examples include the loss of limb and limb impairment standards (49 CFR 391.41(b)(1) and (2)); the cardiovascular standard (49 CFR § 391.41(b)(4)); the rheumatic, arthritic, orthopedic, muscular, neuromuscular, or vascular standard (49 CFR § 391.41(b)(7)); and the loss of consciousness standard (49 CFR § 391.41(b)(8)).

1 49 CFR § 391.41 Physical qualifications for drivers. Available at <https://www.ecfr.gov/current/title-49/subtitle-B/chapter-III/subchapter-B/part-391/subpart-E>.

2 49 CFR § 391.43 Medical examination; certificate of physical examination. Available at <https://www.ecfr.gov/current/title-49/subtitle-B/chapter-III/subchapter-B/part-391/subpart-E/section-391.43>.

In performing a thorough assessment and evaluation of an individual diagnosed with non-insulin-treated diabetes mellitus, the ME may need to consult with the individual's treating healthcare provider who manages the individual's diabetes. The ME may find this helpful in determining whether the individual has any medical conditions or symptoms, such as frequent episodes of hypoglycemia, that may prevent the individual from meeting the physical qualification standards and receiving a Medical Examiner's Certificate, Form MCSA-5876. This voluntary information collection would assist the ME in collecting the appropriate information from the treating healthcare provider in a standardized manner and would assist the ME in making an informed and sound physical qualification determination.

In May 2021, in Task 21-2, FMCSA's Medical Review Board (MRB) deliberated on the topic and the contents of a draft Non-Insulin-Treated Diabetes Mellitus Assessment Form, MCSA-5872. FMCSA directed the MRB to review and comment on whether the information on the proposed form provided sufficient information concerning the treatment, management, and control of an individual's non-insulin-treated diabetes mellitus condition to assist an ME in making an appropriate physical qualification determination. The Agency also requested that the MRB identify any areas of ambiguity as well as additional information that FMCSA should include on the form. Based on its review, the MRB offered some recommendations to improve the clarity and quality of information on the form. The current Non-Insulin-Treated Diabetes Mellitus Assessment Form, MCSA-5872, incorporates the MRB's recommendations.

This ICR supports the U.S. Department of Transportation (DOT) Strategic Goal of Safety by ensuring that individuals operating CMVs are medically qualified to operate trucks and buses on our nation's highways.

2. HOW, BY WHOM, AND FOR WHAT PURPOSE IS THE INFORMATION USED

The public interest in, and right to have, safe highways requires the assurance that individuals operating CMVs can safely perform the increased physical and mental demands of their duties. FMCSA's physical qualification standards provide this assurance by requiring individuals to be examined and medically certified as physically qualified to operate a CMV in interstate commerce.

Information used to determine and certify an individual's physical fitness promotes and maintains safety of our nation's highways. The purpose of the voluntary collection of this information is to obtain specific and relevant information to assist the ME in determining whether the individual diagnosed with non-insulin-treated diabetes mellitus is physically qualified, and to ensure that any medical condition or symptom that could result in the individual's physical condition being inadequate to enable the driver to operate a CMV safely is identified during the physical qualification examination process.

MEs may request that the Non-Insulin-Treated Diabetes Mellitus Assessment Form, MCSA-5872, be completed by treating healthcare providers who manage the diabetes-related care of individuals diagnosed with non-insulin-treated diabetes mellitus. This voluntary new collection will provide a standardized pathway for communication between the certifying MEs

responsible for issuing a Medical Examiner's Certificate, Form MCSA-5876, and treating healthcare providers. Therefore, the collection of this information will assist an ME in determining whether an individual diagnosed with non-insulin-treated diabetes mellitus is physically qualified to receive a Medical Examiner's Certificate and to operate a CMV.

3. EXTENT OF AUTOMATED INFORMATION COLLECTION

The Non-Insulin-Treated Diabetes Mellitus Assessment Form, MCSA-5872, will be available as a fillable pdf and may be downloaded from the FMCSA website. Treating healthcare providers may fax or scan and email the form to the ME. Consistent with OMB's commitment to minimizing respondents' recordkeeping and paperwork burdens and the increased use of secure electronic modes of communication, the Agency anticipates that approximately 50 percent of the Non-Insulin-Treated Diabetes Mellitus Assessment Forms, MCSA-5872, will be transmitted electronically. While we estimated that 50 percent of the forms will be transmitted electronically, we expect those forms that are not will be hand carried by the driver to the ME because the driver will want to be sure the ME has the form when the driver is examined. Therefore, while we have included an option to mail the form, its use/burden would be de minimis.

The FMCSRs covering driver physical qualification examinations and recordkeeping are found at 49 CFR § 391.43, which specifies that a physical qualification examination be performed on individuals operating CMVs and subject to part 391 of the regulations. The results of the examination must be recorded in accordance with the requirements set forth in that section. MEs are required to maintain records of the CMV physical qualification examinations they conduct. FMCSA does not require MEs to maintain these records electronically. However, there is nothing to preclude an ME from maintaining electronic records of the physical qualification examinations that the ME conducts. FMCSA is continuously evaluating new information technology to decrease the burden on MEs.

4. EFFORTS TO IDENTIFY DUPLICATION

FMCSA is the only Federal agency with the authority to regulate the qualifications of individuals operating CMVs in interstate commerce. Therefore, there is no Federal agency duplication.

5. EFFORTS TO MINIMIZE THE BURDEN ON SMALL BUSINESSES

The use of the Non-Insulin-Treated Diabetes Mellitus Assessment Form, MCSA-5872, is voluntary. It was reviewed by FMCSA's MRB to capture only data that is necessary to assist MEs in determining the physical qualification of individuals diagnosed with non-insulin-treated diabetes mellitus. The treating healthcare providers who manage the individuals' diabetes and would complete the Non-Insulin-Treated Diabetes Mellitus Assessment Form, MCSA-5872, charge for their services. In addition, because the treating healthcare providers routinely collect this information, the Agency does not anticipate impacts for them from this information collection.

6. IMPACT OF LESS FREQUENT COLLECTION OF INFORMATION

The use of this ICR is at the discretion of the ME to facilitate communication with treating healthcare providers responsible for the treatment, control, and management of an individual's diagnosed non-insulin-treated diabetes mellitus. This information will assist the ME in determining whether the individual's diabetes mellitus or any diabetes-related medical conditions, symptoms, or treatment results in the individual's physical condition being inadequate to enable the driver to operate a CMV safely. The information will be collected only at the time that it is relevant to make a medical certification determination.

7. SPECIAL CIRCUMSTANCES

There are no special circumstances related to this ICR.

8. COMPLIANCE WITH 5 CFR § 1320.8

On April 13, 2023, FMCSA published a 60-day notice and requested comments from the public on the information collection and the draft Non-Insulin-Treated Diabetes Mellitus Assessment Form, MCSA-5872 (88 FR 22517). FMCSA received one comment from the American College of Occupational and Environmental Medicine (ACOEM) in strong support of the information collection. ACOEM stated there is no standardized resource currently available that provides MEs with a reasonable example of appropriate information to consider when evaluating the medical qualification of a driver with non-insulin-treated diabetes mellitus. The ME would be able to use the information provided to evaluate whether the individual's diabetes mellitus is stable and controlled and to make an informed and sound physical qualification determination for the driver. ACOEM also stated that the burden associated with the form would be reduced if a fillable form is available. FMCSA notes that a fillable form that can be downloaded will be available on FMCSA's website.

9. PAYMENTS OR GIFTS TO RESPONDENTS

With the exception of payments for professional services by healthcare providers, respondents to this ICR do not receive any payments or gifts.

10. ASSURANCE OF CONFIDENTIALITY

The information collected as part of this ICR is information that will be retained by the ME conducting the individual's physical qualification examination. The Agency expects that the Non-Insulin-Treated Diabetes Mellitus Assessment Form, MCSA-5872, will be safeguarded along with all the other medical information that the ME retains. The form must be treated and retained as part of the Medical Examination Report Form, MCSA-5875, in the ME's medical records for the individual. The form must be retained by the ME for at least 3 years from the date of the physical qualification examination. As healthcare providers, MEs are required to retain and disclose medical information and personally identifiable information in accordance with applicable Federal and State privacy laws. Therefore, FMCSA expects that all information

collected by MEs is protected by reasonable security safeguards against loss or unauthorized access, destruction, usage, modification, or disclosure. This is a privacy positive outcome for the Agency because it results in less sensitive data being held by the Agency.

On occasion, however, FMCSA asks an ME to provide medical records relating to the physical qualification examination under the provisions of 49 CFR § 391.43(i).³ FMCSA has a comprehensive information security and privacy program that contains management, operational, and technical safeguards that are appropriate for the protection of the information collected. All medical records are kept confidential and in accordance with applicable Federal privacy laws.

11. JUSTIFICATION FOR COLLECTION OF SENSITIVE INFORMATION

The physical examination process requires the ME to inquire about aspects of individual's physical and mental health, including many underlying medical conditions, treatments, and the effects of the medical condition and treatments. This information is necessary to determine whether the individual meets FMCSA's physical qualification standards and can operate a CMV safely. In addition, the individual must provide consent for the treating healthcare provider to complete the Non-Insulin-Treated Diabetes Mellitus Assessment Form, MCSA-5872, and provide it to the requesting ME.

12. ESTIMATE OF BURDEN HOURS FOR INFORMATION REQUESTED

The burden hours for this information collection are based on the annual number of CMV drivers with non-insulin-treated diabetes mellitus who undergo a physical qualification examination and for whom a treating healthcare provider is requested to complete the Non-Insulin-Treated Diabetes Mellitus Assessment Form, MCSA-5872.

The first step in determining this number is to estimate the number of CMV drivers undergoing a physical qualification examination each year. There are approximately 8.7 million drivers⁴ subject to FMCSA's physical qualification standards. This number reflects both interstate drivers subject to the FMCSRs and intrastate drivers subject to compatible State regulations. Federal regulations do not require States to comply with the physical qualification requirements in the FMCSRs for operators of CMVs in intrastate commerce. But States that receive grants under the Motor Carrier Safety Assistance Program do adopt and apply requirements that are compatible with the Federal requirements. Therefore, FMCSA anticipates that it is likely that individuals subject to State requirements and diagnosed with non-insulin-treated diabetes mellitus will use MEs on FMCSA's National Registry of Certified Medical Examiners for their

³ The burden for the ME to file the driver examination forms and provide medical records relating to the physical qualification examination is covered in the Medical Qualification Requirements ICR, OMB Control Number 2126-0006, which is currently due to expire on March 31, 2025.

⁴ U.S. Department of Transportation, Federal Motor Carrier Safety Administration. 2022 Pocket Guide to Large Truck and Bus Statistics. Page 7. Available at <https://www.fmcsa.dot.gov/sites/fmcsa.dot.gov/files/2023-01/FMCSA%20Pocket%20Guide%202022-FINAL%20508%20121922.pdf> (accessed January 6, 2023).

physical qualification examinations. This may result in MEs also requesting treating healthcare providers of individuals operating CMVs in intrastate commerce to complete the Non-Insulin-Treated Diabetes Mellitus Assessment Form, MCSA-5872. In addition, a small number of drivers transporting 8 or less migrant workers more than 75 miles in interstate commerce who are subject to the medical certification requirements of 49 CFR part 398 are included in this population.

Periodic evaluation and certification are required to assess driver physical qualification, due to the potential for the onset of new conditions or changes in existing conditions. A Medical Examiner's Certificate, Form MCSA-5876, can be issued for up to 2 years after the date of examination. However, drivers with certain medical conditions must be certified more frequently than every 2 years. In addition, MEs have discretion to certify for shorter time periods, on a case-by-case basis, for medical conditions that require closer monitoring or are more likely to change over time. Halving the number of drivers underestimates the total number of examinations that are conducted annually. In addition, for various other reasons, drivers may find that they need to be examined more frequently. As a result of these exceptions to the biennial medical certification schedule, the Agency estimates that the actual number of medical examinations conducted annually is 40.20 percent greater than would be the case if all drivers were only examined biennially. As detailed in the table below, the Agency estimates that approximately 6,098,700 examinations are conducted annually.

**Population of CMV Drivers Subject to FMCSA Medical Standards
and Examined Annually⁵**

Baseline	Exams every 2 years – ½ of that population	Adjustment for out- of-cycle exams	Drivers examined annually
8,700,000	4,350,000	40.20%	6,098,700

Then, FMCSA must estimate the number of these drivers who are diagnosed with non-insulin-treated diabetes mellitus. There is an estimated 14.7 percent incidence of adults diagnosed with diabetes in the United States.⁶ Of those adults with diabetes, non-insulin-treated diabetes mellitus may account for 90 to 95 percent of all diagnosed cases.⁷ As such, FMCSA has estimated the annual number of individuals with non-insulin-treated diabetes mellitus being examined for physical qualification to be 806,858.⁸

⁵ This is the same methodology used to determine the population in the Medical Qualification Requirements ICR, OMB Control Number 2126-0006, which is currently due to expire on March 31, 2025.

⁶ Center for Disease Control and Prevention. National Diabetes Statistics Report. June 25, 2022. Page 2. Available at <https://www.cdc.gov/diabetes/data/statistics-report/diagnosed-undiagnosed-diabetes.html> (accessed January 6, 2023).

⁷ Federal Motor Carrier Safety Administration. Evidence Report: 2010 Update: Diabetes and Commercial Motor Vehicle Driver Safety. May 27, 2011. Page 14. Available at <https://rosap.ntl.bts.gov/view/dot/21200> (accessed January 6, 2023).

⁸ $806,858 = (6,098,700 \times 14.7\%) \times 90\%$

Finally, FMCSA estimates the number of individuals for whom completion of the Non-Insulin-Treated Diabetes Mellitus Assessment Form, MCSA-5872, would be requested. Of the 806,858 estimated individuals with non-insulin-treated diabetes mellitus, FMCSA lacks specific data but estimates that MEs conducting physical qualification examinations of 30 percent of these individuals will request that the treating healthcare provider fill out the voluntary Non-Insulin-Treated Diabetes Mellitus Assessment Form, MCSA-5872. Therefore, FMCSA estimates that MEs will request that forms be completed for 242,057 individuals with a corresponding number of treating healthcare providers completing Non-Insulin-Treated Diabetes Mellitus Assessment Forms, MCSA-5872.⁹

CMV Drivers with Non-Insulin-Treated Diabetes Mellitus for Whom a Non-Insulin-Treated Diabetes Mellitus Assessment Form, MCSA-5872, is Requested

Drivers for Whom a Form is Requested from a Treating Healthcare Provider Annually
242,057

FMCSA estimates that it will take the treating healthcare provider 8 minutes to complete the Non-Insulin-Treated Diabetes Mellitus Assessment Form, MCSA-5872, and to provide it to the certified ME.

Treating Healthcare Provider Task

Task	Time to Complete Task
Complete the Non-Insulin-Treated Diabetes Mellitus Assessment Form, MCSA-5872	8 minutes

Next, FMCSA estimates the average hourly wage for the categories of treating healthcare providers likely to complete the Non-Insulin-Treated Diabetes Mellitus Assessment Form, MCSA-5872, to be \$131.19. Finally, FMCSA estimates the average annual burden hours and salary costs for the treating healthcare providers to complete the forms.

⁹ 806,858 x 30% = 242,057 (rounded to the nearest whole number).

Derivation of Treating Healthcare Provider Average Wage¹⁰

Standard Occupational Code	Title	Mean Hourly Wage	Population Size	Percent of Population	Hourly Comp	Total Hourly Comp = Hourly Comp x (1+50.5%) ¹¹
29-1071	Physician Assistants	57.43	132,940	17%	9.58	14.41
29-1171	Nurse Practitioners	56.75	234,690	29%	16.71	25.15
29-1215	Family Medicine Physicians	113.43	102,930	13%	14.65	22.04
29-1216	General Internal Medicine Physicians	116.44	58,260	7%	8.51	12.81
29-1229	Physicians, All Other ¹²	113.30	256,670	32%	35.84	53.93
29-1241	Ophthalmologists, Except Pediatric	129.85	11,610	1%	1.89	2.85
Average Hourly Wage			797,100	100%	87.18	131.19

Treating Healthcare Provider Annual Burden Hours and Salary Costs to Complete Forms

Hourly wage of treating healthcare providers	Number of forms completed	Time to complete and provide forms to ME	Total annual burden hours to complete and provide form to ME	Total annual salary costs to complete and provide forms to ME
\$131.19	242,057	8 minutes	32,274	\$4,234,055

¹⁰ Please note that some numbers in the table may not add up due to rounding.

¹¹ The 50.5 percent used in this calculation is the fringe benefits rate for 2021. U.S. Department of Labor, Bureau of Labor Statistics. *Table 4: Employer Costs for Employee Compensation for private industry workers by occupational and industry group, December 2021*. Available at https://www.bls.gov/news.release/archives/ecec_03182022.htm (accessed January 6, 2023).

¹² The code 29-1229 is a new code starting with the May 2021 Occupational Employment and Wage Statistics publication. Previously, this occupation was included in 29-1228 (Physicians, All Other; and Ophthalmologists, Except Pediatric). It has since been split into 29-1229 (Physicians, All Other) and 29-1241 (Ophthalmologists, Except Pediatric).

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Annual Burden Hours: 32,274 hours (242,057 forms x 8 minutes/60 minutes = 32,274)

Annual Number of Respondents: 242,057 (242,057 treating healthcare providers completing forms)

Annual Number of Responses: 242,057 (242,057 forms completed)

13. ESTIMATE OF TOTAL ANNUAL COSTS TO RESPONDENTS

There are no additional annual costs to respondents.

14. ESTIMATE OF COST TO THE FEDERAL GOVERNMENT

The cost to the Federal government is minimal because FMCSA does not routinely receive or process the Non-Insulin-Treated Diabetes Mellitus Assessment Form, MCSA-5872, or information collected.

15. EXPLANATION OF PROGRAM CHANGES OR ADJUSTMENTS

This is a new ICR that estimates the burden associated with the voluntary use of the newly developed Non-Insulin-Treated Diabetes Mellitus Assessment Form, MCSA-5872.

16. PUBLICATION OF RESULTS OF DATA COLLECTION

This information will not be published.

17. APPROVAL FOR NOT DISPLAYING THE EXPIRATION DATE OF OMB APPROVAL

No such approval is requested.

18. EXCEPTIONS TO CERTIFICATION STATEMENT

There are no exceptions to the certification statement.