

Supporting Statement for Paperwork Reduction Act Submissions

*National Plan and Provider Enumeration System (NPPES) Supplemental Data Collection
CMS-10749/OMB control number: 0938-NEW*

A. Background

The agency is seeking approval for an ongoing data collection that has been in violation of the PRA since 2017.

The adoption by the Secretary of HHS of the standard unique health identifier for health care providers is a requirement of the Health Insurance Portability and Accountability Act of 1996 (HIPAA). The unique identifier is to be used on standard transactions and may be used for other lawful purposes in the health care system. The CMS Final Rule published on January 23, 2004 adopts the National Provider Identifier (NPI) as the standard unique health identifier for health care providers. Health care providers that are covered entities under HIPAA must apply for and use NPIs in standard transactions. Other health care providers are eligible for NPIs but are not required by regulation to apply for them or use them. Health care providers began applying for NPIs on May 23, 2005.

The National Provider Identifier Application and Update Form is used by health care providers to apply for NPIs and furnish updates to the information they supplied on their initial applications. The form is also used to deactivate their NPIs if necessary. The original application form was approved in February 2005 and has been in use since May 23, 2005. The form is available on paper or can be completed via a web-based process. Health care providers can mail a paper application, complete the application via the web-based process via the National Plan and Provider Enumeration System (NPPES), or have a trusted organization submit the application on their behalf via the Electronic File Interchange (EFI) process. The Enumerator uses the NPPES to process the application and generate the NPI. NPPES is the Medicare contractor tasked with issuing NPIs, and maintaining and storing NPI data.

The National Provider Identifier (NPI) Application processes over 1 million new provider and/or updates to existing application annually.

Less than 2.75% of all changes are made via OMB- 0938-0931(National Provider Identifier (NPI) Application/Update Form- CMS- 10114). This allows providers to submit and update paper application information for the creation of and /or update existing information for the National Provider Identifier (NPI). OMB- 0938-0931 collects data for both individual and organizational applications.

A vast majority of providers (97.4%) utilize the web application (90.1%) or the

Electronic File Interchange (EFI [7.3%]) process. There have been multiple updates to the Web based application to support current CMS operational needs, (Office of Minority Health and the 21st Century Cures Act, interoperability).

The following are included in this new request for the optional data field information:

Office of Minority Health

1. Demographic Information (Ethnicity and Race information)
 - a. Primary and Secondary Languages Spoken by provider
 - b. Identification of primary location as home address.
 - c. Primary and Secondary Languages Spoken in practice locations
2. Organization Information
 - a. Organization Name
 - b. Office Hours
 - c. Office, exam room, medical equipment accessible to individuals with mobility disabilities
 - d. Multiple Practice Locations (only one is collected on the paper form but Web allows multiple)
 - e. Multiple Contact Person (only one is collected on the paper form but Web allows multiple)

21st Century Cures Act, interoperability.

1. Endpoint Information
 - a. Endpoint Type
 - b. Endpoint
 - c. Endpoint description
 - d. Endpoint Use
 - e. Endpoint Content Type
 - f. Is the Endpoint affiliated to another Organization?
 - g. Endpoint Location

This PRA package is solely used for the optional data fields in the WEB application only.

As stated earlier, this information collection has been in violation of the PRA since 2017. The information collection is now being submitted to OMB as an “Existing Collection in use without an OMB Control Number.” To date, 8% of the data collected is specific to Medicare providers. All non-Medicare provider information will be discarded as CMS does not have the authority to collect it.

NPPES Ethnicity and Race populated NPIs analysis

Date 07-07-2022

Description	NPI Count	Response rate % of total NPI Count
Total Unique active type 1 (individuals) NPIs in NPPES	5,611,245	--
Total Unique active NPI count with Ethnicity or Race populated in NPPES and in Medicare	464,451	8%

B. Justification

1. Need and Legal Basis

Data collected for the Office of Minority Health:

The Office of Minority Health (OMH) Authority:

Delegation of Program Authority under Section 3101 of the Public Health Service Act

Cures Act Authority:

Delegation of Authorities under Title IV--Delivery of the 21't Century Cures Act

Delegation of Program Authority under Section 3101 of the Public Health Service Act, in the implementation of a new health data collection and analysis strategy. The Office of Minority Health authorizes this data collection. This strategy contains provisions to strengthen federal data collection efforts by requiring that all national federal data collection efforts collect information on race, ethnicity, sex, primary language and disability status. The law also provides the Department of Health and Human Services (HHS) the opportunity to collect additional demographic data to further improve our understanding of healthcare disparities.

The law requires that data collection standards for these measures be used, to the extent that it is practical, in all national population health surveys. It applies to self-reported optional information only. The law also requires any data standards published by HHS to comply with standards created by the Office of Management and Budget (OMB).

The standards apply to population health surveys sponsored by HHS, where respondents either self-report information or a knowledgeable person responds for all members of a household.

2. Purpose and users of the information

Delegation of Authorities under Title IV--Delivery of the 21st Century Cures Act. The Cures Act fosters innovation in health care to deliver better information, more conveniently, to patients and their providers. It also promotes transparency through modern technology, providing tremendous opportunities for the public to gain visibility into the services, quality, and costs of health care. These requirements support the privacy and security of patient information.

The fields are optional for the provider to complete and application is not affected if the provider does not complete this additional information. While CMS has been collecting the optional data elements since 2017, the demographic data has not been published externally due to data quality issues as providers often only report this information during their initial enrollment and do not provide updates when applicable. For instance, in 2020, we found that among providers initiating/updating after Jan 1, 2018, approximately 50% of providers responded to the race and ethnicity questions and ~60% to the primary language question. CMS has been analyzing the data internally to determine how to utilize the data to support health equity initiatives, such as the impact on individuals with Medicare if a provider with specific or demonstrated ability to provide culturally and linguistically appropriate care to specific populations, for example, individuals who speak a language other than English, or individuals with disabilities, is terminated. This data would also enable us to assess health equity impacts of CMS programs and policies to determine or otherwise assess whether sufficient number of health care professionals exist or serve an area, community, or population, who are able to provide cultural and linguistic services that meet the unique needs of Medicare-covered individuals in local communities. This has a direct impact on access to care that meets the needs of diverse communities and individuals we serve, and without such information CMS is unable to assess our programs for equity impacts – a critical priority for CMS and the Administration. We will continue to monitor the data internally and hope to release the data through analyses to provide better insight on the impact of the data we have on individuals with Medicare, especially for those who live in underserved areas, over the next 3-year approval timeline.

CMS seeks to use the data to understand how many minority providers are serving people in underserved communities and how many providers speak a language other than English to provide better care to patients with limited English proficiency. The data allows for research to determine the impact on providers and patients when providers leave the Medicare program to have a better understanding on the populations the providers serve. However, this data collection is broader than just Medicare or Medicaid providers.

Comprehensive data, including race, ethnicity, language, and accessibility may be used to plan for quality improvements and address changes among the target populations that improve patient outcomes.

3. Use of Information Technology

This collection lends itself to electronic collection methods and is currently available through the NPPES website. The NPPES website is a secure, intelligent and interactive national data storage system maintained and housed at the Virtual Data Center (VDC) hosted by the Companion Data Services (CDS), which is the company that maintains CMS' Data Centers. It has limited user access through strict CMS systems access protocols. Access to the data maintained in NPPES is limited to CMS, NPPES contractor employees responsible for provider NPI processing, and the providers who have NPI files in NPPES. These providers only have access to their own files. The data stored in NPPES mirrors the data collected on the CMS-10114 (National Provider Identifier (NPI) Application/Update Form) (OMB- 0938-0931) and is maintained indefinitely as both historical and current information. NPPES also supports an Internet-based provider/supplier platform which allows the provider/supplier to complete a web-based CMS-10114 application and transmit it to the NPPES contractor database for processing, including an upload file capability (also known as EFI submission) for approved provider organizations that helps to facilitate the enumeration process. NPPES has also adopted an electronic signature standard. Periodically, CMS will require adjustment to the format of the CMS-10114 form (either paper, electronic or both) for clarity and to improve optional data fields. These adjustments do not alter the current OMB data collection approval.

4. Duplication Efforts

The CMS-10114 – OMB- 0938-0931 The National Provider Identifier Application/Update Form Revision (paper application) was published for the 60-day comment period on June 8th. The burden for the NPI application is included in that PRA package. The data fields in the PRA package for OMB-0938-0931 are required by regulations; unlike this new PRA package which only includes burden for the optional data fields, collected on the web application. This new PRA package will eventually be merged into the CMS-10114 – OMB- 0938-0931 and it will be acceptable to have optional and required fields within one PRA package.

5. Small Businesses

There will be minimal impact on small businesses as the length of time to read, complete, and submit the online form is expected to be less than ten minutes.

6. Less Frequent Collection

After the application for an initial NPI, this information is collected on an as needed basis as the regulation also mandates that health care providers notify NPPES of updates to their NPI data within 30 days of the update. This PRA package is for the optional data fields.

7. **Special Circumstances**

There are no special circumstances associated with this collection.

8. **Federal Register Notice/Outside Consultation**

A 60-day notice published in the Federal Register on October 16, 2020 (85 FR 65814). Several comments were received. A 30-day notice published on March 10, 2021 (86 FR 13719).

No outside consultation was sought.

9. **Payments/Gifts to Respondents**

There are no payments or gifts to the respondents as a result of completing this form.

10. **Confidentiality**

CMS will comply with the Delegation of Program Authority under Section 3101 of the Public Health Service Act and the Delegation of Authorities under Title IV--Delivery of the 21st Century Cures Act. The OMH information is not FOIA'able and the NPI registry is public information

The SORB information: SORN 09-70-0555, National Plan and Provider Enumeration System" (NPPES), HHS/CMS/OFM. For purposes of this SOR, the system contains information related to health care providers who are individuals who have applied for and have been assigned a NPI. The definition of a health care provider is limited to those entities that furnish or bill and are paid for, health care services in the normal course of business. The statutory definition of a health care provider is found at 45 CFR 160.103. Authority for maintenance of this system is given under §§ 1173 and 1175 of the Act; as amended by Public Law 104 -191, authorize the assignment of a unique identifier to all health care providers and the maintenance of a data base on containing the information they furnished in their application for an NPI.

11. **Sensitive Questions**

There are no sensitive questions associated with this information.

12. **Burden Estimate (Total Hours & Costs)**

A. Burden Estimate

CMS is calculating burden based on the number of actual applications processed for calendar

year 2020 and NPPES data compiled. Burden has been estimated based on the number of affected users, reasons to collect the data, and the data collection methods.

The hour burden to the respondents is calculated based on the following assumptions:

- There were 712,964 applications for initial NPIs in 2020 using the NPPES Web and NPPES Web using EFI process.
- The electronic and EFI (which is also electronic but takes a different format) collection will be counted in the burden hours.
- Completion of the application takes 0.17 hours (10 minutes).

CMS estimates the new total burden hours for this information collection to be 121,205 hours. These figures are calculated based on when/why and how long it takes a respondent to complete and submit this application.

HOURS ASSOCIATED WITH COMPLETING THE APPLICATION:

A. 674,563 respondents completing the application form via NPPES Web

B. 38,401 respondents completing the application form via NPPES Web using EFI process

- There were 712,964 applications for initial NPIs in 2020 9 using the NNPES Web and NPPES Web using EFI process.
- The electronic and EFI (which is also electronic but takes a different format) collection will be counted in the burden hours.
- Completion of the application takes 0.17 hours (10 minutes).
 - Cost to the respondents is calculated as follows based on the following assumptions:
 - The date fields question can be completed the providers and
 - The record keeping burden is included in the time determined for completion by administrative staff.
 - Based on the information above, CMS has split the cost burden as follows:
 - Office and administrative support workers complete the application in approximately 8 minutes, or 0.135 hours, and
 - Health diagnosing and treating practitioners review and sign the application in approximately 2 minutes, or 0.035 hours.

Table 1: Burden Hours

Collection Types	Respondents	Responses	Time (hours)	Total hours
NPPES WEB Application	674,563	1	0.17	114,676 hours

NPES Web Application using EFI process	38,401	1	0.17	6,528 hours
TOTAL	712,964 Respondents			121,204 hours

B. Burden Estimate (costs)

- CMS used the hourly wage calculations which were taken from the most recent wage data provided by the Bureau of Labor Statistics (BLS) for May 2020 (see http://www.bls.gov/oes/current/oes_nat.htm#43-0000), indicating the mean hourly wage for the general categories of "Office and Administrative Support Occupations" and "Health Diagnosing and Treating Practitioners." CMS adjusts the employee hourly wage estimates by a factor of 100 percent. This is necessarily an estimation, both because fringe benefits and overhead costs vary significantly from employer to employer, and because methods of estimating these costs vary widely from study to study. Nonetheless, there is no practical alternative and we believe that doubling the hourly wage to estimate total cost is a reasonably accurate estimation method.

Table 2: Wage Rates

Wage Category	Base Wage Rate	Wage Rate + Fringe Benefits (100%)
Office and Administrative Support Occupations	\$20.38	\$40.76
Health Diagnosing and Treating Practitioners	\$50.58	\$101.16

The cost burden to the respondents is calculated based on the following assumptions:

COSTS ASSOCIATED WITH COMPLETING THE APPLICATION:

CMS estimates the new total burden cost for this information collection to be \$3,856,798.48 for 712,964 Respondents. These figures are calculated based on when/why and how long it takes a respondent to complete and submit this application as well as who is completing and signing the application.

A. 674,563 respondents completing the application form via NPPES Web

0.135 hours (8 minutes) x \$40.76 = \$5.50 per application completed by office and administrative support workers

0.035 hours (2 minutes) x \$101.16 = \$3.54 per application reviewed and signed by Health Diagnosing and Treating Practitioners

Subtotal 1 = \$5.50 + \$3.54 = \$9.04 per application

Total 1: 674,563 respondents x \$9.04 per application = \$6,098,049.52 annually for completion of the applications via NPPES Web

B. 38,401 respondents completing the application form via NPPES Web using EFI process

0.135 hours (8 minutes) x \$40.76 = \$5.50 per application completed by office and administrative support workers

0.035 hours (2 minutes) x \$101.16 = \$3.54 per application reviewed and signed by Health Diagnosing and Treating Practitioners

Subtotal 1 = \$5.50 + \$3.54 = \$9.04 per application

Total 2:

38,401 respondents x \$9.04 per application = \$347,145.04 annually for completion of the applications via NPPES Web using EFI process

TOTAL FOR APPLICATIONS:

Total 1 + Total 2 = \$6,098,049.52 + \$347,145.04 = \$6,445,194.56 total cost for the application using the form

Table 3: Total Burden for Supplemental Data Collection

Data Collection Activity	Respondents	Responses Per Year	Time Per Response (hours)	Total Burden Per Year (hours)	Cost per Hour	Total Burden Costs Per Year Using Loaded Rate
NPPES Web Application using EFI process	674,563	1				\$6,098,049.52
NPPES Web Application using EFI process	38,401	1				\$347,145.04
Total	712,964					\$6,445,194.56

13. Capital Costs

There are no capital costs associated with this collection.

14. Cost to the Federal Government

There is no cost to the federal government for this information collection.

15. Changes to Burden

This is a new request for an OMB control number.

16. Publication/Tabulation Dates

The NPPES captures the information from the application form, uniquely identifies the health care provider, and assigns it an NPI. Published on the NPIs registry and the NPPES files (https://download.cms.gov/nppes/NPI_Files.html).

17. Expiration Date

The approved OMB control number and expiration date for this package will be listed on the NPPES site. (nppes.cms.hhs.gov).