Act (FD&C Act) by adding clause (ii) ''Small business fee waiver''. The amended language gave FDA the discretion, beginning in fiscal year 2025, to waive the annual registration fee for device establishments that are small businesses if FDA determines that paying the fee for such year represents a financial hardship. Additionally, the amended statute acknowledges that device establishments may be located in countries without a National Taxing Authority. As a result of this amended statutory language, FDA is issuing this guidance to update the guidance ''Medical Device User Fee Small Business Qualification and Certification'' to describe how FDA plans to determine if a small business is experiencing ''financial hardship'', which makes them eligible for a waiver of their registration fee. The guidance details what information FDA intends to review and consider in making this determination. The guidance further clarifies the various fee waivers and reductions available to small businesses, and describes under what circumstances a small business may avail itself of them.

A notice of availability of the guidance appeared in the **Federal Register** of February 22, 2024 (89 FR 13349). FDA considered comments received and revised the guidance as appropriate in response to the comments, including describing the applicability of the waiver to previous years, how often a waiver may be used, and clarifying the conditions under which FDA may grant the waiver.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on Medical Device User Fee Small Business Qualification and Determination Guidance. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. FDA considered the applicability of Executive Order 14192, per OMB guidance in M–25–20, and finds this action to be deregulatory in nature.

II. Electronic Access

Persons interested in obtaining a copy of the guidance may do so by downloading an electronic copy from the internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at *https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/guidance-documents-medical-devices-and-radiation-emitting-products.* This guidance document is also available at *https://www.regulations.gov, https://www.fda.gov/regulatory-information/search-fda-guidance-documents.* Persons unable to download an electronic copy of ''Medical Device User Fee Small Business Qualification and Determination Guidance'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number GUI00018007 and complete title to identify the guidance you are requesting.

III. Paperwork Reduction Act of 1995

The guidance refers to previously approved FDA collections of information. The collections of information related to Medical Device User Fee Small Business Qualification and Determination have been approved under OMB control number 0910–0508.

Dated: July 28, 2025.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–14460 Filed 7–30–25; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

[CMS–0063–N]

RIN 0938–ZB90

National Plan and Provider Enumeration System (NPPES) Data Changes

AGENCY: Office of the Secretary, Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: This notice provides information on changes to a data element collected by the National Plan and Provider Enumeration System (NPPES) when a provider applies for a National Provider Identifier (NPI), which changes are made pursuant to provisions of the January 20, 2025, Executive Order, 14168 (90 FR 8615). This notice also provides an explanation of the nature and rationale for the changes, and their effect on public-facing data available in NPPES downloadable files and the query-only database on the internet.

FOR FURTHER INFORMATION CONTACT: Michael Cimmino at (410) 786–6408; *AdministrativeSimplification@cms.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

A. Legislative and Regulatory Background

Through subtitle F of title II of the Health Insurance Portability and Accountability Act of 1996 (HIPAA), Congress added Part C, ''Administrative Simplification'' to title XI of the Social Security Act (the Act) (Public Law (Pub. L.) 104–191). Part C of title XI consists of sections 1171 through 1180 of the Act. These sections define various terms and require the Secretary of the Department of Health and Human Services (HHS) (the Secretary) to adopt standards and operating rules with respect to certain electronic transactions, unique health identifiers, code sets, and associated implementation specifications relating to health information. Health plans, health care clearinghouses, and certain health care providers (collectively known as covered entities) must comply with the provisions adopted by the Secretary. The Secretary delegated authority for administering and enforcing HIPAA Administrative Simplification provisions related to transactions, code sets, unique identifiers, and operating rules, implemented in 45 CFR parts 160 and 162, to the Centers for Medicare & Medicaid Services (CMS) (68 FR 60694).

Section 1173(b) of the Act requires the Secretary to adopt a unique standard health identifier for individuals, employers, health plans, and health care providers for use in the health care system and to specify the purposes for which the identifiers may be used. A proposed rule titled ''National Standard Health Care Provider Identifier'' (hereinafter referred to as the national provider identifier (NPI) proposed rule) appeared in the May 7, 1998, **Federal Register** (63 FR 25320), and proposed a standard unique health identifier, or NPI, for health care providers (providers) and requirements concerning its implementation. A final rule titled ''HIPAA Administrative Simplification: Standard Unique Health Identifier for Health Care Providers,'' (hereinafter referred to as the NPI final rule) appeared in the January 23, 2004, **Federal Register** (69 FR 3434), and adopted the NPI as the standard unique health identifier for health care providers. The NPI final rule established that HIPAA covered entities must use NPIs to identify health care providers in electronic transactions for which the Secretary has adopted a standard.

In the March 4, 2024, **Federal Register** (89 FR 15581), we published a notice that added additional gender code choices to align with Executive Order

14075 ''Advancing Equality for Lesbian, Gay, Bisexual, Transgender, Queer, and Intersex Individuals'' (87 FR 37189) (hereinafter, Executive Order 14075). Executive Order 14075 was rescinded on January 20, 2025, by Executive Order 14168, ''Defending Women from Gender Ideology Extremism and Restoring Biological Truth to the Federal Government'' (hereinafter, ''Defending Women E.O.'').

B. Operational and System Background

The NPI final rule established that NPIs are assigned to health care providers through the National Provider System (NPS). The preamble to the NPI final rule included an ''NPS Data Elements Table'' (69 FR 3457) that listed the data elements HHS expected to collect from health care providers via the NPS, and certain data, including the NPI itself, that are NPS-generated. The NPS, now called the National Plan and Provider Enumeration System (NPPES),[1] uniquely identifies health care providers through an application process and assigns NPIs. NPPES creates a record for each health care provider to whom it assigns an NPI. The records are updated when health care providers furnish updates to NPPES; regulations at 45 CFR 162.410(a)(4) require health care providers to notify the NPPES within 30 days of any change in required data elements.

NPPES categorizes health care providers into two types: individuals, such as physicians, and organizations, such as hospitals. A health care provider may apply for an NPI in one of three ways, by: (1) completing form CMS–10114 (NPI Application/Update Form) and mailing it to NPPES; (2) applying online at *https://NPPES.cms.hhs.gov/;* or (3) having an approved Electronic File Interchange Organization (EFIO) submit its NPI application data to NPPES in an electronic format defined by HHS.[2] [3] Health care providers who apply online self-select user identifiers and passwords to gain system access, and, by virtue of that, obtain electronic access to the information in their own NPPES records. This access allows those health care providers to submit updates to their NPPES data electronically via the internet.

The NPI final rule requires that the NPS (now NPPES) disseminate data in response to approved requests. Following publication of the NPI final rule, CMS, as the NPPES administrator, published a notice that appeared in the May 30, 2007, **Federal Register** (72 FR 30011) describing the data dissemination strategy and process for NPI data maintained in NPPES (hereinafter referred to as the NPPES Data Dissemination notice). The NPPES Data Dissemination notice included a list of data elements that CMS determined are required to be disclosed under the Freedom of Information Act (FOIA) (72 FR 30012).

The health care industry needs access to NPPES health care provider data to obtain provider NPIs to submit HIPAA-compliant health care transactions. In anticipation of an extraordinary demand from the health care industry for FOIA-disclosable NPPES health care provider data, in September 2007, CMS began making this information available to the public, in accordance with the Electronic Freedom of Information Act Amendments of 1996 (Pub. L. 104–231), via the internet in two forms:

- *NPI Registry:* The NPI Registry is a query-only database that is updated daily to enable users to query NPPES (for example, search by NPI, provider name, etc.) and retrieve the FOIA-disclosable data from the search results. There is no charge to view the data.
- *NPI Downloadable Data:* These data include the following files: (1) Full Replacement Monthly NPI File; (2) Weekly Incremental NPI File; and (3) Full Replacement NPI Deactivation File. There is no charge to download the data.

II. Provisions of This Notice

The ''Defending Women E.O.'' directed HHS to provide to the U.S. Government, external partners, and the public clear guidance expanding on the sex-based definitions it set forth.[4] HHS's guidance [5] recited the definition of sex provided in the Defending Women E.O.: a person's immutable biological classification as either male or female, stating there are only two sexes because there are only two types of gametes. The guidance stated that HHS has long recognized that the biological differences between females and males require sex-specific practices in medicine and research to ensure optimal health outcomes and rigorous research, including by considering sex as a biological variable. The guidance also stated that recognizing the immutable and biological nature of sex is essential to ensuring the protection of women's health, safety, private spaces, sports, and opportunities, and that restoring biological truth to the federal government is critical to scientific inquiry, public safety, morale, and trust in government itself.

The NPI final rule acknowledged that the data elements and information presented in the data elements table were not intended for data design purposes and that the names and attributes of the data elements could be revised during the NPS design and development.[6] As such, while we anticipated collecting these types of data, the exact data elements and values were not static and subject to change.

The data elements table in the NPI final rule included the data element named ''provider gender code.'' [7] Our operational experience from nearly two decades with the enumeration system after the publication of the final rule yields no evidence that this data element was necessary to support the unique identification of a health care provider. Therefore, we are making a change to the data element name from ''provider gender code'' to ''provider sex code''; revising the code description by replacing the word ''gender'' with ''sex,''; and providing sex code selection choices of M (male) and F (female).

This effects a change in position from what we articulated in the March 2024 notice, where we implemented a different policy for this data element under the now-rescinded Executive Order 14075. Our change in position is rational and justified given the lack of evidence that the gender code was necessary to support the unique identification of a health care provider as previously contemplated in the 2004 NPI final rule (69 FR 3456), the rescission of the prior executive order that was superseded by the ''Defending Women E.O.,'' and HHS's new guidance issued on February 19, 2025. Our prior approach to this data element has been rendered outmoded and would conflict with HHS's current policy position.

[1] *https://nppes.cms.hhs.gov/#/.*

[2] The information collection request is currently approved under OMB control number 0938–0931. (*https://www.reginfo.gov/public/do/DownloadNOA?requestID=311118.*)

[3] The Electronic File Interchange (EFI), also referred to as ''bulk enumeration,'' is a process by which a provider or group of providers can have an EFIO apply for NPIs on their behalf. EFIOs are approved by CMS through a certification process and submit information in a format designated by CMS; *https://www.cms.gov/medicare/regulations-guidance/administrative-simplification/efi.*

[4] Defending Women E.O. at section 3(a).

[5] *https://womenshealth.gov/sites/default/files/_images/2025/2.19.25%20Defining%20Sex%20Guidance%20for%20Federal%20Agencies%2C%20External%20Partners%2C%20and%20the%20Public%20FINAL.pdf.*

[6] HIPAA Administrative Simplification: Standard Unique Health Identifier for Health Care Providers (NPI final rule) (69 FR 3455) *https://www.federalregister.gov/documents/2004/01/23/04-1149/hipaa-administrative-simplification-standard-unique-health-identifier-for-health-care-providers#p-394.*

[7] We note that while the NPI proposed rule used the term ''sex,'' (*see* 63 FR 25335 and 25338) this term was changed to ''gender'' in the NPI final rule.

We realize that, under our approach subsequent to the March 2024 notice, providers may have submitted information pertaining to this data element to the NPPES; this notice makes providers aware how that data will be treated going forward. In this section, we discuss our prospective approach to the data element, how the previously collected data will be stored and disseminated, and providers' options for updating data elements previously submitted to the provider enumeration system.

The data element relevant to this notice is listed in Table 1, along with the descriptions of the information contained in each column of Table 1 are as follows:

- *Data Element Name:* The name of the data element residing in the NPPES.
- *Description:* The definition of the data element and related information.
- *Data Status:* The instruction for furnishing the information requested for the data element. The abbreviations used in this column are as follows:

++ *Required (R):* Required for NPI assignment.

++ *NPPES-generated (NG):* Generated or assigned by the NPPES.

++ *Optional (O):* Not required for NPI assignment.

++ *Situational (S):* If a certain condition exists, the data element is required. Otherwise, it is not required.

++ *Repeat (RPT):* Indicates that the data element is a repeating field. A repeating field is one that can accommodate more than one separate entry. Each separate entry must meet the edits, if any, designated for that data element.

- *Data Condition:* Describes the condition(s) under which a ''Situational'' data element must be furnished.
- *Entity Types:* The ''Entity type codes'' to which the data element applies. Code describing the type of health care provider that is being assigned an NPI. Codes are as follows:

++*1* = (Person): individual human being who furnishes health care.

++*2* = (Non-person): entity other than an individual human being that furnishes health care (for example, hospital, SNF, hospital subunit, pharmacy, or HMO).

- *Use:* The purpose for which the information is being collected or will be used. The abbreviations used in this column are as follows:

++I: The data element supports the unique identification of a health care provider.

++A: The data element supports administrative implementation specification.

TABLE 1—NPPES DATA ELEMENT AT ISSUE IN THIS NOTICE

Data element name	Description	Data status	Data condition	Entity types	Use
Provider sex code.	The code designates the provider's sex if the provider is a person.	O	Collected if the provider's NPI is Entity type code = 1; submission of a missing or blank value will not cause an application to be rejected.	1	I

The NPI final rule identified provider gender code as a required data element if the provider's NPI is Entity type code = 1. While neither the NPI final rule nor the NPPES Data Dissemination notice identified the gender codes that NPPES would collect and disseminate when an individual provider applied for an NPI, providers were given the option to click on a box that captured gender as either male or female. NPPES stored that selection as code (F) when an individual selected female and (M) when an individual selected male. The NPI Registry query-only database displayed the descriptions ''Male'' and ''Female'' in disseminating the provider gender information, and NPI downloadable files displayed the information using the codes (M) and (F).

NPPES will disseminate sex code options of M and F to promote improved accuracy in publicly available data. Provider gender code selections made after March 4, 2024, that are no longer available in accordance with the Defending Women E.O. will now appear as blank (that is, will have no value selected) in public facing files. Although the provider sex code is collected on the NPI application when a provider indicates their entity type is ''1,'' it will now be an optional data element. For clarity, we emphasize that an applicant who is an individual (Entity type code = 1) *may* leave the data field empty (doing so *will not* affect an applicant's ability to enumerate), and this data element will no longer fall within the contours of 45 CFR 162.410(a)(4), which requires reporting to the NPPES changes to required data elements within 30 days of the change. Providers with Entity type code = 1 who previously furnished to NPPES a provider gender code other than M or F in accordance with the March 4, 2024 notice (89 FR 15581) may elect to update or change their selection in NPPES to align with the new provider sex code's parameters (or have the EFIO that submitted their NPI application data to NPPES cause them to be changed in NPPES) or they may elect to do nothing, in which case the sex code field will appear as blank in public facing files.

III. Collection of Information Requirements

This document does not impose any new information collection, recordkeeping requirements, or budgetary changes. The information collection request for these NPPES data is currently approved under OMB control number 0938–0931 and expires March 31, 2028.

Robert F. Kennedy, Jr.

Secretary, Department of Health and Human Services.

[FR Doc. 2025–14478 Filed 7–30–25; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.