



**Open Payments Change Summary:
Program Year 2021 and Onwards
Submission Data Mapping Document**

Centers for Medicare & Medicaid Services

June 2021

Version 2.0

OPEN PAYMENTS

CREATING PUBLIC TRANSPARENCY
INTO INDUSTRY-PHYSICIAN
FINANCIAL RELATIONSHIPS

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1 Introduction

This document lists the changes made to the Submission Data Mapping Document and CSV templates (also known as sample files) for program years 2021 and onwards compared to Program Years 2016-2020 Submission Data Mapping Document/CSV templates.

These changes are being provided to Applicable Manufacturers and Applicable Group Purchasing Organizations (GPOs) to aid in data collection activities for Program Years 2021 and onwards. The changes described in this document should **not** be implemented for the Program Years 2013 – 2015 Submission Data Mapping Document/CSV templates nor for the Program Years 2016 – 2020 Submission Data Mapping Document/CSV templates.

This document is organized into the following sections:

- General updates;
- Changes to the four tabs of the Submission Data Mapping Document (General Payments tab, Research Payments tab, Physician Ownership tab, and Allowed Special Characters); and
- Changes to CSV templates/sample files.

To understand changes to the Submission Data Mapping Document, follow the steps below:

1. Note which tab in the Submission Data Mapping Document is affected. Then, note the Data Element Name and the Data Element Number (DE#) for a specific entry.
The change to the Data Element is listed below the Data Element Name and Data Element Number.
2. In the Submission Data Mapping Document, select the affected tab and then find the corresponding Data Element Number, located in Column A. and the Data Element Name listed in Column B.
3. Once you have located the Data Element Name and Data Element Number in the Submission Data Mapping Document, you can match it to the update(s) noted in this document.

2 Changes Made in June 2021

2.1 Changes to the Submission Data Mapping Document

This section of the Change Summary Document lists the changes that were made to the Submission Data Mapping Document in June 2021. This creates version 1.0 of the Program Year 2021 and Onwards Submission Data Mapping Document, as shown in its Revision Log tab.

This Submission Data Mapping Document should be used when submitting payments or other transfers of value for Program Year 2021-Onwards. To submit payments or other transfers of value for a previous program year, refer to the Program Years 2016-2020 Submission Data Mapping Document and 2013-2015 Submission Data Mapping Document.

2.1.1 General Updates

- The Submission Data Mapping Document and Change Summary File on the CMS Open payments Resources page are named as below:
 - PY 2021 and Onwards Submission Data Mapping Document [XLSX]
 - Change Summary: PY 2021 and Onwards Submission Data Mapping Document [PDF]

2.1.2 Changes to the General Payments (Non-Research) Tab

- (DE#06) Data Element Name: Covered Recipient Type
 - Updated “Definition/Description” (Column C) to include: or non-physician practitioner i.e. physician assistant, nurse practitioner, clinical nurse specialist, certified registered nurse anesthetist or anesthesiologist assistant, certified nurse-midwife.
 - Updated “Format” (Column E) to include: "10" = Non-Physician Practitioner
 - Updated “Required?” (Column F) to include Select value "10" if covered recipient type is physician assistant, nurse practitioner, clinical nurse specialist, certified registered nurse anesthetist or anesthesiologist assistant, certified nurse-midwife.
 - Updated “Field Size” (Column G) to delete: 1
 - Updated “Field Size” (Column G) to include: ≤ 2
- (DE#07) Data Element Name: Teaching Hospital Name
 - Updated “Required?” (Column F) to delete: IF DE# 6 Covered Recipient Type = "1" (Physician), this field must be blank.
 - Updated “Required?” (Column F) to include: IF DE# 6 is any other value, this field must be blank.
- (DE#08) Data Element Name: Teaching Hospital Tax ID Number (TIN)
 - Updated “Required?” (Column F) to delete: IF DE# 6 Covered Recipient Type = "1" (Physician), this field must be blank.
 - Updated “Required?” (Column F) to include: IF DE# 6 is any other value, this field must be blank.
- (DE#09) Data Element Name: Covered Recipient First Name (DE#09)
 - Updated “Data Element Name” (Column B) to delete: Physician
 - Updated “Data Element Name” (Column B) to include: Covered Recipient
 - Updated “Definition/Description” (Column C) to include: or non-physician practitioner (covered recipient) in the first bullet.
 - Updated “Required?” (Column F) to include: OR "10" (Non-Physician Practitioner) in the second bullet.
 - Updated “CSV Field Name” (Column J) to delete: PHYSICIAN
 - Updated “CSV Field Name” (Column J) to include: COVERED_RECIPIENT

- (DE#10) Data Element Name: Covered Recipient Middle Name (DE#10)
 - Updated “Data Element Name” (Column B) to delete: Physician
 - Updated “Data Element Name” (Column B) to include: Covered Recipient
 - Updated “Definition/Description” (Column C) to include: or non-physician practitioner (covered recipient) in the first bullet.
 - Updated “CSV Field Name” (Column J) to delete: PHYSICIAN
 - Updated “CSV Field Name” (Column J) to include: COVERED_RECIPIENT

- (DE#11) Data Element Name: Covered Recipient Last Name (DE#11)
 - Updated “Data Element Name” (Column B) to delete: Physician
 - Updated “Data Element Name” (Column B) to include: Covered Recipient
 - Updated “Definition/Description” (Column C) to include: or non-physician practitioner (covered recipient) in the first bullet.
 - Updated “Required?” (Column F) to include: OR "10" (Non-Physician Practitioner)
 - Updated “CSV Field Name” (Column J) to delete: PHYSICIAN
 - Updated “CSV Field Name” (Column J) to include: COVERED_RECIPIENT

- (DE#12) Data Element Name: Covered Recipient Name Suffix (DE#12)
 - Updated “Data Element Name” (Column B) to delete: Physician
 - Updated “Data Element Name” (Column B) to include: Covered Recipient
 - Updated “Definition/Description” (Column C) to include: or non-physician practitioner (covered recipient) in the first bullet.
 - Updated “CSV Field Name” (Column J) to delete: PHYSICIAN
 - Updated “CSV Field Name” (Column J) to include: COVERED_RECIPIENT

- (DE#13) Data Element Name: Recipient Primary Business Street Address Line 1 (DE#13)
 - Updated “Definition/Description” (Column C) to include: or non-physician practitioner

- (DE#14) Data Element Name: Recipient Primary Business Street Address Line 2 (DE#14)
 - Updated “Definition/Description” (Column C) to include: or non-physician practitioner

- (DE#15) Data Element Name: Recipient City
 - Updated “Definition/Description” (Column C) to include: or non-physician practitioner

- (DE#16) Data Element Name: Recipient State (DE#16)
 - Updated “Definition/Description” (Column C) to include: or non-physician practitioner

- (DE#17) Data Element Name: Recipient Zip Code (DE#17)
 - Updated “Definition/Description” (Column C) to include: or non-physician practitioner

- (DE#18) Data Element Name: Recipient Country

- Updated “Definition/Description” (Column C) to include: or non-physician practitioner
- (DE#19) Data Element Name: Recipient Province (DE#19)
 - Updated “Definition/Description” (Column C) to delete: or teaching hospital
 - Updated “Definition/Description” (Column C) to include: or non-physician practitioner
- (DE#20) Data Element Name: Recipient Postal Code
 - Updated “Definition/Description” (Column C) to delete: or teaching hospital
 - Updated “Definition/Description” (Column C) to include: or non-physician practitioner
- (DE#22) Data Element Name: Covered Recipient Primary Type
 - Updated “Data Element Name” (Column B) to delete: Physician
 - Updated “Data Element Name” (Column B) to include: Covered Recipient
 - Updated “Definition/Description” (Column C) to include:
 - or non-physician practitioner in first bullet
 - NOTE: For non-physician practitioners, you may select multiple Primary Types as applicable based on your knowledge and the relevant definitions in the Final Rule as the second bullet.
 - Updated “Format” (Column E) to include:
 - "101" = Physician assistant
 - "102" = Nurse practitioner
 - "103" = Clinical nurse specialist
 - "104" = Certified registered nurse anesthetist
 - "105" = Certified nurse-midwife
 - "106" = Anesthesiologist Assistant
 - Updated “Required?” (Column F) to include: then enter only one value between Covered Recipient Primary Type= "1" and Covered Recipient Primary Type= "6" as applicable OR IF DE# 6 Covered Recipient Type = "10" (Non-Physician Practitioner) then enter up to 6 comma-separated values between Covered Recipient Primary Type= "101" and Covered Recipient Primary Type= "106" as applicable
 - Updated “Field Size” (Column G) to delete: 1
 - Updated “Field Size” (Column G) to include: ≤ 20
 - Updated “Validation Rules” (Column H) to include:
 - IF DE# 6 Covered Recipient Type = "1" (Physician)
 - Allowed comma separated multiple values between "101", "102", "103", "104", "105" or "106" IF DE# 6 as second bullet. Covered Recipient Type = "10" (Non-Physician Practitioner) as second bullet.
 - Updated “CSV Field Name” (Column J) to delete: PHYSICIAN
 - Updated “CSV Field Name” (Column J) to include: COVERED_RECIPIENT
- (DE#23) Data Element Name: Covered Recipient NPI
 - Updated “Data Element Name” (Column B) to delete: Physician
 - Updated “Data Element Name” (Column B) to include: Covered Recipient

- Updated “Definition/Description” (Column C) to include: or non-physician practitioner
 - Updated “Required?” (Column F) to include: OR Non-Physician Practitioner has an NPI in the second bullet.
 - Updated “CSV Field Name” (Column J) to delete: PHYSICIAN
 - Updated “CSV Field Name” (Column J) to include: COVERED_RECIPIENT
- (DE#24) Data Element Name: Covered Recipient Specialty (DE#24)
 - Updated “Data Element Name” (Column B) to delete: Physician
 - Updated “Data Element Name” (Column B) to include: Covered Recipient
 - Updated “Definition/Description” (Column C) to include: or the non-physician practitioner’s specialty, chosen from the standardized "Physician and Non-Physician Practitioner taxonomy" code list.
Added “NOTE: For covered recipient non-physician practitioners, you may enter multiple Taxonomy codes as applicable based on Taxonomy list available on the CMS website.”
 - Updated “Required?” (Column F) to include: OR "10" (Non-Physician Practitioner) then Enter up to 6 commas separated Taxonomy code values as applicable in the second bullet.
 - Updated “CSV Field Name” (Column J) to delete: PHYSICIAN
 - Updated “CSV Field Name” (Column J) to include: COVERED_RECIPIENT
 - Updated “Additional Notes” (Column K) to include: and Non-Physician Practitioner
- (DE#25) Data Element Name: Covered Recipient License State and License Number
 - Updated “Data Element Name” (Column B) to delete: Physician
 - Updated “Data Element Name” (Column B) to include: Covered Recipient
 - Updated “Definition/Description” (Column C) to include: or the covered recipient non-physician practitioner at the end of the first sentence.
 - “Covered Recipient prior to License State and License Number” in the second sentence.
 - “If the covered recipient physician or the non-physician practitioner” prior to “is licensed in multiple states” in the second sentence.
 - Updated “Required?” (Column F) to include: OR "10" (Non-Physician Practitioner)
 - Updated “CSV Field Name” (Column J) to delete: PHYSICIAN from all five bullets.
 - Updated “CSV Field Name” (Column J) to include COVERED_RECIPIENT in all five bullets.
- (DE#30) Data Element Name: Marketed Name of Drug, Device, Biological, or Medical Supply
 - Updated “Required?” (Column F) to delete: and Indicate Drug, Device, Biological, or Medical Supply (DE#28) is "1" or "3" from the first bullet.
- (DE#32) Updated “Required?” (Column F) to include: OR Related Product Indicator (DE #26) is "Yes", Covered or Non-covered Product Indicator (DE #27) is "Non-covered", Indicate Drug, Device, Biological, or Medical Supply (DE#28) is "2" or "4" and an

Associated Primary Device Identifier (DE#32) has been provided. Updated “Validation Rules” (Column H) to include: Validated against the CMS-approved Device and Medical Supply Names and Primary Device Identifier dataset. Data Element Name: Primary Device Identifier

- Added “Data Element Name” (Column B) to include: Primary Device Identifier
 - Added “Definition/Description” (Column C) to include: For each covered device or covered medical supply listed in relation to the payment or other transfer of value, provide the associated Primary Device Identifier (DI) (if applicable). The device identifier is the mandatory, fixed portion of a unique device identifier (UDI) that identifies the specific version or model of a device and the labeler of that device. Up to 5 Primary Device Identifiers can be provided. Primary Device Identifiers are required for all devices and medical supplies that have Primary Device Identifiers. If the reported device or medical supply does not have a Primary Device Identifier this field may be left blank. Report this element for devices and medical supplies only. Do not report this element if the payment or other transfer of value is not related to any products.
 - Added “Data Type” (Column D) to include: Alpha-numeric Text
 - Added “Format” (Column E) to include: Free form text
 - Added “Required?” (Column F) to include: Yes IF, Related Product Indicator (DE #26) is "Yes" and Covered or Non-covered Product Indicator (DE #27) is "Covered" or "Non-Covered", Indicate Drug, Device, Biological, or Medical Supply (DE#28) is "2" or "4" and when the reported device or medical supply has a Primary Device Identifier. IF DE# 26 = "N" or if DE# 28 = "1" or "3", this field must be blank.
 - Added “Field Size” (Column G) to include: < 100 Char
 - Added, “Validation Rules” (Column H) to include: Validated against format and field size (columns E and G). If a device or medical supply named in the record (DE#30) has a Primary Device Identifier, the Primary Device Identifier must be reported with the same record. The order of Primary Device Identifiers provided must match the order of named devices or medical supplies in DE#30. If no Primary Device Identifier exists for a named device or medical supply in DE#30, leave the corresponding Primary Device Identifier field blank for that device or medical supply. Validated combination of Name of Associated Covered Device or Medical Supply (DE#30) and Associated Device or Medical Supply Primary Device Identifier (DE#32) against the CMS-approved GUDID Device/Medical Supply Names and Primary Device Identifier dataset.
 - Added “Publicly Displayed” (Column I) to include: Yes
 - Added “CSV Field Name” (Column J) to include: PRIMARY_DEVICE_IDENTIFIER_1
PRIMARY_DEVICE_IDENTIFIER_2
PRIMARY_DEVICE_IDENTIFIER_3
PRIMARY_DEVICE_IDENTIFIER_4
PRIMARY_DEVICE_IDENTIFIER_5
 - Added “Additional Notes” (Column K) to include: No notes
 - Added “Allowed Special Characters” (Column L) to include: no, only values given in Format Column E are allowed
- (DE#40) Data Element Number: Due to the addition of a new Data Element of Primary Device Identifier (DE #32), all other data element numbers (Column A) are amended to reflect the impact of the addition of DE #32. For example, the data element labeled “Applicable Manufacturer or Applicable GPO Making Payment Name” is renumbered

from DE #32 to DE #33. Further, all other fields that refer back to any data elements DE #32 to DE #50 have been amended to refer to the new numbering. Data Element Name: Nature of Payments or Transfer of Value

- Updated "Format" (Column E) to delete: "12" = Compensation for serving as faculty or as a speaker for a non-accredited and noncertified continuing education program and "13" = Compensation for serving as faculty or as a speaker for an accredited or certified continuing education program.
 - Updated "Format" (Column E) to include: "16" = Compensation for serving as faculty or as a speaker for a medical education program, "17" = Debt forgiveness, "18" = Long term medical supply or device loan, "19" = Acquisition.
 - Updated "Validation Rules" (Column H) to delete: characters 1 through 15
 - Updated "Validation Rules" (Column H) to include: characters 1 through 19 with exception of 12 and 13
- (DE#44) Data Element Name: Physician Ownership Indicator (DE#44)
 - Updated "Required?" (Column F) to include: OR IF DE# 6 Covered Recipient Type = "10" (Non-Physician Practitioner) as the second bullet.
 - (DE#45) Data Element Name: Third Party Payment Recipient Indicator
 - Updated "Definition/Description" (Column C) to include: non-physician practitioner or

2.1.3 Changes to the Research Payment Tab

- (DE#06) Data Element Name: Covered Recipient Type
 - Updated "Definition/Description" (Column C) to include: or a covered recipient non-physician practitioner i.e. physician assistant, nurse practitioner, clinical nurse specialist, certified registered nurse anesthetist or anesthesiologist assistant, certified nurse-midwife.
 - Updated "Format" (Column E) to include: or "10" = Covered Recipient Non-Physician Practitioner
 - Updated "Required?" (Column F) to include: Select value "10" if covered recipient type is physician assistant, nurse practitioner, clinical nurse specialist, certified registered nurse anesthetist or anesthesiologist assistant, certified nurse-midwife.
 - Updated "Field Size" (Column G) to delete: 1
 - Updated "Field Size" (Column G) to include: ≤ 2
 - Updated "Validation Rules" (Column H) to include: or 10
- (DE#10) Data Element Name: Covered Recipient First Name
 - Updated "Data Element Name" (Column B) to delete: Physician
 - Updated "Data Element Name" (Column B) to include: Covered Recipient
 - Updated "Definition/Description" (Column C) to include: or non-physician practitioner (covered recipient) in first bullet.
 - Updated "Required?" (Column F) to include: OR "10" (Covered Recipient Non-Physician Practitioner) in second bullet.
 - Updated "CSV Field Name" (Column J) to delete: PHYSICIAN
 - Updated "CSV Field Name" (Column J) to include: COVERED_RECIPIENT

- (DE#11) Data Element Name: Covered Recipient Middle Name
 - Updated “Data Element Name” (Column B) to delete: Physician
 - Updated “Data Element Name” (Column B) to include: Covered Recipient
 - Updated “Definition/Description” (Column C) to include: or non-physician practitioner (covered recipient) in first bullet.
 - Updated “CSV Field Name” (Column J) to delete: PHYSICIAN
 - Updated “CSV Field Name” (Column J) to include: COVERED_RECIPIENT
- (DE#12) Data Element Name: Covered Recipient Last Name
 - Updated “Data Element Name” (Column J) to delete: Physician
 - Updated “Data Element Name” (Column B) to include: Covered Recipient
 - Updated “Definition/Description” (Column C) to include: or non-physician practitioner (covered recipient) in first bullet.
 - Updated “Required?” (Column F) to include: OR "10" (Covered Recipient Non-physician practitioner)
 - Updated “CSV Field Name” (Column J) to delete: PHYSICIAN
 - Updated “CSV Field Name” (Column J) to include: COVERED_RECIPIENT
- (DE#13) Data Element Name: Covered Recipient Name Suffix
 - Updated “Data Element Name” (Column J) to delete: Physician
 - Updated “Data Element Name” (Column B) to include: Covered Recipient
 - Updated “Definition/Description” (Column C) to include: or non-physician practitioner (covered recipient) in first bullet.
 - Updated “CSV Field Name” (Column J) to delete: PHYSICIAN
 - Updated “CSV Field Name” (Column J) to include: COVERED_RECIPIENT
- (DE#14) Data Element Name: Recipient Business Street Address Line 1 (DE#14)
 - Updated “Definition/Description” (Column C) to include: or non-physician practitioner
 - Updated “Required?” (Column F) to include: OR "10" (Covered Recipient Non-Physician Practitioner)
- (DE#15) Data Element Name: Recipient Business Street Address Line 2 (DE#15)
 - Updated “Definition/Description” (Column C) to include: or non-physician practitioner
- (DE#16) Data Element Name: Recipient City (DE#16)
 - Updated “Definition/Description” (Column C) to include: or non-physician practitioner
 - Updated “Required?” (Column F) to include: OR "10" (Covered Recipient Non-Physician Practitioner)
- (DE#17) Data Element Name: Recipient State
 - Updated “Definition/Description” (Column C) to include: or non-physician practitioner

- (DE#18) Data Element Name: Recipient Zip Code
 - Updated “Definition/Description” (Column C) to include: or non-physician practitioner
- (DE#19) Data Element Name: Recipient Country
 - Updated “Definition/Description” (Column C) to include: or non-physician practitioner
 - Update “Required?” (Column F) to include: OR "10" (Covered Recipient Non-Physician Practitioner)
- (DE#20) Data Element Name: Recipient Province
 - Updated “Definition/Description” (Column C) to delete: or teaching hospital
 - Updated “Definition/Description” (Column C) to include: or non-physician practitioner
- (DE#21) Data Element Name: Recipient Postal Code (DE#21)
 - Updated “Definition/Description” (Column C) to delete: or teaching hospital
 - Updated “Definition/Description” (Column C) to include: or non-physician practitioner
 - Update “Required?” (Column F) to delete: OR "2"
 - Update “Required?” (Column F) to include: OR "10"
- (DE#22) Data Element Name: Recipient Email Address
 - Updated “Definition/Description” (Column C) to include: or non-physician practitioner
- (DE#23) Data Element Name: Covered Recipient NPI
 - Updated “Data Element Name” (Column B) to delete: Physician
 - Updated “Data Element Name” (Column B) to include: Covered Recipient
 - Updated “Definition/Description” (Column C) to include:
 - Or non-physician practitioner in the first sentence.
 - Or non-physician practitioner has an NPI in the second sentence.
 - Updated “Required?” (Column F) to include: or Covered Recipient Non-Physician Practitioner
 - Updated “CSV Field Name” (Column J) to delete: PHYSICIAN
 - Updated “CSV Field Name” (Column J) to include: COVERED_RECIPIENT
- (DE#24) Data Element Name: Covered Recipient Primary Type
 - Updated “Data Element Name” (Column B) to delete: Physician
 - Updated “Data Element Name” (Column B) to include: Covered Recipient
 - Updated “Definition/Description” (Column C) to include:
 - Or the covered recipient non-physician practitioner in first bullet.
 - NOTE: For covered recipient non-physician practitioners, you may select multiple Primary Types as applicable based on your knowledge and the relevant definitions in the Final Rule as second bullet.
 - Updated “Format” (Column E) to include:
 - "101" = Physician assistant

- "102" = Nurse practitioner
 - "103" = Clinical nurse specialist
 - "104" = Certified registered nurse anesthetist
 - "105" = Certified nurse-midwife
 - "106" = Anesthesiologist Assistant
 - Updated "Required?" (Column F) to include: then enter only one value between Covered Recipient Primary Type= "1" and Covered Recipient Primary Type= "6" as applicable OR "10" (Covered Recipient Non-Physician Practitioner) then enter up to 6 comma separated values between Covered Recipient Primary Type= "101" and Covered Recipient Primary Type= "106" as applicable
 - Updated "Field Size" (Column G) to delete: 1
 - Updated "Field Size" (Column G) to include: ≤ 20
 - Updated "Validation Rules" (Column H) to include:
 - If DE# 6 Covered Recipient Type = "1" (Covered Recipient Physician) in first bullet.
 - Allowed comma separated multiple values between "101", "102", "103", "104", "105" or "106" if DE# 6 in second bullet.
 - Covered Recipient Type = "10" (Covered Recipient Non-Physician Practitioner) in third bullet.
 - Updated "CSV Field Name" (Column J) to delete: PHYSICIAN
 - Updated "CSV Field Name" (Column J) to include: COVERED_RECIPIENT
- (DE#25) Data Element Name: Covered Recipient Specialty
 - Updated "Data Element Name" (Column B) to delete: Physician
 - Updated "Data Element Name" (Column B) to include: Covered Recipient
 - Updated "Definition/Description" (Column C) to include: or the non-physician practitioner's specialty , chosen from the standardized Physician and Non-Physician Practitioner taxonomy" code list.
Added "NOTE: For non-physician practitioners, you may enter multiple Taxonomy codes as applicable based on Taxonomy list available on the CMS website."
 - Updated "Required?" (Column F) to include: OR "10" (Covered Recipient Non-Physician Practitioner) then enter up to 6 comma separated Taxonomy code values as applicable
 - Updated "CSV Field Name" (Column J) to delete: PHYSICIAN
 - Updated "CSV Field Name" (Column J) to include: COVERED_RECIPIENT
 - Update "Additional Notes" (Column K) to include: Non-Physician Practitioner
 - (DE#26) Data Element Name: Covered Recipient License State and License Number
 - Updated "Data Element Name" (Column B) to delete: Physician
 - Updated "Data Element Name" (Column B) to include: Covered Recipient
 - Updated "Definition/Description" (Column C) to include: "or the covered recipient non-physician practitioner" in the first sentence.
 - "If the covered recipient physician or the non-physician practitioner is licensed in multiple states" at the end of second sentence.
 - Updated "Required?" (Column F) to include: OR "10" (Covered Recipient Non-Physician Practitioner)

- Updated “CSV Field Name” (Column J) to delete: PHYSICIAN from all bullets
- Updated “CSV Field Name” (Column J) to include: COVERED_RECIPIENT_LICENSE in all five bullets
- (DE#31) Data Element Name: Marketed Name of Drug, Device, Biological, or Medical Supply
 - Updated “Required?” (Column F) to delete: and Indicate Drug, Device, Biological, or Medical Supply (DE#29) is "1" or "3" from first bullet.
 - Updated “Required?” (Column F) to include: OR Related Product Indicator (DE #27) is "Yes", Covered or Non-covered Product Indicator (DE #28) is "Non-covered", Indicate Drug, Device, Biological, or Medical Supply (DE#29) is "2" or "4" and an Associated Device or Medical Supply Primary Device Identifier (DE#33) has been provided.
 - Updated “Validation Rules” (Column H) to include: Validated against the CMS approved Device and Medical Supply Names and Primary Device Identifier dataset
- (DE#33) Data Element Name: Primary Device Identifier (DE#33)
 - Added “Data Element Name” (Column B) to include: Primary Device Identifier
 - Added “Definition/Description” (Column C) to include: For each covered device or covered medical supply listed in relation to the payment or other transfer of value, provide the associated Primary Device Identifier (DI) (if applicable).
 - The device identifier is the mandatory, fixed portion of a unique device identifier (UDI) that identifies the specific version or model of a device and the labeler of that device.
 - Up to 5 Primary Device Identifiers can be provided. Primary Device Identifiers are required for all devices and medical supplies that have Primary Device Identifiers. If the reported device or medical supply does not have a Primary Device Identifier this field may be left blank. Report this element for devices and medical supplies only. Do not report this element if the payment or other transfer of value is not related to any products.
 - Added “Data Type” (Column D) to include: Alpha-numeric Text
 - Added “Format” (Column E) to include: Free form text
 - Added “Required?” (Column F) to include: Yes IF Related Product Indicator (DE #27) is "Yes" and Covered or Non-covered Product Indicator (DE #28) is "Covered" or "Non-Covered", Device, Biological, or Medical Supply (DE#29) is "2" or "4", and when the reported device or medical supply has a Primary Device Identifier. IF DE# 27 = "N" or if DE# 29 = "1" or "3", this field must be blank.
 - Added “Field Size” (Column G) to include: 100 Characters
 - Added “Validation Rules” (Column H) to include: Validated against format and field size (columns E and G). If a device or medical supply named in the record DE#31 has a Primary Device Identifier, the Primary Device Identifier must be reported with the same record. The order of Primary Device Identifiers provided must match the order of named devices or medical supplies in DE#31. If no Primary Device Identifier exists for a named device or medical supply in DE#31,

- leave the corresponding Primary Device Identifier field blank for that device or medical supply Validated combination of Name of Associated Covered Device or Medical Supply (DE#31) and Associated Device or Medical Supply Primary Device Identifier (DE#33) against the CMS approved GUDID Device/Medical Supply Names and Primary Device Identifier dataset.
- Added “Publicly Displayed” (Column I) to include: Yes
 - Added “CSV Field Name” (Column J) to include: PRIMARY_DEVICE_IDENTIFIER_1
PRIMARY_DEVICE_IDENTIFIER_2 PRIMARY_DEVICE_IDENTIFIER_3
PRIMARY_DEVICE_IDENTIFIER_4 PRIMARY_DEVICE_IDENTIFIER_5
 - Added “Additional Notes” (Column K) to include: No notes
 - Added “Allowed Special Characters” (Column L) to include: no, only values given in Format Column E are allowed
- (DE#46) Data Element Name: Principal Investigator Covered Recipient Indicator
 - Updated “Data Element Name” (Column B) to delete: Physician
 - Updated “Definition/Description” (Column C) to include: or non-physician practitioner
 - Updated “Validation Rules” (Column H) to delete: Physician from first bullet.
 - Updated “Validation Rules” (Column H) to include: “or non-physician practitioners” prior to “can be entered” in the first sentence of the first bullet. “Or non-physician practitioner” prior to “cannot be entered as a principal investigator” in the second sentence of the first bullet. “Or non-physician practitioner” prior to “receiving the payment is also the only Principal Investigator,” in the first sentence of third bullet.
 - “Or non-physician practitioner's” prior to “information.” in the last sentence of forth bullet.
 - Updated “CSV Field Name” (Column J) to delete: PHYSICIAN
 - (DE#47) Data Element Name: Principal Investigator Covered Recipient Type (DE#47)
 - Added “Data Element Name” (Column B) to include: Principal Investigator Covered Recipient Type
 - Added “Definition/Description” (Column C) to include: Indicator showing if the Principal Investigator covered recipient of the payment or other transfer of value is a covered recipient physician, or a covered recipient non-physician practitioner i.e. physician assistant, nurse practitioner, clinical nurse specialist, certified registered nurse anesthetist or anesthesiologist assistant, certified nurse-midwife.
 - Added “Data Type” (Column D) to include: Enumeration
 - Added “Format” (Column E) to include: "1" = Covered Recipient Physician or "10" = Covered Recipient Non-Physician Practitioner
 - Added “Required?” (Column F) to include: Yes IF DE# 46, "Principal Investigator Covered Recipient Indicator" = "Y" Select value "1" if principal investigator is a Covered Recipient Physician OR select value "10" if principal investigator is a Covered Recipient Non-Physician Practitioner.
 - Added “Field Size” (Column G) to include: ≤ 2 Char
 - Added “Validation Rules” (Column H) to include: Validates that only 1 or 10 is provided

- Added “Publicly Displayed” (Column I) to include: Yes
 - Added “CSV Field Name” (Column J) to include:
PRINCIPAL1_INVESTIGATOR_COVERED_RECIPIENT_TYPE
 - Added “Additional Notes” (Column K) to include: No Notes
 - Added “Allowed Special Characters” (Column L) to include: No, only values given in Format Column E are allowed.
- (DE#48) Data Element Name: Principal Investigator First Name
 - Updated “Definition/Description” (Column C) to include: or Covered Recipient Non-Physician Practitioner.
 - Updated “Required?” (Column F) to delete: Physician
 - Updated “Required?” (Column F) to include: AND DE # 47, "Principal Investigator Covered Recipient Type" = "1" or "10"
 - (DE#49) Data Element Name: Principal Investigator Middle Name
 - Updated “Definition/Description” (Column C) to include: or Covered Recipient Non-Physician Practitioner.
 - (DE#50) Data Element Name: Principal Investigator Last Name (DE#50)
 - Updated “Definition/Description” (Column C) to include: or Covered Recipient Non-Physician Practitioner.
 - Updated “Required?” (Column F) to delete: Physician
 - Updated “Required?” (Column F) to include: AND DE # 47, "Principal Investigator Covered Recipient Type" = "1" or "10"
 - (DE#51) Data Element Name: Principal Investigator Name Suffix
 - Updated “Definition/Description” (Column C) to include: or Covered Recipient Non-Physician Practitioner.
 - (DE#52) Data Element Name: Principal Investigator Business Street Address Line 1
 - Updated “Definition/Description” (Column C) to include: or Covered Recipient Non-Physician Practitioner.
 - Updated “Required?” (Column F) to delete: Physician
 - Updated “Required?” (Column F) to include: AND DE # 47, "Principal Investigator Covered Recipient Type" = "1" or "10"
 - (DE#54) Data Element Name: Principal Investigator City
 - Updated “Required?” (Column F) to delete: Physician
 - Updated “Required?” (Column F) to include: AND DE # 47, "Principal Investigator Covered Recipient Type" = "1" or "10"
 - (DE#55) Data Element Name: Principal Investigator State
 - Updated “Required?” (Column F) to delete: Physician from first bullet.
 - 56 from third bullet.
 - Updated “Required?” (Column F) to include:
 - AND DE # 47, "Principal Investigator Covered Recipient Type" = "1" or "10" as second bullet
 - 57 in third bullet.

- (DE#56) Data Element Name: Principal Investigator Zip Code
 - Updated “Required?” (Column F) to delete: Physician from first bullet.
 - 56 from third bullet.
 - Updated “Required?” (Column F) to include:
 - AND DE # 47, "Principal Investigator Covered Recipient Type" = "1" or "10" in second bullet
 - 57 in third bullet.
 - Updated “Validation Rules” (Column H) to delete: 54
 - Updated “Validation Rules” (Column H) to include: 55

- (DE#57) Data Element Name: Principal Investigator Country
 - Updated “Required?” (Column F) to delete: Physician from first bullet
 - Updated “Required?” (Column F) to include: AND DE # 47, "Principal Investigator Covered Recipient Type" = "1" or "10" as second bullet.

- (DE#59) Data Element Name: Principal Investigator Postal Code
 - Updated “Required?” (Column F) to delete: 55
 - Updated “Required?” (Column F) to include: 56

- (DE#60) Data Element Name: Principal Investigator Physician Primary Type
 - Updated “Data Element Name” (Column B) to delete: Physician
 - Updated “Definition/Description” (Column C) to include: NOTE: For covered recipient non-physician practitioners, you may select multiple Primary Types as applicable based on your knowledge and the relevant definitions in the Final Rule as second bullet.
 - Updated “Format” (Column E) to include:
 - "101" = Physician assistant
 - "102" = Nurse practitioner
 - "103" = Clinical nurse specialist
 - "104" = Certified registered nurse anesthetist
 - "105" = Certified nurse-midwife
 - "106" = Anesthesiologist Assistant
 - Updated “Required?” (Column F) to delete: Physician from first bullet.
 - Updated “Required?” (Column F) to include:
 - AND DE # 47, "Principal Investigator Covered Recipient Type" = "1" or "10" in second bullet.
 - IF DE # 47, "Principal Investigator Covered Recipient Type" = "1" then enter only one value between Principal Investigator Primary Type= "1" and Principal Investigator Primary Type= "6" as applicable is third bullet.
 - IIF DE # 47, "Principal Investigator Covered Recipient Type" = "10" then enter up to 6 comma separated values between Principal Investigator Primary Type= "101" and Principal Investigator Primary Type= "106" as applicable in third bullet.
 - Updated “Field Size” (Column G) to delete: 1
 - Updated “Field Size” (Column G) to include: ≤ 20
 - Updated “Validation Rules” (Column H) to include:

- If the Principal Investigator is a Covered Recipient Physician in first bullet.
 - Allowed comma separated multiple values between "101", "102", "103", "104", "105" or "106" if the Principal Investigator is a Covered Recipient Non-Physician Practitioner in second bullet.
 - Updated "CSV Field Name" (Column J) to delete: PHYSICIAN
- (DE#61) Data Element Name: Principal Investigator NPI (DE#61)
 - Updated "Definition/Description" (Column C) to include: or non-physician practitioner
 - Updated "Required?" (Column F) to include: or Non-Physician Practitioner
- (DE#62) Data Element Name: Principal Investigator Specialty
 - Updated "Required?" (Column F) to delete: Physician from first bullet.
 - Updated "Required?" (Column F) to include: AND IF DE # 47, "Principal Investigator Covered Recipient Type" = "1" or "10" (Covered Recipient Non-Physician Practitioner) then enter up to 6 comma separated Taxonomy code values as applicable in second bullet.
 - Updated "Definition/Description" (Column C) to include: or the non-physician practitioner's specialty, chosen from the standardized Physician and Non-Physician Practitioner taxonomy" code list.
Added "NOTE: For non-physician practitioners, you may enter multiple Taxonomy codes as applicable based on Taxonomy list available in CMS website."
- (DE#63) Data Element Name: Principal Investigator License State and License Number
 - Updated "Definition/Description" (Column C) to delete: Physician from first bullet.
 - Updated "Definition/Description" (Column C) to include:
 - "non-physician practitioner covered recipient" in the first sentence.
 - "or Non-Physician Practitioner" in the second sentence.
 - Updated "Required?" (Column F) to delete: Physician
 - Updated "Required?" (Column F) to include: AND IF DE # 47, "Principal Investigator Covered Recipient Type" = "1" or "10"
- (DE#64) Data Element Name: Principal Investigator Covered Recipient Type (DE#64)
 - Added "Data Element Name" (Column B) to include: Principal Investigator Covered Recipient Type
 - Added "Definition/Description" (Column C) to include: Indicator showing if the Principal Investigator covered recipient of the payment or other transfer of value is a covered recipient physician, or a covered recipient non-physician practitioner i.e. physician assistant, nurse practitioner, clinical nurse specialist, certified registered nurse anesthetist or anesthesiologist assistant, certified nurse-midwife.
 - Added "Data Type" (Column D) to include: Enumeration
 - Added "Format" (Column E) to include: "1" = Covered Recipient Physician or "10" = Covered Recipient Non-Physician Practitioner

- Added “Required?” (Column F) to include: No, unless indicating multiple Principal Investigators
 - Added “Field Size” (Column G) to include: ≤ 2 Char
 - Added “Validation Rules” (Column H) to include: Validated against data type, format, and field size (columns D, E, G)
 - Added “Publicly Displayed” (Column I) to include: Yes
 - Added “CSV Field Name” (Column J) to include: PRINCIPAL2_INVESTIGATOR_COVERED_RECIPIENT_TYPE
 - Added “Additional Notes” (Column K) to include: No Notes
 - Added “Allowed Special Characters” (Column L) to include: No, only values given in Format Column E are allowed.
- (DE#65) Data Element Name: Principal Investigator First Name (DE#65)
 - Updated “Definition/Description” (Column C) to include: or Covered Recipient Non-Physician Practitioner.
 - (DE#66) Data Element Name: Principal Investigator Middle Name
 - Updated “Definition/Description” (Column C) to include: or Covered Recipient Non-Physician Practitioner.
 - (DE#67) Data Element Name: Principal Investigator Last Name
 - Updated “Definition/Description” (Column C) to include: or Covered Recipient Non-Physician Practitioner.
 - (DE#68) Data Element Name: Principal Investigator Name Suffix
 - Updated “Definition/Description” (Column C) to include: or Covered Recipient Non-Physician Practitioner.
 - (DE#69) Data Element Name: Principal Investigator Business Street Address Line 1
 - Updated “Definition/Description” (Column C) to include: or Covered Recipient Non-Physician Practitioner.
 - (DE#76) Data Element Name: Principal Investigator Postal Code (DE#76)
 - Updated “Required?” (Column F) to delete: 71
 - Updated “Required?” (Column F) to include: 74
 - (DE#77) Data Element Name: Principal Investigator Primary Type
 - Updated “Data Element Name” (Column B) to delete: Physician
 - Updated “Data Element Name” (Column B) to include: Principal Investigator Primary Type
 - Updated “Definition/Description” (Column C) to include: NOTE: For covered recipient non-physician practitioners, you may select multiple Primary Types as applicable based on your knowledge and the relevant definitions in the Final Rule.
 - Updated “Format” (Column E) to include:
 - "101" = Physician assistant
 - "102" = Nurse practitioner

- "103" = Clinical nurse specialist
 - "104" = Certified registered nurse anesthetist
 - "105" = Certified nurse-midwife
 - "106" = Anesthesiologist Assistant
 - Updated "Field Size" (Column G) to delete: 1 Char
 - Updated "Field Size" (Column G) to include: ≤ 20
 - Updated "CSV Field Name" (Column J) to delete: PHYSICIAN
 - Updated "CSV Field Name" (Column J) to include: PRINCIPAL2_INVESTIGATOR_PRIMARY_TYPE
- (DE#78) Data Element Name: Principal Investigator NPI (DE#78)
 - Updated "Definition/Description" (Column C) to include: or Non-Physician Practitioner.
- (DE#79) Data Element Name: Principal Investigator Specialty
 - Updated "Definition/Description" (Column C) to include: NOTE: For covered recipient non-physician practitioners, you may enter multiple Taxonomy codes as applicable based on Taxonomy list available on the CMS website.
 - Updated "Additional Notes" (Column K) to include: and Non-Physician Practitioner
- (DE#80) Data Element Name: Principal Investigator License State and License Number
 - Updated "Definition/Description" (Column C) to include:
 - Or Non-Physician Practitioner in the first sentence.
 - Or Non-Physician Practitioner in the second sentence.
- (DE#81) Data Element Name: Principal Investigator Covered Recipient Type
 - Added "Data Element Name" (Column B) to include: Principal Investigator Covered Recipient Type
 - Added "Definition/Description" (Column C) to include: Indicator showing if the Principal Investigator covered recipient of the payment or other transfer of value is a covered recipient physician, or a covered recipient non-physician practitioner i.e. physician assistant, nurse practitioner, clinical nurse specialist, certified registered nurse anesthetist or anesthesiologist assistant, certified nurse-midwife.
 - Added "Data Type" (Column D) to include: Enumeration
 - Added "Format" (Column E) to include: "1" = Covered Recipient Physician or "10" = Covered Recipient Non-Physician Practitioner
 - Added "Required?" (Column F) to include: No, unless indicating multiple Principal Investigators
 - Added "Field Size" (Column G) to include: ≤ 2 Char
 - Added "Validation Rules" (Column H) to include: Validated against data type, format, and field size (columns D, E, G)
 - Added "Publicly Displayed" (Column I) to include: Yes
 - Added "CSV Field Name" (Column J) to include: PRINCIPAL3_INVESTIGATOR_COVERED_RECIPIENT_TYPE
 - Added "Additional Notes" (Column K) to include: No Notes

- Added “Allowed Special Characters” (Column L) to include: No, only values given in Format Column E are allowed.
- (DE#82) Data Element Name: Principal Investigator First Name (DE#82)
 - Updated “Definition/Description” (Column C) to include: or Covered Recipient Non-Physician Practitioner.
- (DE#83) Data Element Name: Principal Investigator Middle Name (DE#83)
 - Updated “Definition/Description” (Column C) to include: or Covered Recipient Non-Physician Practitioner.
- (DE#84) Data Element Name: Principal Investigator Last Name (DE#84)
 - Updated “Definition/Description” (Column C) to include: or Covered Recipient Non-Physician Practitioner.
- (DE#85) Data Element Name: Principal Investigator Name Suffix
 - Updated “Definition/Description” (Column C) to include: or Covered Recipient Non-Physician Practitioner.
- (DE#86) Data Element Name: Principal Investigator Business Street Address Line 1
 - Updated “Definition/Description” (Column C) to include: or Covered Recipient Non-Physician Practitioner.
- (DE#94) Data Element Name: Principal Investigator Primary Type
 - Updated “Data Element Name” (Column B) to delete: Physician
 - Updated “Data Element Name” (Column B) to include: Principal Investigator Primary Type
 - Updated “Definition/Description” (Column C) to include: NOTE: For covered recipient non-physician practitioners, you may select multiple Primary Types as applicable based on your knowledge and the relevant definitions in the Final Rule.
 - Updated “Format” (Column E) to include:
 - "101" = Physician assistant
 - "102" = Nurse practitioner
 - "103" = Clinical nurse specialist
 - "104" = Certified registered nurse anesthetist
 - "105" = Certified nurse-midwife
 - "106" = Anesthesiologist Assistant
 - Updated “Field Size” (Column G) to delete: 1 Char
 - Updated “Field Size” (Column G) to include: ≤ 20
 - Updated “CSV Field Name” (Column J) to delete: PHYSICIAN
 - Updated “CSV Field Name” (Column J) to include: PRINCIPAL3_INVESTIGATOR_PRIMARY_TYPE
- (DE#95) Data Element Name: Principal Investigator NPI
 - Updated “Definition/Description” (Column C) to include: or Non-Physician Practitioner.

- (DE#96) Data Element Name: Principal Investigator Specialty
 - Updated Definition/Description (Column C) to include: NOTE: For covered recipient non-physician practitioners, you may enter multiple Taxonomy codes as applicable based on the Taxonomy list available on the CMS website.
 - Updated “Additional Notes” (Column K) to include: and Non-Physician Practitioner
- (DE#97) Data Element Name: Principal Investigator License State and License Number
 - Updated “Definition/Description” (Column C) to include: or Non-Physician Practitioner
- (DE#98) Data Element Name: Principal Investigator Covered Recipient Type
 - Added “Data Element Name” (Column B) to include: Principal Investigator Covered Recipient Type
 - Added, “Definition/Description” (Column C) to include: Indicator showing if the Principal Investigator covered recipient of the payment or other transfer of value is a covered recipient physician, or a covered recipient non-physician practitioner i.e. physician assistant, nurse practitioner, clinical nurse specialist, certified registered nurse anesthetist or anesthesiologist assistant, certified nurse-midwife.
 - Added “Data Type” (Column D) to include: Enumeration
 - Added “Format” (Column E) to include: "1" = Covered Recipient Physician or "10" = Covered Recipient Non-Physician Practitioner
 - Added “Required?” (Column F) to include: No, unless indicating multiple Principal Investigators
 - Added “Field Size” (Column G) to include: ≤ 2 Char
 - Added “Validation Rules” (Column H) to include: Validated against data type, format, and field size (columns D, E, G)
 - Added “Publicly Displayed” (Column I) to include: Yes
 - Added “CSV Field Name” (Column J) to include: PRINCIPAL4_INVESTIGATOR_COVERED_RECIPIENT_TYPE
 - Added “Additional Notes” (Column K) to include: No Notes
 - Added, “Allowed Special Characters” (Column L) to include: No, only values given in Format Column E are allowed.
- (DE#99) Data Element Name: Principal Investigator First Name
 - Updated “Definition/Description” (Column C) to include: or Covered Recipient Non-Physician Practitioner.
- (DE#100) Data Element Name: Principal Investigator Middle Name
 - Updated “Definition/Description” (Column C) to include: or Covered Recipient Non-Physician Practitioner.
- (DE#101) Data Element Name: Principal Investigator Last Name
 - Updated “Definition/Description” (Column C) to include: or Covered Recipient Non-Physician Practitioner.

- (DE#102) Data Element Name: Principal Investigator Name Suffix
 - Updated “Definition/Description” (Column C) to include: or Covered Recipient Non-Physician Practitioner.
- (DE#103) Data Element Name: Principal Investigator Business Street Address Line 1
 - Updated “Definition/Description” (Column C) to include: or Covered Recipient Non-Physician Practitioner.
- (DE#111) Data Element Name: Principal Investigator Primary Type
 - Updated “Data Element Name” (Column B) to delete: Physician
 - Updated “Data Element Name” (Column B) to include: Principal Investigator Primary Type
 - Updated “Definition/Description” (Column C) to include: NOTE: For covered recipient non-physician practitioners, you may select multiple Primary Types as applicable based on your knowledge and the relevant definitions in the Final Rule.
 - Updated “Format” (Column E) to include:
 - "101" = Physician assistant
 - "102" = Nurse practitioner
 - "103" = Clinical nurse specialist
 - "104" = Certified registered nurse anesthetist
 - "105" = Certified nurse-midwife
 - "106" = Anesthesiologist Assistant
 - Updated “Field Size” (Column G) to delete: 1 Char
 - Updated “Field Size” (Column G) to include: ≤ 20
 - Updated “CSV Field Name” (Column J) to delete: PHYSICIAN
 - Updated “CSV Field Name” (Column J) to include: PRINCIPAL4_INVESTIGATOR_PRIMARY_TYPE
- (DE#112) Data Element Name: Principal Investigator NPI
 - Updated “Definition/Description” (Column C) to include: or Non-Physician Practitioner
 - Updated “Additional Notes” (Column K) to include: and Non-Physician Practitioner
- (DE#113) Data Element Name: Principal Investigator Specialty
 - Updated Definition/Description (Column C) to include: NOTE: For non-physician practitioners, you may enter multiple Taxonomy codes as applicable based on Taxonomy list available on the CMS website.
 - Updated “Additional Notes” (Column K) to include: and Non-Physician Practitioner
- (DE#114) Data Element Name: Principal Investigator License State and License Number (DE#114)
 - Updated “Definition/Description” (Column C) to include: or Non-Physician Practitioner

- (DE#115) Data Element Name: Principal Investigator Covered Recipient Type
 - Added “Data Element Name” (Column B) to include: Principal Investigator Covered Recipient Type
 - Added, “Definition/Description” (Column C) to include: Indicator showing if the Principal Investigator covered recipient of the payment or other transfer of value is a covered recipient physician, or a covered recipient non-physician practitioner i.e. physician assistant, nurse practitioner, clinical nurse specialist, certified registered nurse anesthetist or anesthesiologist assistant, certified nurse-midwife.
 - Added “Data Type” (Column D) to include: Enumeration
 - Added “Format” (Column E) to include: "1" = Covered Recipient Physician or "10" = Covered Recipient Non-Physician Practitioner
 - Added “Required?” (Column F) to include: No, unless indicating multiple Principal Investigators
 - Added “Field Size” (Column G) to include: ≤ 2 Char
 - Added “Validation Rules” (Column H) to include: Validated against data type, format, and field size (columns D, E, G)
 - Added “Publicly Displayed” (Column I) to include: Yes
 - Added “CSV Field Name” (Column J) to include: PRINCIPAL5_INVESTIGATOR_COVERED_RECIPIENT_TYPE
 - Added “Additional Notes” (Column K) to include: No Notes
 - Added, “Allowed Special Characters” (Column L) to include: No, only values given in Format Column E are allowed.

- (DE#116) Data Element Name: Principal Investigator First Name
 - Updated “Definition/Description” (Column C) to include: or Covered Recipient Non-Physician Practitioner.

- (DE#117) Data Element Name: Principal Investigator Middle Name
 - Updated “Definition/Description” (Column C) to include: or Covered Recipient Non-Physician Practitioner.

- (DE#118) Data Element Name: Principal Investigator Last Name
 - Updated “Definition/Description” (Column C) to include: or Covered Recipient Non-Physician Practitioner.

- (DE#119) Data Element Name: Principal Investigator Name Suffix
 - Updated “Definition/Description” (Column C) to include: or Covered Recipient Non-Physician Practitioner.

- DE#120) Data Element Name: Principal Investigator Business Street Address Line 1 (
 - Updated “Definition/Description” (Column C) to include: or Covered Recipient Non-Physician Practitioner.

- (DE#128) Data Element Name: Principal Investigator Primary Type (DE#128)
 - Updated “Data Element Name” (Column B) to delete: Physician

- Updated “Data Element Name” (Column B) to include: Principal Investigator Primary Type
 - Updated “Definition/Description” (Column C) to include: NOTE: For covered recipient non-physician practitioners, you may select multiple Primary Types as applicable based on your knowledge and the relevant definitions in the Final Rule.
 - Updated “Format” (Column E) to include:
 - "101" = Physician assistant
 - "102" = Nurse practitioner
 - "103" = Clinical nurse specialist
 - "104" = Certified registered nurse anesthetist
 - "105" = Certified nurse-midwife
 - "106" = Anesthesiologist Assistant
 - Updated “Field Size” (Column G) to delete: 1 Char
 - Updated “Field Size” (Column G) to include: ≤ 20
 - Updated “CSV Field Name” (Column J) to delete: PHYSICIAN
 - Updated “CSV Field Name” (Column J) to include: PRINCIPALS5_INVESTIGATOR_PRIMARY_TYPE
- (DE#129) Data Element Name: Principal Investigator NPI
 - Updated “Definition/Description” (Column C) to include: or Non-Physician Practitioner
 - Updated “Additional Notes” (Column K) to include: and Non-Physician Practitioner
 - (DE#130) Data Element Name: Principal Investigator Specialty
 - Updated Definition/Description (Column C) to include: NOTE: For non-physician practitioners, you may enter multiple Taxonomy codes as applicable based on Taxonomy list available on the CMS website.
 - Updated “Additional Notes” (Column K) to include: and Non-Physician Practitioner
 - (DE#131) Data Element Name: Principal Investigator License State and License Number
 - Updated “Definition/Description” (Column C) to include: or Non-Physician Practitioner
 - Data Element Number: Due to the addition of new data element of Primary Device Identifier (DE #33), Principal Investigator Covered Recipient Type (DE#47, DE#64, DE#81, DE#98, DE#115), all other data element numbers (Column A) are amended to reflect the impact of the addition of DE #33. For example, the data element labeled “Applicable Manufacturer or Applicable GPO Making Payment Name” is renumbered from DE #33 to DE # 146. Further, all other fields that refer back to any data elements DE #33 to DE #126 have been amended to refer to the new numbering.

2.1.4 Changes to the Physician Ownership Tab

- No changes were made to the Physician Ownership tab

2.1.5 Allowed Special Characters Tab

- No changes were made to the Allowed Special Characters tab

3 Changes Made to CSV Templates

- The CSV sample files to be used for submitting payments are named on the CMS Open payments Resources page as below:
 - PY 2021 and Onwards CSV Sample File: General Payments [CSV]
 - PY 2021 and Onwards CSV Sample File: Research Payments [CSV]
- The CSV templates to be used for submitting payments are renamed within the Open payments system Resources tab as below:
 - PY 2021 and Onwards CSV Template File: Research Payments [CSV]
 - PY 2021 and Onwards CSV Template File: General Payments [CSV]

3.1 Disclosure

- **Disclaimer:** The contents of this document do not have the force and effect of law and are not meant to bind the public in any way unless specifically incorporated into a contract. This document is intended only to provide clarity to the public regarding existing requirements under the law.
- **Activities/persons addressed by this document:** Guidance for Reporting Entities to use with 2021 data collection and submission. A summary of changes made to the Submission Mapping Document since it was last updated in 2015. Review page 1 for detailed instructions on how to use this document to understand updates to the Submission Data Mapping Document. ONLY use this file for records dated on or after January 1, 2021
- **Date of document issuance:** 9/1/2021
- **Replacement / Revision Status:** Revision to previous versions
- **Agency Identifier:** CPI DASG/CPI DTP/DASG/CPI 1613
- **Summary of Document:** Guidance for Reporting Entities to use with 2021 data collection and submission. A summary of changes made to the Submission Mapping Document since it was last updated in 2015.
- **Citation to statutory provision/regulation applicable to this document:**
 - **Statute citation:** SEC. 1128G. [42 U.S.C. 1320a-7h]
 - **Rule citation:** 42 C.F.R. §403.900-14