

Revisions Crosswalk (CMS-10419)

| DE# revised                            | DE# | Data element name | Action to be performed | Changes to the submission file specifications   | Reason for the Change   |
|--|-----|-------------------|------------------------|---|---|
| n/a                                    | n/a | n/a               | Edit                   | The name of this document is changed from data templates to submission file specifications. | Submission file specifications is an accurate term for applicable manufactures and applicable GPOs to use as guidance to build systems to support data collection.  |
| n/a                                    | n/a | n/a               | Edit                   | The column header row # is changed to DE #, data element.                                   | Data element accurately reflects the information contained in that row for the submission file specifications.  |
| n/a                                    | n/a | n/a               | Edit                   | The value column is broken into two columns, data type and format.                          | Presenting this information in two columns will assist applicable manufacturers and applicable GPOs in implementing the submission file specifications in their systems by understanding the data type and format that the OPEN PAYMENTS system will collect.   |
| n/a                                    | n/a | n/a               | Edit                   | The data element size is changed to field size.   | Based on comments requesting clarification regarding character lengths to ensure accurate reporting, the data element size is edited to reflect field size, which describes the field. Additional, the field size includes references to less than or equal to a specific character size, if applicable. This provides guidance for applicable manufacturers and applicable GPOs to not include more characters than what was originally specified. |
| n/a                                    | n/a | n/a               | Addition               | A CMS validation column was added.  | The validation column explains to applicable manufactures and applicable GPOs how their data will be validated in the OPEN PAYMENTS system to help eliminate errors when submitting reports.  |
| n/a                                    | n/a | n/a               | Edit                   | References made to NPPTP are changed to OPEN PAYMENTS.                                      | Documents disseminated to the public now reference OPEN PAYMENTS, rather than NPPTP, therefore the data submission specifications are edited for consistency.   |
| <b>General Payments (Non-Research)</b> |     |                   |                        |   |   |
| 2.                                     | 2.  | Applicable        | Edit                   | 1. The description field is edited to: OPEN   | The description is edited to provide guidance to  |

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|             |     | manufacturer or applicable GPO registration ID submitting file |                        | <p>PAYMENTS system generated identifier used to identify the Applicable Manufacturer or GPO (populated only with CMS provided identifier). If this file contains a single Applicable Manufacturer/GPO's set of payment/transfer of value records, this Applicable Manufacturer/GPO ID will be used for all records in the file. If this file contains a Consolidated Report, this Applicable Manufacturer/GPO ID will be used as the Consolidated Reporter and the Applicable Manufacturer/GPO Names and Open Payments System IDs of the sub-companies making the payments/transfers of value will be recorded with every payment/transfer of value record in the file.</p> <p>2. The field size is edited to: system generated.</p> | collect the information required for to reporting. The field size is edited to reflect the registration ID will be system generated.  |
| 6.          | 6.  | Covered Recipient Type   | Edit                   | <p>1. The description field is edited to: Indicator showing if recipient of the payment or transfer of value is a physician covered recipient or a teaching hospital. Standardized list of covered Teaching Hospital names and information will be provided.</p> <p>2. The field size is edited to: 1 character.</p>   | The description is edited to provide guidance to collect the information required for to reporting. The field size is edited to collect the appropriate characters designated in the format column. |
| 7.          | 7.  | Teaching Hospital Name   | Edit                   | <p>1. The description field is edited to: The name of Teaching Hospital receiving the payment or transfer of value. Standardized list of covered Teaching Hospital names and information will be</p>   | The description is edited to provide guidance to collect the information required for to reporting.   |

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|                    |            |                                       |                               | provided.   |  |
| 8.                 | 8.         | Teaching Hospital Tax ID Number (TIN) | Edit                          | 1. The field size is edited to: 9 characters.   | The field size is edited to collect the appropriate characters designated in the format column.  |
| 9.                 | 9.         | Physician first name                  | Edit                          | 1. The description field is edited to: textual first name, as listed in the National Plan & Provider Enumeration System (NPPES) of the physician (covered recipient) receiving the payment or transfer of value.<br>2. The field size is limited to less than or equal to 20 characters.                    | The description is edited to provide guidance to collect the information required for to reporting. The field size is edited to be consistent with data collection in NPPES. |
| 10.                | 10.        | Physician middle name                 | Edit                          | 1. The description field is edited to: textual middle initial or middle name, as listed in the National Plan & Provider Enumeration System (NPPES) of the physician (covered recipient) receiving the payment or transfer of value.<br>2. The field size is limited to less than or equal to 20 characters. | The description is edited to provide guidance to collect the information required for to reporting. The field size is edited to be consistent with data collection in NPPES. |
| 11.                | 11.        | Physician last name                   | Edit                          | 1. The description field is edited to: textual last name, as listed in the National Plan & Provider Enumeration System (NPPES) of the physician (covered recipient) receiving the payment or transfer of value.<br>2. The field size is limited to less than or equal to 35 characters.                     | The description is edited to provide guidance to collect the information required for to reporting. The field size is edited to be consistent with data collection in NPPES. |
| 12.                | 12.        | Physician name suffix                 | Edit                          | 1. The description field is edited to: suffix, as listed in the as listed in the National Plan & Provider Enumeration System (NPPES) of the physician (covered  | The description is edited to provide guidance to collect the information required for to reporting. The field size is edited to be consistent with data collection in NPPES. |

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|                    |            |  |                               | <p>recipient) receiving the payment or transfer of value chosen from a constrained list of values. (Examples: Jr., Sr., III).</p> <p>2. The field size is limited to less than or equal to five characters.</p>  |  |
| 13.                | 13.        | Recipient Primary (practice location) Business Street Address Line 1 | Edit                          | <p>1. The data element name was edited to: Recipient Primary (practice location) Business Street Address Line 1.</p> <p>2. The field size is limited to less than or equal to 55 characters.</p>   | The data element name is edited to clarify the information required for to reporting. The field size is edited to be consistent with data collection in NPPEs. |
| 14.                | 14.        | Recipient Primary (practice location) Business Street Address line 2 | Edit                          | <p>1. The data element name was edited to: Recipient Primary (practice location) Business Address Line 2.</p> <p>2. The field size is limited to less than or equal to 55 characters.</p>  | The data element name is edited to clarify the information required for to reporting. The field size is edited to be consistent with data collection in NPPEs. |
| 15.                | 15.        | Recipient City   | Edit                          | <p>1. The field size is limited to less than or equal 40 characters.</p>   | The field size is edited to be consistent with data collection in NPPEs.   |
| 17.                | 17.        | Recipient Zip Code   | Edit                          | <p>1. The description field is edited to: The 9 digit zip code for the primary practice location of the physician or teaching hospital (covered recipient) receiving the payment or transfer of value if the primary practice address is in the United States.</p> <p>2. The field size is edited to less than or equal to 9 characters.</p> | Based on comments received the field size is increased to accommodate a 5 digit zip code with an option to report the additional 4 digits.                     |
| 19.                | 19.        | Recipient Province   | Edit                          | <p>1. The description field is edited to: The primary practice province name of the</p>  | The description is edited to provide guidance to collect the information required for to reporting.  |

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|                    |            |  |                               | <p>physician or teaching hospital (covered recipient) receiving the payment or transfer of value if the primary practice address is outside the United States, and if applicable.</p> <p>2. The required field is edited to: no.</p> | The required field is edited to no because based on comments received not all countries outside the United States necessarily have provinces.  |
| 20.                | 20.        | Recipient Postal Code                      | Edit                          | 1. The field size is less than or equal to 20 characters.  | The field size is edited to be consistent with data collection in NPPESS.  |
| 21.                | 21.        | Recipient Email Address                    | Edit                          | 1. The field size is increased to less than or equal to 100 characters.  | The field size is increased to allow applicable manufacturers and applicable GPOs to accurately report a recipient's email address.  |
| 22.                | 22.        | Physician Primary Type                     | Edit                          | <p>1. The description field is edited to: Primary type of medicine practiced by the physician covered recipient.</p> <p>2. The field size is limited to 1 character.</p>   | The description is edited to provide guidance to collect the information required for to reporting. The field size is limited to accurately collect characters in the format column.   |
| 23.                | 23.        | Physician NPI                              | Edit                          | <p>1. The description field is edited to: Individual NPI for Physician (not NPI of any group physician belonging to), required if applicable.</p> <p>2. The required field is changed to: no.</p>                                    | The required field is changed to no because applicable manufacturers and applicable GPOs are only required to report a physician's NPI if applicable.  |
| 24.                | 24.        | Physician Specialty                        | Edit                          | <p>1. The description field is changed to: Physician's single specialty chosen from the standardized "provider taxonomy" list.</p> <p>2. The field size is edited to be limited to 10 characters.</p>                                | Based on comments received the "provider taxonomy" list from the Washington Publishing Company will be provided. This is the same list that can be retrieved through the NPPESS website. The field size is edited to accurately reflect the characters for collection. |
| 25.                | 25.        | Physician License State and License Number | Edit                          | <p>1. The data element name is changed to: Physician License State and License Number</p> <p>2. The description field is changed to: Paired state and state license number of the covered physician; the pairing</p>                 | The physician's license number and state are combined in order to reflect the appropriate state with the license number because multiple license numbers and states may be reported. The field size is edited to accurately reflect the characters for collection.     |

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|             |     |                         |                        | <p>includes the 2 letter state abbreviation followed by the state license number and may include up to 5 "Physician License State and License Number" pairs.</p> <p>3. The field size is edited to: less than or equal to 13 characters.</p> |   |
| -----       | 26. | Physician License State | Delete                 | 1. This data element was deleted.  | This data element was combined with Physician Licenses State(s) and License Number(s) for simplification. |

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| 26.         | ----- | Product Indicator               | Addition               | <p>1. The description field is: Indicator allows the Applicable Manufacturer or GPO to select whether the payment or other transfer of value is associated with ONLY covered drugs, devices, biologicals or medical supplies("Covered"), ONLY non-covered drugs, devices, biologicals or medical supplies ("Non-covered"), neither covered or non-covered drugs, devices, biologicals or medical supplies("None"), or both covered and/or non-covered drugs, devices, biologicals or medical supplies ("Covered" or "Combination"). If the payment or other transfer of value is associated with both covered drugs, devices, biologicals or medical supplies AND non-covered drugs, devices, biologicals or medical supplies, the Applicable Manufacturer may choose either "Covered" or "Combination", where: (1) "Covered" represents covered <math>\geq 1</math> AND non-covered product <math>\geq 0</math> AND that "Combination" is not selected OR (2) "Combination" to represent covered <math>\geq 1</math> AND non-covered product <math>\geq 1</math> AND that "Covered" is not selected.</p> <p>2. The required field is: yes.</p> <p>3. The field size is: 1 character.</p> | <p>Based on comments requesting clarification how applicable manufacturers and applicable GPOs will report "None", "Non-Covered", or report covered products and have the ability to indicate "Non-Covered" the product indicator data element was added. This data element provides clarification for applicable manufacturers' and applicable GPOs' options for when payments or other transfer of value were associated with covered or non-covered products. The Product Indicator should be "None" if the payment or other transfer of value was not associated with any products. The Product Indicator should be "Non-covered" if the payment or transfer of value was only associated with non-covered products. The Product Indicator should be "Combination" if the payment or other transfer of value was associated with at least one covered product and one non-covered product. The payment indicator should be "Covered" if the payment or other transfer of value was associated with only covered products. However, applicable manufacturers and applicable GPOs also have the option to indicate "Covered" if the payment or other transfer of value was associated with at least one covered and one non-covered product and choose to not report that the payment or other transfer of value was also associated with a non-covered product.</p> |
| 27.         | 27.   | Name of Associated Covered Drug | Edit                   | <p>1. The data element name is changed to: Name of Associated Covered Drug or Biological.</p>   | <p>Based on comment received the Name of Associated Covered Drug or Biological data element is separate from the Name of Associated Covered Device or</p>  |

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|             |     | or Biological                        |                        | <p>2. The description field is changed to: The marketed name of the drug or biological associated with this payment or transfer of value; may report the marketed name of up to 5 covered drugs, devices, biologicals, or medical supplies provided in either line 27 or line 29. If the drug or biological associated with this payment or transfer does not have a marketed name, report the drug or biological name as it is registered on clinicaltrials.gov.</p> <p>3. The required field is changed to: Yes IF the "Product Indicator" (line 26) is "Covered" or "Combination" AND there is not at least 1 covered device or medical supply listed in line 29 "Name of Associated Covered Device or Medical Supply".</p> | <p>Medical Supply data element. The required field is edited because this data element is only required based on the product indicator chosen by the applicable manufacturer or applicable GPO, as well as, if the applicable manufacturer or applicable GPOs did not provide at least one covered device or medical supply in the data element Name of Associated Covered Device or Medical supply. A covered product is required for reporting when an applicable manufacturer or applicable GPO indicates either Covered or Combination in the product indicator.</p> |
| 28.         | 28. | NDC of Associated Drug or Biological | Edit                   | <p>1. The data element name is edited to: NDC of Associated Drug or Biological.</p> <p>2. The description is edited to: The National Drug Code, if any, of the drug(s) or biological(s) associated with the payment or other transfer of value. If no NDC for any named covered drug or biological in line 27, enter, "null." If more than one NDC provided, order must match order of named covered drugs or biologicals in line 27, "Name of Associated Covered Drug or Biological;" if no NDC for any named drug or biological in line 27, enter</p>  | <p>The data name and description are changed to accurately define that an NDC is collected for an associated drug or biological, if applicable. The requirement is edited to reflect an NDC of Associated Drug or Biological is only collected if applicable. The field size is edited to limit the character size to 10 characters per NDC.</p>   |



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|             |     |   |                        | <p>"null."</p> <p>3. The requirement field is edited to: Yes IF the Drug(s) or Biological(s) reported in Line 27 (Name of Associated Drug or Biological) has (have) an associated NDC.</p> <p>4. The field size is edited to: 10 characters.</p>   |   |
| 29.         | 29. | Name of Associated Covered Device or Medical Supply | Edit                   | <p>1. The data element name is: Name of Associated Covered Device or Medical Supply</p> <p>2. The description is: The marketed name of the device or medical supply associated with this payment or transfer of value; may report the marketed name of up to 5 covered drugs, devices, biologicals, or medical supplies provided in either line 27 or line 29. Applicable Manufacturer or GPO may provide either (1) the marketed name under which the device or medical supply is or was marketed OR (2) the Therapeutic Area or Product Category. A list of Therapeutic Area or Product Category will be provided.</p> <p>3. The required field is: Yes IF the "Product Indicator" (line 26) is "Covered" or "Combination" AND there is not at least 1 covered drug or biological listed in line 27 "Name of Associated Covered Drug or Biological"</p> <p>4. The field size is: 100 characters.</p> | <p>Based on comment received the Name of Associated Covered Device or Medical Supply data element is separate from the Name of Associated Covered Drug or Biological data element. This will allow for accurate data collection when applicable manufactures or applicable GPOs are choosing how to report a covered device or medical supply, marketed name, therapeutic are or product category. The required filed is edited because this data element is only required based on the product indicator chosen by the applicable manufacturer or applicable GPO, as well as, if the applicable manufacturer or applicable GPOs did not provide at least one covered drug or biological in the data element Name of Associated Covered Drug or Biological. A covered product is required for reporting when an applicable manufacturer or applicable GPO indicates either Covered or Combination in the product indicator.</p> |

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| -----              | 32.        | Entity making Indirect Payment    | Delete                        | 1. This data element is deleted.  | Based on comments received, this data element is deleted because applicable manufacturers and applicable GPOs are not required to distinguish between direct and indirect payments. If an indirect payment is provided to a covered recipient, physician owner or physician investor applicable manufacturers and applicable GPOs are required to report the indirect payment amount in the name of the covered recipient, physician owner or physician investor. |
| 32.                | 33.        | Resubmitted Payment Record ID     | Edit                          | 1. The field size is edited to: system generated.<br>2. The required field is edited to: no.  | The field size is edited to reflect the Resubmitted Payment Record ID will be system generated. The required field is changed to no indicating this field is only required when applicable.   |
| 33.                | 34.        | Total Amount of Payment           | Edit                          | 1. The description field is edited to: U.S. Dollar amount of payment or transfer of value to recipient (manufacturer must convert to dollar currency if necessary). The “total amount of payment” should be tied to a singular transaction or a singular purchased service (items listed in “Nature of Payment” line 37). | The description is edited to provide guidance to collect the information required for to reporting  |
| -----              | 38.        | Details Regarding Form of Payment | Delete                        | 1. This data element is deleted.  | The Details Regarding Form of Payment is deleted because is not required. The Contextual Information field provides applicable manufacturers and applicable GPOs the opportunity to provide a statement with additional context for the payment or other transfer of value.   |
| 42.                | 44.        | Payment Recipient Indicator       | Edit                          | 1. The description is edited to: Indicates if a payment or transfer of value was paid to a third party entity or individual at the request of or on behalf of a covered   | Based on comments received the description is edited to provide guidance for applicable manufactures and applicable GPOs to indicate when a payment or other transfer of value was provided to  |

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|                    |            |   |                               | <p>recipient (physician or teaching hospital).</p> <p>2. The field size is edited to: 1 character</p>  | a third party. The field size is edited to accurately collect the characters required from the formal column.  |
| 43.                | 45.        | Name of third party Entity Receiving the Payment or Transfer of Value | Edit                          | <p>1. The description is edited to: The name of the entity that received the payment or other transfer of value.</p> <p>2. The required field is edited to: Yes if Payment Recipient Indicator is 1.</p>   | Based on comments received the description is edited to provide guidance for applicable manufactures and applicable GPOs to indicate the name of third party entity that received the payment or transfer of value. The required field is edited to determine when applicable manufactures and applicable GPOs are required to provide the name of the third party entity. |
| 44.                | ---        | Charity Indicator   | Addition                      | <p>1. The data element name is: Charity Indicator.</p> <p>2. The description is: Indicates the third party entity that received the payment or other transfer of value is a charity.</p> <p>3. The field size is: 1 character.</p> <p>4. The requirement field is: no.</p>   | The Charity Indicator, which was previously included in the Name of Third Party Entity Receiving Payment or Transfer of Value, in order to allow applicable manufactures and applicable GPOs when covered recipients opted to donate their payment or other transfer of value to a charity.  |
| 45.                | ---        | Third Party Equals Covered Recipient Indicator                        | Addition                      | <p>1. The data element name is: Third Party Equals Covered Recipient Indicator</p> <p>2. The description field is: The Indicator showing the third party that received the payment or transfer of value is a covered recipient.</p> <p>3. The field size is: 1 character.</p> <p>4. The requirement field is: yes, if the Payment Recipient Indicator equals "1" or "2".</p> | This data element is added to indicate if the third party receiving the payment or other transfer of value is a covered recipient. This indicator prevents the OPEN PAYMENTS system from counting the same payment or transfer of value provided twice because the payment or other transfer of value is reported under distinct covered recipients.                       |
| 46.                | 46.        | Contextual Information  | Edit                          | <p>1. The required field is edited to: yes, if the Delay in Publication of Research Payment Indicator equals "1" or "2"</p> <p>2. The field size is edited to: 500 characters.</p>   | The required field is edited to all the OPEN PAYMENTS system to associate payments for delayed publication to a research report. The field size is edited to match contextual information data element in the general payments data file specification.  |

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| 47.         | --- | Delay in Publication of Research Payment Indicator | Addition               | <ol style="list-style-type: none"> <li>1. The data element name is: Delay in Publication of Research Payment Indicator</li> <li>2. The description field is: Indicator showing if an Applicable Manufacturer/GPO is requesting a delay in publication of a payment or other transfer of value when the payment or transfer of value is made in connection with: (1) research on or development of a new product (drug, device, biological, or medical supply) or (2) clinical investigation regarding a new product (drug, device, biological, or medical supply). If the Delay in Publication of Research Payment Indicator equals "1" or "2", indicate the name of the related research study in line 46, "Contextual information." Applicable Manufacturers/GPOs not requesting a delay in publication of a payment or other transfer of value should select (3) not requesting a delay in publication to indicate that no delay is requested. CMS will display payments or other transfers of value no later than four years after the initial request for delay in publication of the [payment or transfer of value. Further details regarding notification to CMS of FDA approval will be forthcoming in guidance.</li> <li>3. The field size is: 1 character.</li> <li>4. The requirement field is: yes.</li> </ol> | This data element allows applicable manufacturers and applicable GPOs to indicate a payment or transfer of value that was outside to the research protocol or agreement should be delayed for publication. |

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| <b>Research</b> |       |   |                        |  |  |
| 6.              | 6.    | Recipient Type  | Edit                   | <ol style="list-style-type: none"> <li>The description field is edited to: Indicator showing if recipient of the payment or transfer of value is a physician covered recipient, teaching hospital covered recipient, non-covered recipient entity or non-covered recipient individual. Standardized list of covered Teaching Hospital names and information will be provided.</li> <li>The field size is edited to: 1 character</li> </ol> | <p>The description field is edited to provide applicable manufactures with four options to indicate the recipient type that is receiving the research payment.</p> <p>The field size is edited to collect the appropriate characters in the format column.</p>   |
| 7.              | ----- | Non-covered Recipient Entity Name                       | Addition               | <ol style="list-style-type: none"> <li>The description field is: The name of the non-covered recipient entity receiving the payment or transfer of value.</li> <li>The required field is: Yes if line 6 is equal to non-covered recipient, "3".</li> </ol>   | This data element is added in order for applicable manufactures to provide the name of the non-covered recipient that received the research payment or other transfer of value. The required field is edited because applicable manufacturers are required to provide the non-covered recipient entity name if the recipient type is a non-covered recipient.                                    |
| 8.              | 7.    | Covered Recipient Teaching Hospital Name                | Edit                   | <ol style="list-style-type: none"> <li>The data element name is edited to: Covered Recipient Teaching Hospital Name.</li> <li>The required field is edited to: Yes if line 6 is equal to Covered Recipient Teaching Hospital Name, "2".</li> </ol>   | The data element name is edited to indicate the information that is being collected. The required field is edited to determine when applicable manufactures are required to provide the teaching hospital name. The required field is edited because applicable manufacturers are required to provide the teaching hospital name if the recipient type is a teaching hospital covered recipient. |
| 9.              | 8.    | Covered Recipient Teaching Hospital Tax ID Number (TIN) | Edit                   | <ol style="list-style-type: none"> <li>The data element name is edited to: Covered Recipient Teaching Hospital Tax ID Number (TIN)</li> <li>The description field is edited to: Tax Identification number of Teaching Hospital receiving the payment or</li> </ol>   | The data element name is edited to indicate the information that is being collected. The description is edited to provide guidance to collect the information required for to reporting. The field size is edited to collect the information required in the format column. The required field is edited because   |

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|                    |            |   |                               | <p>transfer of value. Standardized list of covered Teaching Hospital names and information will be provided.</p> <p>3. The required field is edited to: Yes if 6 is equal to covered recipient teaching hospital, "2".</p> <p>3. The field size is edited to: 9 characters</p>  | applicable manufacturers are required to provide the teaching hospital name TIN if the recipient type is a teaching hospital covered recipient.  |
| 10.                | 9.         | Covered Recipient Physician First Name  | Edit                          | <p>1. The data element name is edited to: Covered Recipient Physician First Name</p> <p>2. The description field is edited to: textual first name, as listed in the National Plan &amp; Provider Enumeration System (NPPES) of the physician (covered recipient) receiving the payment or other transfer of value.</p> <p>3. The required field is edited to: Yes if line 6 equals "1" covered recipient physician.</p> <p>4. The field size is limited to less than or equal to 20 characters.</p> | The data element name is edited to indicate the information that is being collected. The description is edited to provide guidance to collect the information required for to reporting. The field size is edited to be consistent with data collection in NPPES. The required field is edited because applicable manufactures are required to provide the first name of the physician covered recipient if the recipient type is a covered recipient physician. |
| 11.                | 10.        | Covered Recipient Physician Middle Name | Edit                          | <p>1. The data element name is edited to: Covered Recipient Physician Middle Name.</p> <p>2. The description field is edited to: textual middle initial or middle name, as listed in the National Plan &amp; Provider Enumeration System (NPPES) of the physician (covered recipient) receiving the payment or other transfer of value.</p> <p>3. The field size is limited to less than or equal to 20 characters.</p>   | The description is edited to provide guidance to collect the information required for to reporting. The field size is edited to be consistent with data collection in NPPES.   |
| 12.                | 11.        | Covered Recipient                       | Edit                          | <p>1. The data element name is edited to: Covered Recipient Physician Last</p>  | The description is edited to provide guidance to collect the information required for to reporting.  |

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|                    |            | Physician Last Name                     |                               | <p>Name.</p> <p>2. The description field is edited to: textual last name, as listed in the National Plan &amp; Provider Enumeration System (NPPES) of the physician (covered recipient) receiving the payment or other transfer of value.</p> <p>3. The required field is edited to: Yes if line 6 equals “1” covered recipient physician.</p> <p>4. The field size is limited to less than or equal to 35 characters.</p>   | The field size is edited to be consistent with data collection in NPPES. The required field is edited because applicable manufacturers are required to provide a physician’s last name if the recipient type is a covered recipient physician.   |
| 13.                | 12.        | Covered Recipient Physician Name Suffix | Edit                          | <p>1. The data element name is edited to: Covered Recipient Physician Name Suffix.</p> <p>2. The description field is edited to: name suffix, as listed in the as listed in the National Plan &amp; Provider Enumeration System (NPPES) of the physician (covered recipient) receiving the payment or other transfer of value chosen from a constrained list of values. (Examples: Jr., Sr., III).</p> <p>3. The field size is limited to less than or equal to five characters.</p> | The description is edited to provide guidance to collect the information required for to reporting. The field size is edited to be consistent with data collection in NPPES.   |
| 14.                | 13.        | Recipient Business Address Line 1       | Edit                          | <p>1. The field size is edited to: less than or equal to 55 characters.</p> <p>2. The required field is edited to: Yes if Line 6 is equal to “1” covered recipient physician. “2” covered recipient teaching hospital, or “3” non-covered recipient entity.</p>  | The field size is edited to be consistent with data collection in NPPES. The required field is edited because applicable manufacturers are required to provide the address if the recipient type is a covered recipient physician, covered recipient teaching hospital, or non-covered recipient entity. |
| 15.                | 14.        | Recipient                               | Edit                          | 1. The field size is edited to: less than or   | The data element name is edited to clarify the   |

| <b>DE# revised</b> | <b>DE#</b> | <b>Data element name</b> | <b>Action to be performed</b> | <b>Changes to the submission file specifications</b>   | <b>Reason for the Change</b>   |
|--------------------|------------|--------------------------|-------------------------------|--|--|
|                    |            | Business Address Line 2  |                               | <p>equal to 55 characters.</p> <p>2. The required field is edited to: no.</p>  | information required for to reporting. The field size is edited to be consistent with data collection in NPPEs.  |
| 16.                | 15.        | Recipient City           | Edit                          | <p>1. The field size is edited to: less than or equal to 40 characters.</p> <p>2. The required field is edited to: Yes if Line 6 is equal to “1” covered recipient physician. “2” covered recipient teaching hospital, or “3” non-covered recipient entity.</p>  | The field size is edited to be consistent with data collection in NPPEs. The required field is edited because applicable manufacturers are required to provide the address if the recipient type is a covered recipient physician, covered recipient teaching hospital, or non-covered recipient entity. |
| 17.                | 18.        | Recipient State          | Edit                          | <p>1. The required field is edited to: Yes if Recipient Country Line 19 is the United States.</p>  | The required field is edited because applicable manufacturers are required to provide the state if the address is in the United States.  |
| 18.                | 17.        | Recipient Zip Code       | Edit                          | <p>1. The description field is edited to: The 9 digit zip code for the primary practice of the physician, teaching hospital, or non-covered recipient entity receiving the payment or transfer of value if the primary practice address is in the United States.</p> <p>2. The required field is edited to: Yes if Recipient Country Line 19 is the United States.</p> <p>3. The field size is edited to less than or equal to 9 characters.</p> | Based on comments received the field size is increased to accommodate a 5 digit zip code with an option or reporting the additional 4 digits. The required field is edited because applicable manufacturers are required to provide the zip code if the country is the United States.                    |
| 19.                | 16.        | Recipient Country        | Edit                          | <p>1. The required field is edited to: Yes if Line 6 is equal to “1” covered recipient physician. “2” covered recipient teaching hospital, or “3” non-covered recipient entity.</p>  | The required field is edited because applicable manufacturers are required to provide the address if the recipient type is a covered recipient physician, covered recipient teaching hospital, or non-covered recipient entity.  |
| 20.                | 19.        | Recipient Province       | Edit                          | <p>1. The required field is edited to: no.</p>   | The required field is edited to no because based on comments received not all countries outside the  |



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|--------------------|------------|--|-------------------------------|--|---|
|                    |            |  |                               |  | United States necessarily have provinces.   |
| 21.                | 20.        | Recipient Postal Code                    | Edit                          | <ol style="list-style-type: none"> <li>1. The required field is edited to: Yes if Line 6 is equal to “1” covered recipient physician, “2” covered recipient teaching hospital, or “3” non-covered recipient entity and if Recipient Country Line 19 is the United States.</li> <li>2. The field size is less than or equal to 20 characters.</li> </ol>                          | The field size is edited to be consistent with data collection in NPES. The required field is edited because applicable manufacturers are required to provide the address if the recipient type is a covered recipient physician, covered recipient teaching hospital, or non-covered recipient entity.   |
| 22.                | 21.        | Recipient Email Address                  | Edit                          | <ol style="list-style-type: none"> <li>1. The description field is edited to: The primary email address for physician, teaching hospital, or non-covered recipient entity to be used communication purposes.</li> <li>2. The field size is edited to: less than or equal to 100 characters.</li> </ol>   | The description is edited to provide guidance to collect the information required for to reporting. The field size is increased to allow applicable manufacturers and applicable GPOs to accurately report a recipient’s email address.   |
| 23.                | 23.        | Covered Recipient Physician NPI          | Edit                          | <ol style="list-style-type: none"> <li>1. The data element name is edited to: Covered Recipient Physician or Teaching Hospital NPI.</li> <li>2. The description field is edited to: Individual NPI for Physician (not NPI of any group physician belonging to) required if, applicable.</li> <li>3. The required field is edited to: no.</li> </ol>                              | The required filed is changed to no because applicable manufacturers and applicable GPOs are only required to report a physician’s NPI if applicable.   |
| 24.                | 22.        | Covered Recipient Physician Primary Type | Edit                          | <ol style="list-style-type: none"> <li>1. The data element name is edited to: Covered Recipient Physician Primary Type.</li> <li>2. The description field is edited to: Primary type of medicine practiced by the covered recipient physician.</li> <li>3. The required field is edited to: Yes if line 6 recipient type is equal to “1” covered recipient physician.</li> </ol> | The description is edited to provide guidance to collect the information required for to reporting. The required field is edited because applicable manufacturers are required to provide the physician primary type if the recipient type is a covered recipient physician. The field size is limited to accurately collect characters in the format column. |

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|--------------------|------------|--|-------------------------------|---|---|
|                    |            |  |                               | 4. The field size is edited to: 1 character.  |   |
| 25.                | 24.        | Covered Recipient Physician Specialty                        | Edit                          | <ol style="list-style-type: none"> <li>1. The data element name is edited to: Covered Recipient Physician Specialty.</li> <li>2. The required field is edited to: Yes if line 6 recipient type is equal to “1” covered recipient physician.</li> <li>3. The field size is edited to be limited to 10 characters.</li> </ol>   | Based on comments received the “provider taxonomy” list from the Washington Publishing Company will be provided. The required field is edited because applicable manufacturers are required to provide the physician primary type if the recipient type is a covered recipient physician. This is the same list that can be retrieved through the NPPESS website. The field size is edited to accurately reflect the characters for collection.                       |
| 26.                | 25.        | Covered Recipient Physician License State and License Number | Edit                          | <ol style="list-style-type: none"> <li>1. The data element name is changed to: Covered Recipient Physician Licenses State and License Number.</li> <li>2. The description field is changed to: Paired state and state license number of the covered physician; the pairing includes the 2 letter state abbreviation followed by the state license number and may include up to 5 “Physician License State and License Number” pair.</li> <li>3. The required field is edited to: Yes if line 6 recipient type is equal to “1” covered recipient physician.</li> <li>3. The field size is edited to: less than or equal to 20 characters.</li> </ol> | The recipient/physician’s license number and state are combined in order to reflect the appropriate state with the license number because multiple license numbers and states may be reported. The required field is edited because applicable manufacturers are required to provide the physician primary type if the recipient type is a covered recipient physician. The field size is edited to less than or equal to 20 characters per state and license number. |
| -----              | 26.        | Recipient/Physician State                                    | Delete                        | 1. This data element was deleted.   | This data element was combined with Physician Licenses State(s) and License Number(s) for simplification.   |
| 27.                | -----      | Product Indicator  | Addition                      | 1. The description field is: Indicator allows the Applicable Manufacturer to select whether the payment or other transfer of value is associated with ONLY covered  | Based on comments requesting clarification how applicable manufacturers will report “None”, “Non-Covered”, or report covered products and have the ability to indicate “Non-Covered” the product  |

| DE# revised | DE# | Data element name                     | Action to be performed | Changes to the submission file specifications  | Reason for the Change  |
|-------------|-----|---------------------------------------|------------------------|--|--|
|             |     |                                       |                        | <p>drugs, devices, biologicals or medical supplies("Covered"), ONLY non-covered drugs, devices, biologicals or medical supplies ("Non-covered"), neither covered or non-covered drugs, devices, biologicals or medical supplies("None"), or both covered and/or non-covered drugs, devices, biologicals or medical supplies ("Covered" or "Combination").</p> <ol style="list-style-type: none"> <li>2. The required field is: yes.</li> <li>3. The field size is: 1 character.</li> </ol> | <p>indicator data element was added. This data element provides clarification for applicable manufacturers' options for when payments or other transfer of value were associated with covered or non-covered products. The Product Indicator should be "None" if the payment or other transfer of value was not associated with any products. The Product Indicator should be "Non-covered" if the payment or transfer of value was only associated with non-covered products. The Product Indicator should be "Combination" if the payment or other transfer of value was associated with at least one covered product and one non-covered product. The payment indicator should be "Covered" if the payment or other transfer of value was associated with only covered products. However, applicable manufacturers also have the option to indicate "Covered" if the payment or other transfer of value was associated with at least one covered and one non-covered product and choose to not report that the payment or other transfer of value was also associated with a non-covered product.</p> |
| 28.         | 27. | Name of Associated Drug or Biological | Edit                   | <ol style="list-style-type: none"> <li>1. The data element name is changed to: Name of Associated Covered Drug or Biological.</li> <li>2. The description field is changed to: The marketed name of the drug or biological associated with this payment or transfer of value; may report the marketed name of up to 5 covered drugs, devices, biologicals, or medical supplies provided in either line 27 or line 29. If the drug or biological associated with</li> </ol>                 | <p>Based on comment received the Name of Associated Covered Drug or Biological data element is separate from the Name of Associated Covered Device or Medical Supply data element. The required field is edited because this data element is only required based on the product indicator chosen by the applicable manufacturer or applicable GPO, as well as, if the applicable manufacturer or applicable GPOs did not provide at least one covered device or medical supply in the data element Name of Associated Covered Device or Medical supply. A</p>  |

| DE# revised | DE# | Data element name                    | Action to be performed | Changes to the submission file specifications  | Reason for the Change  |
|-------------|-----|--------------------------------------|------------------------|--|--|
|             |     |                                      |                        | <p>this payment or transfer does not have a marketed name, report the drug or biological name as it is registered on clinicaltrials.gov.</p> <p>3. The required field is changed to: Yes IF the "Product Indicator" (line 26) is "Covered" or "Combination" AND there is not at least 1 covered device or medical supply listed in line 29 "Name of Associated Covered Device or Medical Supply".</p>  | <p>covered product is required for reporting when an applicable manufacturer or applicable GPO indicates either Covered or Combination in the product indicator.</p>   |
| 29.         | 28. | NDC of Associated Drug or Biological | Edit                   | <ol style="list-style-type: none"> <li>1. The data element name is edited to: NDC of Associated Drug or Biological.</li> <li>2. The description is edited to: The National Drug Code (NDC), if any, of the drug or biological associated with the payment or other transfer of value (if applicable; up to 5 NDCs). If no NDC for any named covered drug or biological in line 28, enter, "null." If more than one NDC provided, order must match order of named covered drugs or biologicals in line 28, "Name of Associated Covered Drug or Biological;" if no NDC for any named drug or biological, enter "null."</li> <li>3. The requirement field is edited to: Yes IF "Product Indicator" line 27 is "1" = "Covered" OR is "2" = "Combination" AND there is not at least 1 covered device or medical supply provided in line 30 "Name of Associated Covered Device or Medical Supply"</li> </ol> | <p>The data name and description are changed to accurately define that an NDC is collected for an associated drug or biological, if applicable. The requirement is edited to reflect an NDC of Associated Drug or Biological is only collected if applicable. The field size is edited to limit the character size to less than or equal to 12 characters per NDC.</p> |

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|--------------------|------------|---|-------------------------------|---|--|
|                    |            |   |                               | 4. The field size is edited to: less than or equal to 12 characters.  |  |
| 30.                | 29.        | Name of Associated Device or Medical Supply | Edit                          | <ol style="list-style-type: none"> <li>1. The data element name is: Name of Associated Covered Device or Medical Supply</li> <li>2. The description is: If the payment or other transfer of value is associated with at least one (1) covered device or medical supply that has a marketed name, report the marketed name (or names up to 5) of only the covered device or medical supply. Applicable Manufacturer or GPO may provide either (1) the marketed name under which the device or medical supply is or was marketed OR (2) the Therapeutic Area or Product Category. A list of Therapeutic Area or Product Category will be provided.</li> <li>3. The required field is: Yes IF "Product Indicator" line 27 is "1" = "Covered" OR is "2" = "Combination" AND there is not at least 1 covered drug or biological provided in line 28 "Name of Associated Covered Drug or Biological".</li> <li>4. The field size is: less than or equal to 100 characters.</li> </ol> | Based on comment received the Name of Associated Covered Device or Medical Supply data element is separate from the Name of Associated Covered Drug or Biological data element. This will allow for accurate data collection when applicable manufactures or applicable GPOs are choosing how to report a covered device or medical supply, marketed name, therapeutic are or product category. The required filed is edited because this data element is only required based on the product indicator chosen by the applicable manufacturer or applicable GPO, as well as, if the applicable manufacturer or applicable GPOs did not provide at least one covered drug or biological in the data element Name of Associated Covered Drug or Biological. A covered product is required for reporting when an applicable manufacturer or applicable GPO indicates either Covered or Combination in the product indicator. |
|                    | 52.        | Date of Payment                             | Edit                          | 1. The required field is edited to: no  | Based on comments received this data element is not required.  |
| -----              | 53.        | Multiyear Payment Structure Indicator       | Delete                        | This data element is deleted.   | Based on comments received this data element is deleted.   |

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|--------------------|------------|---|-------------------------------|--|---|
| -----              | 54.        | Total Number of Years for this Research Payment | Delete                        | This data element is deleted.  | Based on comments received this data element is deleted.  |
| -----              | 55.        | Total Number of Years for this Research Project | Delete                        | This data element is deleted.  | Based on comments received this data element is deleted.  |
| -----              | 56.        | Total Research Budget of this Project           | Delete                        | This data element is deleted.  | Based on comments received this data element is deleted.  |
| 35.                | -----      | Form of Payment or Other Transfer of Value      | Addition                      | <ol style="list-style-type: none"> <li>1. The data element name is: Form of Payment or Other Transfer of Value.</li> <li>2. The description field is edited to: The method of payment used to pay the covered recipient or to make the transfer of value.</li> <li>3. The required field is: yes.</li> <li>4. The field size is: 1 character</li> </ol>  | This data element is added to align with the information that is also required in data collection for payment or other transfers of value that are not related to research. |
| 36.                | 64.        | Expenditure Category                            | Edit                          | <ol style="list-style-type: none"> <li>1. The description field is edited to: Contextual category for this research payment or transfer of value chosen from an enumerated list to be provided. There can be multiple contextual categories for this research reported; however, for every Expenditure Category reported, an Expenditure Category percentage must also be reported.</li> <li>2. The data element size is edited to: less than or equal to 5 characters per category and percentage.</li> </ol> | The description field is edited to provide to provide guidance that for each expenditure category is required to be followed by the percent for that category.              |

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|--------------------|------------|---|-------------------------------|---|--|
| -----              | 65.        | Expenditure Category Percentage                 | Delete                        | This data element is deleted.   | Based on comments received this data element is deleted.   |
| 38.                | 61.        | Delay in Publication Research Payment Indicator | Edit                          | <p>1. The description field is edited to: Indicator showing if an Applicable Manufacturer/GPO is requesting a delay in publication of a payment or other transfer of value when the payment or transfer of value is made in connection with: (1) research on or development of a new product (drug, device, biological, or medical supply) or (2) clinical investigation regarding a new product (drug, device, biological, or medical supply). Applicable Manufacturers/GPOs not requesting a delay in publication of a payment or other transfer of value should select (3) not requesting a delay in publication to indicate that no delay is requested. CMS will display payments or other transfers of value no later than four years after the initial request for delay in publication of the [payment or transfer of value. Further details regarding notification to CMS of FDA approval will be forthcoming in guidance.</p> <p>2. The data element size is edited to: 1 character.</p> | Based on comments received the data element description is edited to reflect the reasons an applicable manufacturer may indicate a delay in publication. If an applicable manufacturer is not indicating a delay in publication research by choosing either (1) or (2) the applicable manufacturer is required to choose (3) alerting the OPEN PAYMENTS system the information is available for publication. The data element size is edited to accurately reflect the character size. |
| -----              | 62.        | Lift in Delay in Publication Indicator          | Delete                        | This data element is deleted.   | Based on comments received this data element is deleted.   |

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|--------------------|------------|--|-------------------------------|---|--|
| -----              | 66.        | Physician Ownership Indicator                                | Delete                        | This data element is deleted.   | Based on comments received this data element is deleted.   |
| 39.                | 58.        | Name of Study  | Edit                          | 1. The data element size is edited to: less than or equal to 500 characters.  | Based on comments received this data element size is edited to less than or equal to 500 characters in order to accurately capture the name of a study.  |
| 40.                | 59.        | Context of Research  | Edit                          | 1. The required field is edited to: no.   | Based on comments received the context of research data element is optional.   |
| 43.                | 30.        | Principal Investigator Covered Recipient Physician Indicator | Edit                          | 1. The description field is edited to: Indicator showing the Principal Investigator of the research study is a covered recipient physician. If there are multiple Principal Investigators, indicate "Yes" if at least one (1) is a covered recipient physician and provide the identifiers (data elements 45-60) for each Principal Investigator (up to 5), who is a covered recipient physician. If the Principal Investigator is the same as the Covered Recipient Physician receiving the payment (identified in data elements 10-13), it is not necessary to duplicate the information for the Principal Investigator fields (Data Elements 45-60).<br>2. The required field is edited to: yes. |  |
| 44.                | 31.        | Principal Investigator First Name                            | Edit                          | 1. The description field is changed to: Textual first name of the Principal Investigator(s) of the research study, if the Principal Investigator is a Covered Recipient Physician. If the Principal Investigator is the same as the Covered Recipient Physician receiving the   | The description is edited to provide guidance to collect the information required for reporting. The field size is edited to be consistent with data collection in NPES. The required field is edited because applicable manufactures are required to report information regarding principal investigator if they indicated there is a principal investigator. |



| DE# revised | DE# | Data element name                  | Action to be performed | Changes to the submission file specifications  | Reason for the Change   |
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|             |     |                                    |                        | <p>payment (identified in data elements 10-13), it is not necessary to duplicate the information for the Principal Investigator fields (Data Elements 45-60).</p> <p>2. The required field is edited to: Yes IF Line 43, "Principal Investigator Physician Covered Recipient Indicator" = "Y"</p> <p>3. The field size is edited to: less than or equal to 20 characters.</p>                    |   |
| 45.         | 32. | Principal Investigator Middle Name | Edit                   | <p>1. The description field is edited to: Textual middle initial or middle name of the Principal Investigator of the research study, if the Principal Investigator is a Covered Recipient Physician.</p> <p>2. The field size is edited to: is less than or equal to 20 characters.</p>  | The description is edited to provide guidance to collect the information required for to reporting. The field size is edited to be consistent with data collection in NPES.   |
| 46.         | 33. | Principal Investigator Last Name   | Edit                   | <p>1. The description field is edited to: Textual last name of the Principal investigator of the research study, if the Principal Investigator is a Covered Recipient Physician.</p> <p>2. The required field is edited to: Yes IF Line 43, "Principal Investigator Physician Covered Recipient Indicator" = "Y"</p> <p>3. The field size is edited to: less than or equal to 35 characters.</p> | The description is edited to provide guidance to collect the information required for to reporting. The field size is edited to be consistent with data collection in NPES. The required field is edited because applicable manufactures are required to report information regarding principal investigator if they indicated there is a principal investigator. |
| 47.         | 34. | Principal Investigator Name Suffix | Edit                   | <p>1. The description field is edited to: Suffix of the Principal Investigator of the research study chosen from a constrained list of values (Examples: Jr.,</p>  | The description is edited to provide guidance to collect the information required for to reporting. The field size is edited to be consistent with data collection in NPES.   |

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|--------------------|------------|---|-------------------------------|--|--|
|                    |            |   |                               | <p>Sr, III), if the Principal Investigator is a Covered Recipient Physician.</p> <p>2. The field size is edited to: less than or equal to 5 characters.</p>  |  |
| 48.                | 35.        | Principal Investigator Business Street Address Line 1 | Edit                          | <p>1. The description field is edited to: The first line of the primary business street address of the Principal Investigator of the research study, if the Principal Investigator is a Covered Recipient Physician. If the Principal Investigator is the same as the Covered Recipient Physician receiving the payment (identified in data elements 10-13), it is not necessary to duplicate the information for the Principal Investigator fields (Data Elements 45-60).</p> <p>2. The required field is edited to: Yes IF Line 44, "Principal Investigator Physician Covered Recipient Indicator" = "Y"</p> <p>3. The field size is edited to: less than or equal to 55 characters.</p> | The description is edited to provide guidance to collect the information required for to reporting. The field size is edited to be consistent with data collection in NPPES. The required field is edited because applicable manufactures are required to report information regarding principal investigator if they indicated there is a principal investigator. |
| 49.                | 36.        | Principal Investigator Business Street Address Line 2 | Edit                          | <p>1. The description field is edited to: The second line of the primary business street address of the Principal investigator of the research study.</p> <p>2. The required field is edited to: no.</p> <p>3. The field size is edited to: less than or equal to 55 characters.</p>   | The description is edited to provide guidance to collect the information required for to reporting. The field size is edited to be consistent with data collection in NPPES.   |
| 50.                | 37.        | Principal Investigator City                           | Edit                          | <p>1. The description field is edited to: The primary business address city of the Principal investigator of the research</p>  | The description is edited to provide guidance to collect the information required for to reporting. The field size is edited to be consistent with data  |

| <b>DE# revised</b> | <b>DE#</b> | <b>Data element name</b>        | <b>Action to be performed</b> | <b>Changes to the submission file specifications</b>   | <b>Reason for the Change</b>  |
|--------------------|------------|---------------------------------|-------------------------------|--|---|
|                    |            |                                 |                               | <p>study.</p> <p>2. The required field is edited to: Yes IF Line 43, "Principal Investigator Physician Covered Recipient Indicator" = "Y"</p> <p>3. The field size is edited to: less than or equal to 40 characters.</p>  | collection in NPPES. The required field is edited because applicable manufactures are required to report information regarding principal investigator if they indicated there is a principal investigator.  |
| 51.                | 40.        | Principal Investigator State    | Edit                          | 1. The required field is edited to: Yes IF Line 43, "Principal Investigator Physician Covered Recipient Indicator" = "Y" and recipient country, line 53 is the United States.  | The required field is edited because applicable manufactures are required to report information regarding principal investigator if they indicated there is a principal investigator and state is only required if the country is the United States.  |
| 52.                | 39.        | Principal Investigator Zip Code | Edit                          | <p>1. The description field is edited to: The 9 digit zip code of the primary business address location of the Principal investigator of the research study, if the primary practice address is in the United States.</p> <p>2. The required field is edited to: Yes IF Line 43, "Principal Investigator Physician Covered Recipient Indicator" = "Y"</p> <p>3. The field size is edited to: less than or equal to 9 characters.</p> | Based on comments received the description is edited to provide guidance to collect the information required for to reporting. The field size is edited to be consistent with data collection in NPPES. The required field is edited because applicable manufactures are required to report information regarding principal investigator if they indicated there is a principal investigator. |
| 53.                | 38.        | Principal Investigator Country  | Edit                          | <p>1. The required field is edited to: Yes IF Line 43, "Principal Investigator Physician Covered Recipient Indicator" = "Y"</p> <p>2. The field size is edited to: less than or equal to 40 characters.</p>  | The field size is edited to be consistent with data collection in NPPES. The required field is edited because applicable manufactures are required to report information regarding principal investigator if they indicated there is a principal investigator.  |
| 54.                | 41.        | Principal Investigator Province | Edit                          | 1. The required field is edited to: no.  | Based on comments received the required field is edited to no because not all countries necessarily have provinces.   |

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|--------------------|------------|---|-------------------------------|--|---|
| 55.                | 42.        | Principal Investigator Postal Code            | Edit                          | <ol style="list-style-type: none"> <li>1. The required field is edited to: Yes IF Recipient Country Line 53 is outside the United States</li> <li>2. The field size is edited to: less than or equal to 20 characters.</li> </ol>  | The required field is edited because the postal code is only required if the country is outside the United States.  |
| 56.                | 44.        | Principal Investigator Physician Primary Type | Edit                          | <ol style="list-style-type: none"> <li>1. The description field is edited to: Primary type of medicine practiced by the Principal Investigator. If the Principal Investigator is the same as the Covered Recipient Physician receiving the payment (identified in data elements 10-13), it is not necessary to duplicate the information for the Principal Investigator fields (Data Elements 45-60).</li> <li>2. The required field is edited to: Yes IF Line 44, "Principal Investigator Physician Covered Recipient Indicator" = "Y"</li> <li>3. The field size is edited to: 1 character.</li> </ol> | The description is edited to provide guidance to collect the information required for to reporting. The required field is edited because applicable manufactures are required to report information regarding principal investigator if they indicated there is a principal investigator. |
| 57.                | 43.        | Principal Investigator NPI                    | Edit                          | <ol style="list-style-type: none"> <li>1. The description field is edited to: Individual NPI for Physician (not NPI of any group physician belonging to) required, if applicable. If the Principal Investigator is the same as the Covered Recipient Physician receiving the payment (identified in data elements 10-13), it is not necessary to duplicate the information for the Principal Investigator fields (Data Elements 45-60).</li> <li>2. The required field is edited to: no.</li> </ol>  | The description is edited to provide guidance to collect the information required for to reporting. The required filed is changed to no because applicable manufacturers are only required to report a physician's NPI if applicable.   |
| 58.                | 45.        | Principal                                     | Edit                          | <ol style="list-style-type: none"> <li>1. The description field is edited to:</li> </ol>   | Based on comments received the "provider  |

| DE# revised | DE# | Data element name                                       | Action to be performed | Changes to the submission file specifications  | Reason for the Change  |
|-------------|-----|---|------------------------|--|--|
|             |     | Investigator Specialty                                  |                        | <p>Principal Investigator's single specialty chosen from "provider taxonomy" code list. If the Principal Investigator is the same as the Covered Recipient Physician receiving the payment (identified in data elements 10-13), it is not necessary to duplicate the information for the Principal Investigator fields (Data Elements 45-60).</p> <p>2. The required field is edited to: Yes IF Line 43, "Principal Investigator Physician Covered Recipient Indicator" = "Y"</p> <p>3. The field size is edited to: 10 characters</p>   | <p>taxonomy" list from the Washington Publishing Company will be provided. This is the same list that can be retrieved through the NPPESS website. The field size is edited to accurately reflect the characters for collection. The required field is edited because applicable manufactures are required to report information regarding principal investigator if they indicated there is a principal investigator.</p> |
| 59.         | 46. | Principal Investigator License State and License Number | Edit                   | <p>1. The description field is edited to: Paired state and state license number of the Principal Investigator, who is a physician covered recipient; the pairing includes the 2 letter state abbreviation, followed by a hyphen, followed by the state license number and may include up to 5 "Physician License State and License Number" pairs. If a Principal investigator is licensed in multiple states, provide only one state and license number pair.</p> <p>2. The required field is edited to: Yes IF Line 43, "Principal Investigator Physician Covered Recipient Indicator" = "Y"</p> <p>3. The field size is edited to: less than or equal to 20 characters per state and</p> | <p>The physician's license number and state are combined in order to reflect the appropriate state with the license number because multiple license numbers and states may be reported. The field size is edited to accurately reflect the characters for collection.</p>  |

| <b>DE# revised</b> | <b>DE#</b> | <b>Data element name</b>             | <b>Action to be performed</b> | <b>Changes to the submission file specifications</b>  | <b>Reason for the Change</b>  |
|--------------------|------------|--------------------------------------|-------------------------------|---|---|
|                    |            |                                      |                               | license number.   |   |
| -----              | 47.        | Principal Investigator License State | Delete                        | This data element is deleted.   | This data element is deleted because the license state is combined with the license number.   |
| 60.                | -----      | Principal Investigator First Name    | Addition                      | <ol style="list-style-type: none"> <li>1. The data element name is: Principal Investigator First Name</li> <li>2. The description is: Textual first name of the Principal Investigator(s) of the research study; required, if the Principal Investigator is a Covered Recipient Physician. If the Principal Investigator is the same as the Covered Recipient Physician receiving the payment (identified in data elements 10-13), it is not necessary to duplicate the information for the Principal Investigator fields (Data Elements 45-60).</li> <li>3. The required field is: no, unless indicating multiple principal investigators</li> <li>4. The field size is: less than or equal to 20 characters.</li> </ol> | Based on comments received additional data elements were added to allow applicable manufactures to report multiple principal investigators that are covered recipients. |
| 61.                | -----      | Principal Investigator Middle Name   | Addition                      | <ol style="list-style-type: none"> <li>1. The data element name is: Principal Investigator Middle Name</li> <li>2. The description is: Textual middle initial or middle name of the Principal Investigator of the research study, if the Principal Investigator is a Covered Recipient Physician.</li> <li>3. The required field is: no, unless indicating multiple principal investigators</li> </ol>  | Based on comments received additional data elements were added to allow applicable manufactures to report multiple principal investigators that are covered recipients. |

| <b>DE# revised</b> | <b>DE#</b> | <b>Data element name</b>                              | <b>Action to be performed</b> | <b>Changes to the submission file specifications</b>   | <b>Reason for the Change</b>  |
|--------------------|------------|---|-------------------------------|--|---|
|                    |            |   |                               | 4. The field size is: less than or equal to 20 characters.   |   |
| 62.                | -----      | Principal Investigator Last Name                      | Addition                      | <ol style="list-style-type: none"> <li>1. The data element name is: Principal Investigator Last Name</li> <li>2. The description is: Textual last name of the Principal investigator of the research study; required if, the Principal Investigator is a Covered Recipient Physician.</li> <li>3. The required field is: no, unless indicating multiple principal investigators</li> <li>4. The field size is: less than or equal to 35 characters.</li> </ol>   | Based on comments received additional data elements were added to allow applicable manufactures to report multiple principal investigators that are covered recipients. |
| 63.                | -----      | Principal Investigator Name Suffix                    | Addition                      | <ol style="list-style-type: none"> <li>1. The data element name is: Principal Investigator Name Suffix</li> <li>2. The description is: Suffix of the Principal Investigator of the research study chosen from a constrained list of values (Examples: Jr., Sr, III), if the Principal Investigator is a Covered Recipient Physician.</li> <li>3. The required field is: no, unless indicating multiple principal investigators</li> <li>4. The field size is: less than or equal to 5 characters.</li> </ol> | Based on comments received additional data elements were added to allow applicable manufactures to report multiple principal investigators that are covered recipients. |
| 64.                | -----      | Principal Investigator Business Street Address Line 1 | Addition                      | <ol style="list-style-type: none"> <li>1. The data element name is: Principal Investigator Business Street Address Line 1</li> <li>2. The description is: The first line of the primary business street address of the Principal Investigator of the research</li> </ol>   | Based on comments received additional data elements were added to allow applicable manufactures to report multiple principal investigators that are covered recipients. |

| DE# revised | DE#   | Data element name                                     | Action to be performed | Changes to the submission file specifications  | Reason for the Change   |
|-------------|-------|---|------------------------|--|---|
|             |       |   |                        | <p>study, if the Principal Investigator is a Covered Recipient Physician. If the Principal Investigator is the same as the Covered Recipient Physician receiving the payment (identified in data elements 10-13), it is not necessary to duplicate the information for the Principal Investigator fields (Data Elements 45-60).</p> <p>3. The required field is: no, unless indicating multiple principal investigators</p> <p>4. The field size is: less than or equal to 55 characters.</p>  |   |
| 65.         | ----- | Principal Investigator Business Street Address Line 2 | Addition               | <p>1. The data element name is: Principal Investigator Business Street Address Line 2</p> <p>2. The description is: The first line of the primary business street address of the Principal Investigator of the research study, if the Principal Investigator is a Covered Recipient Physician. If the Principal Investigator is the same as the Covered Recipient Physician receiving the payment (identified in data elements 10-13), it is not necessary to duplicate the information for the Principal Investigator fields (Data Elements 45-60).</p> <p>3. The required field is: no, unless indicating multiple principal investigators</p> <p>4. The field size is: less than or equal to 55</p> | Based on comments received additional data elements were added to allow applicable manufactures to report multiple principal investigators that are covered recipients. |



| <b>DE# revised</b> | <b>DE#</b> | <b>Data element name</b>        | <b>Action to be performed</b> | <b>Changes to the submission file specifications</b>   | <b>Reason for the Change</b>  |
|--------------------|------------|---------------------------------|-------------------------------|--|---|
|                    |            |                                 |                               | characters.  |   |
| 66.                | -----      | Principal Investigator City     | Addition                      | <ol style="list-style-type: none"> <li>1. The data element name is: Principal Investigator City</li> <li>2. The description is: The primary business address city of the Principal investigator of the research study.</li> <li>3. The required field is: no, unless indicating multiple principal investigators</li> <li>4. The field size is: less than or equal to 40 characters</li> </ol>   | Based on comments received additional data elements were added to allow applicable manufactures to report multiple principal investigators that are covered recipients. |
| 67.                | -----      | Principal Investigator State    | Addition                      | <ol style="list-style-type: none"> <li>1. The data element name is: Principal Investigator State</li> <li>2. The description is: The primary business address state or territory abbreviation of the Principal investigator of the research study, if the primary practice address is in the United States.</li> <li>3. The required field is: no, unless indicating multiple principal investigators</li> <li>4. The field size is: 2 characters</li> </ol> | Based on comments received additional data elements were added to allow applicable manufactures to report multiple principal investigators that are covered recipients. |
| 68.                | -----      | Principal Investigator Zip Code | Addition                      | <ol style="list-style-type: none"> <li>1. The data element name is: Principal Investigator Zip Code</li> <li>2. The description is: The 9 digit zip code of the primary business address location of the Principal investigator of the research study, if the primary practice address is in the United States.</li> <li>3. The required field is: no, unless indicating multiple principal investigators</li> </ol>   | Based on comments received additional data elements were added to allow applicable manufactures to report multiple principal investigators that are covered recipients. |

| <b>DE# revised</b> | <b>DE#</b> | <b>Data element name</b>           | <b>Action to be performed</b> | <b>Changes to the submission file specifications</b>  | <b>Reason for the Change</b>  |
|--------------------|------------|------------------------------------|-------------------------------|---|---|
|                    |            |                                    |                               | 4. The field size is: less than or equal to 9 characters  |   |
| 69.                | -----      | Principal Investigator Country     | Addition                      | <ol style="list-style-type: none"> <li>1. The data element name is: Principal Investigator Country</li> <li>2. The description is: The primary business address country name of the Principal investigator of the research study.</li> <li>3. The required field is: no, unless indicating multiple principal investigators</li> <li>4. The field size is: less than or equal to 40 characters</li> </ol>   | Based on comments received additional data elements were added to allow applicable manufactures to report multiple principal investigators that are covered recipients. |
| 70.                | -----      | Principal Investigator Province    | Addition                      | <ol style="list-style-type: none"> <li>1. The data element name is: Principal Investigator Province</li> <li>2. The description is: The primary business address province name of the Principal investigator of the research study, if the primary practice address is outside the United States.</li> <li>3. The required field is: no, unless indicating multiple principal investigators</li> <li>4. The field size is: less than or equal to 20 characters</li> </ol> | Based on comments received additional data elements were added to allow applicable manufactures to report multiple principal investigators that are covered recipients. |
| 71.                | -----      | Principal Investigator Postal Code | Addition                      | <ol style="list-style-type: none"> <li>1. The data element name is: Principal Investigator Postal Code</li> <li>2. The description is: The international postal code of the primary business location of the Principal investigator of the research study if the primary practice address is outside the United States.</li> </ol>  | Based on comments received additional data elements were added to allow applicable manufactures to report multiple principal investigators that are covered recipients. |

| DE# revised | DE#   | Data element name                             | Action to be performed | Changes to the submission file specifications  | Reason for the Change   |
|-------------|-------|---|------------------------|--|---|
|             |       |   |                        | <ol style="list-style-type: none"> <li>3. The required field is: no, unless indicating multiple principal investigators</li> <li>4. The field size is: less than or equal to 20 characters.</li> </ol>   |   |
| 72.         | ----- | Principal Investigator Physician Primary Type | Addition               | <ol style="list-style-type: none"> <li>1. The data element name is: Principal Investigator Physician Primary Type</li> <li>2. The description is: Primary type of medicine practiced by the Principal Investigator. If the Principal Investigator is the same as the Covered Recipient Physician receiving the payment (identified in data elements 10-13), it is not necessary to duplicate the information for the Principal Investigator fields (Data Elements 45-60).</li> <li>3. The required field is: no, unless indicating multiple principal investigators</li> <li>4. The field size is: 1 character.</li> </ol> | Based on comments received additional data elements were added to allow applicable manufactures to report multiple principal investigators that are covered recipients. |
| 73.         | ----- | Principal Investigator NPI                    | Addition               | <ol style="list-style-type: none"> <li>1. The data element name is: Principal Investigator NPI</li> <li>2. The description is: Individual NPI for Physician (not NPI of any group physician belonging to) required, if applicable. If the Principal Investigator is the same as the Covered Recipient Physician receiving the payment (identified in data elements 10-13), it is not necessary to duplicate the information for the Principal Investigator fields (Data Elements 45-</li> </ol>  | Based on comments received additional data elements were added to allow applicable manufactures to report multiple principal investigators that are covered recipients. |

| DE# revised | DE#   | Data element name                                       | Action to be performed | Changes to the submission file specifications   | Reason for the Change   |
|-------------|-------|---|------------------------|---|---|
|             |       |   |                        | <p>60).</p> <p>3. The required field is: no, unless indicating multiple principal investigators</p> <p>4. The field size is: 10 characters</p>  |   |
| 74.         | ----- | Principal Investigator Specialty                        | Addition               | <p>1. The data element name is: Principal Investigator Specialty</p> <p>2. The description is: Principal Investigator's single specialty chosen from "provider taxonomy" list. If the Principal Investigator is the same as the Covered Recipient Physician receiving the payment (identified in data elements 10-13), it is not necessary to duplicate the information for the Principal Investigator fields (Data Elements 45-60).</p> <p>3. The required field is: no, unless indicating multiple principal investigators</p> <p>4. The field size is: 10 characters</p> | Based on comments received additional data elements were added to allow applicable manufactures to report multiple principal investigators that are covered recipients. |
| 75.         | ----- | Principal Investigator License State and License Number | Addition               | <p>1. The data element name is: Principal Investigator License State and License Number</p> <p>2. The description is: Paired state and state license number of the Principal Investigator, who is a physician covered recipient; the pairing includes the 2 letter state abbreviation, followed by a hyphen, followed by the state license number and may include up to 5 "Physician License State and License Number" pairs. If a Principal</p>  | Based on comments received additional data elements were added to allow applicable manufactures to report multiple principal investigators that are covered recipients. |

| DE# revised | DE#   | Data element name                  | Action to be performed | Changes to the submission file specifications  | Reason for the Change   |
|-------------|-------|------------------------------------|------------------------|--|---|
|             |       |                                    |                        | <p>investigator is licensed in multiple states, provide only one state and license number pair.</p> <p>3. The required field is: no, unless indicating multiple principal investigators</p> <p>4. The field size is: less than or equal to 20 characters per state and license number.</p>   |   |
| 76.         | ----- | Principal Investigator First Name  | Addition               | <p>1. The data element name is: Principal Investigator First Name</p> <p>2. The description is: Textual first name of the Principal Investigator(s) of the research study; required, if the Principal Investigator is a Covered Recipient Physician. If the Principal Investigator is the same as the Covered Recipient Physician receiving the payment (identified in data elements 10-13), it is not necessary to duplicate the information for the Principal Investigator fields (Data Elements 45-60).</p> <p>3. The required field is: no, unless indicating multiple principal investigators</p> <p>4. The field size is: less than or equal to 20 characters.</p> | Based on comments received additional data elements were added to allow applicable manufactures to report multiple principal investigators that are covered recipients. |
| 77.         | ----- | Principal Investigator Middle Name | Addition               | <p>1. The data element name is: Principal Investigator Middle Name</p> <p>2. The description is: Textual middle initial or middle name of the Principal Investigator of the research study, if the Principal Investigator is a Covered</p>   | Based on comments received additional data elements were added to allow applicable manufactures to report multiple principal investigators that are covered recipients. |

| <b>DE# revised</b> | <b>DE#</b> | <b>Data element name</b>           | <b>Action to be performed</b> | <b>Changes to the submission file specifications</b>  | <b>Reason for the Change</b>  |
|--------------------|------------|------------------------------------|-------------------------------|---|---|
|                    |            |                                    |                               | <p>Recipient Physician.</p> <p>3. The required field is: no, unless indicating multiple principal investigators</p> <p>4. The field size is: less than or equal to 20 characters.</p>   |   |
| 78.                | -----      | Principal Investigator Last Name   | Addition                      | <p>1. The data element name is: Principal Investigator Last Name</p> <p>2. The description is: Textual last name of the Principal investigator of the research study; required if, the Principal Investigator is a Covered Recipient Physician.</p> <p>3. The required field is: no, unless indicating multiple principal investigators</p> <p>4. The field size is: less than or equal to 35 characters.</p>   | Based on comments received additional data elements were added to allow applicable manufactures to report multiple principal investigators that are covered recipients. |
| 79.                | -----      | Principal Investigator Name Suffix | Addition                      | <p>1. The data element name is: Principal Investigator Name Suffix</p> <p>2. The description is: Suffix of the Principal Investigator of the research study chosen from a constrained list of values (Examples: Jr., Sr, III), if the Principal Investigator is a Covered Recipient Physician.</p> <p>3. The required field is: no, unless indicating multiple principal investigators</p> <p>4. The field size is: less than or equal to 5 characters.</p> | Based on comments received additional data elements were added to allow applicable manufactures to report multiple principal investigators that are covered recipients. |
| 80.                | -----      | Principal Investigator             | Addition                      | <p>1. The data element name is: Principal Investigator Business Street Address</p>  | Based on comments received additional data elements were added to allow applicable  |

| DE# revised | DE#   | Data element name                                     | Action to be performed | Changes to the submission file specifications  | Reason for the Change   |
|-------------|-------|---|------------------------|--|---|
|             |       | Business Street Address Line 1                        |                        | <p>Line 1</p> <p>2. The description is: The first line of the primary business street address of the Principal Investigator of the research study, if the Principal Investigator is a Covered Recipient Physician. If the Principal Investigator is the same as the Covered Recipient Physician receiving the payment (identified in data elements 10-13), it is not necessary to duplicate the information for the Principal Investigator fields (Data Elements 45-60).</p> <p>3. The required field is: no, unless indicating multiple principal investigators</p> <p>4. The field size is: less than or equal to 55 characters.</p> | manufactures to report multiple principal investigators that are covered recipients.  |
| 81.         | ----- | Principal Investigator Business Street Address Line 2 | Addition               | <p>1. The data element name is: Principal Investigator Business Street Address Line 2</p> <p>2. The description is: The first line of the primary business street address of the Principal Investigator of the research study, if the Principal Investigator is a Covered Recipient Physician. If the Principal Investigator is the same as the Covered Recipient Physician receiving the payment (identified in data elements 10-13), it is not necessary to duplicate the information for the Principal Investigator fields (Data Elements 45-60).</p>   | Based on comments received additional data elements were added to allow applicable manufactures to report multiple principal investigators that are covered recipients. |

| <b>DE# revised</b> | <b>DE#</b> | <b>Data element name</b>        | <b>Action to be performed</b> | <b>Changes to the submission file specifications</b>   | <b>Reason for the Change</b>  |
|--------------------|------------|---------------------------------|-------------------------------|--|---|
|                    |            |                                 |                               | <ul style="list-style-type: none"> <li>3. The required field is: no, unless indicating multiple principal investigators</li> <li>4. The field size is: less than or equal to 55 characters.</li> </ul>   |   |
| 82.                | -----      | Principal Investigator City     | Addition                      | <ul style="list-style-type: none"> <li>1. The data element name is: Principal Investigator City</li> <li>2. The description is: The primary business address city of the Principal investigator of the research study.</li> <li>3. The required field is: no, unless indicating multiple principal investigators</li> <li>4. The field size is: less than or equal to 40 characters</li> </ul>   | Based on comments received additional data elements were added to allow applicable manufactures to report multiple principal investigators that are covered recipients. |
| 83.                | -----      | Principal Investigator State    | Addition                      | <ul style="list-style-type: none"> <li>1. The data element name is: Principal Investigator State</li> <li>2. The description is: The primary business address state or territory abbreviation of the Principal investigator of the research study, if the primary practice address is in the United States.</li> <li>3. The required field is: no, unless indicating multiple principal investigators</li> <li>4. The field size is: 2 characters</li> </ul> | Based on comments received additional data elements were added to allow applicable manufactures to report multiple principal investigators that are covered recipients. |
| 84.                | -----      | Principal Investigator Zip Code | Addition                      | <ul style="list-style-type: none"> <li>1. The data element name is: Principal Investigator Zip Code</li> <li>2. The description is: The 9 digit zip code of the primary business address location of the Principal investigator of the research study, if the primary</li> </ul>   | Based on comments received additional data elements were added to allow applicable manufactures to report multiple principal investigators that are covered recipients. |



| <b>DE# revised</b> | <b>DE#</b> | <b>Data element name</b>           | <b>Action to be performed</b> | <b>Changes to the submission file specifications</b>   | <b>Reason for the Change</b>  |
|--------------------|------------|------------------------------------|-------------------------------|--|---|
|                    |            |                                    |                               | <p>practice address is in the United States.</p> <p>3. The required field is: no, unless indicating multiple principal investigators</p> <p>4. The field size is: less than or equal to 9 characters</p>   |   |
| 85.                | -----      | Principal Investigator Country     | Addition                      | <p>1. The data element name is: Principal Investigator Country</p> <p>2. The description is: The primary business address country name of the Principal investigator of the research study.</p> <p>3. The required field is: no, unless indicating multiple principal investigators</p> <p>4. The field size is: less than or equal to 40 characters</p>   | Based on comments received additional data elements were added to allow applicable manufactures to report multiple principal investigators that are covered recipients. |
| 86.                | -----      | Principal Investigator Province    | Addition                      | <p>1. The data element name is: Principal Investigator Province</p> <p>2. The description is: The primary business address province name of the Principal investigator of the research study, if the primary practice address is outside the United States.</p> <p>3. The required field is: no, unless indicating multiple principal investigators</p> <p>4. The field size is: less than or equal to 20 characters</p> | Based on comments received additional data elements were added to allow applicable manufactures to report multiple principal investigators that are covered recipients. |
| 87.                | -----      | Principal Investigator Postal Code | Addition                      | <p>1. The data element name is: Principal Investigator Postal Code</p> <p>2. The description is: The international postal code of the primary business</p>   | Based on comments received additional data elements were added to allow applicable manufactures to report multiple principal investigators that are covered recipients. |

| DE# revised | DE#   | Data element name                             | Action to be performed | Changes to the submission file specifications   | Reason for the Change   |
|-------------|-------|---|------------------------|---|---|
|             |       |   |                        | <p>location of the Principal investigator of the research study if the primary practice address is outside the United States.</p> <p>3. The required field is: no, unless indicating multiple principal investigators</p> <p>4. The field size is: less than or equal to 20 characters.</p>   |   |
| 88.         | ----- | Principal Investigator Physician Primary Type | Addition               | <p>1. The data element name is: Principal Investigator Physician Primary Type</p> <p>2. The description is: Primary type of medicine practiced by the Principal Investigator. If the Principal Investigator is the same as the Covered Recipient Physician receiving the payment (identified in data elements 10-13), it is not necessary to duplicate the information for the Principal Investigator fields (Data Elements 45-60).</p> <p>3. The required field is: no, unless indicating multiple principal investigators</p> <p>4. The field size is: 1 character.</p> | Based on comments received additional data elements were added to allow applicable manufactures to report multiple principal investigators that are covered recipients. |
| 89.         | ----- | Principal Investigator NPI                    | Addition               | <p>1. The data element name is: Principal Investigator NPI</p> <p>2. The description is: Individual NPI for Physician (not NPI of any group physician belonging to) required, if applicable. If the Principal Investigator is the same as the Covered Recipient Physician receiving the payment</p>   | Based on comments received additional data elements were added to allow applicable manufactures to report multiple principal investigators that are covered recipients. |

| DE# revised | DE#   | Data element name                                       | Action to be performed | Changes to the submission file specifications   | Reason for the Change   |
|-------------|-------|---|------------------------|---|---|
|             |       |   |                        | <p>(identified in data elements 10-13), it is not necessary to duplicate the information for the Principal Investigator fields (Data Elements 45-60).</p> <p>3. The required field is: no, unless indicating multiple principal investigators</p> <p>4. The field size is: 10 characters</p>  |   |
| 90.         | ----- | Principal Investigator Specialty                        | Addition               | <p>1. The data element name is: Principal Investigator Specialty</p> <p>2. The description is: Principal Investigator's single specialty chosen from "provider taxonomy" list. If the Principal Investigator is the same as the Covered Recipient Physician receiving the payment (identified in data elements 10-13), it is not necessary to duplicate the information for the Principal Investigator fields (Data Elements 45-60).</p> <p>3. The required field is: no, unless indicating multiple principal investigators</p> <p>4. The field size is: 10 characters</p> | Based on comments received additional data elements were added to allow applicable manufactures to report multiple principal investigators that are covered recipients. |
| 91.         | ----- | Principal Investigator License State and License Number | Addition               | <p>1. The data element name is: Principal Investigator License State and License Number</p> <p>2. The description is: Paired state and state license number of the Principal Investigator, who is a physician covered recipient; the pairing includes the 2 letter state abbreviation, followed</p>   | Based on comments received additional data elements were added to allow applicable manufactures to report multiple principal investigators that are covered recipients. |

| DE# revised | DE#   | Data element name                 | Action to be performed | Changes to the submission file specifications  | Reason for the Change   |
|-------------|-------|-----------------------------------|------------------------|--|---|
|             |       |                                   |                        | <p>by a hyphen, followed by the state license number and may include up to 5 "Physician License State and License Number" pairs. If a Principal investigator is licensed in multiple states, provide only one state and license number pair.</p> <p>3. The required field is: no, unless indicating multiple principal investigators</p> <p>4. The field size is: less than or equal to 20 characters per state and license number.</p>  |   |
| 92.         | ----- | Principal Investigator First Name | Addition               | <p>1. The data element name is: Principal Investigator First Name</p> <p>2. The description is: Textual first name of the Principal Investigator(s) of the research study; required, if the Principal Investigator is a Covered Recipient Physician. If the Principal Investigator is the same as the Covered Recipient Physician receiving the payment (identified in data elements 10-13), it is not necessary to duplicate the information for the Principal Investigator fields (Data Elements 45-60).</p> <p>3. The required field is: no, unless indicating multiple principal investigators</p> <p>4. The field size is: less than or equal to 20 characters.</p> | Based on comments received additional data elements were added to allow applicable manufactures to report multiple principal investigators that are covered recipients. |
| 93.         | ----- | Principal Investigator            | Addition               | <p>1. The data element name is: Principal Investigator Middle Name</p>   | Based on comments received additional data elements were added to allow applicable  |

| <b>DE# revised</b> | <b>DE#</b> | <b>Data element name</b>           | <b>Action to be performed</b> | <b>Changes to the submission file specifications</b>  | <b>Reason for the Change</b>  |
|--------------------|------------|------------------------------------|-------------------------------|---|---|
|                    |            | Middle Name                        |                               | <p>2. The description is: Textual middle initial or middle name of the Principal Investigator of the research study, if the Principal Investigator is a Covered Recipient Physician.</p> <p>3. The required field is: no, unless indicating multiple principal investigators</p> <p>4. The field size is: less than or equal to 20 characters.</p>  | manufactures to report multiple principal investigators that are covered recipients.  |
| 94.                | -----      | Principal Investigator Last Name   | Addition                      | <p>1. The data element name is: Principal Investigator Last Name</p> <p>2. The description is: Textual last name of the Principal investigator of the research study; required if, the Principal Investigator is a Covered Recipient Physician.</p> <p>3. The required field is: no, unless indicating multiple principal investigators</p> <p>4. The field size is: less than or equal to 35 characters.</p> | Based on comments received additional data elements were added to allow applicable manufactures to report multiple principal investigators that are covered recipients. |
| 95.                | -----      | Principal Investigator Name Suffix | Addition                      | <p>1. The data element name is: Principal Investigator Name Suffix</p> <p>2. The description is: Suffix of the Principal Investigator of the research study chosen from a constrained list of values (Examples: Jr., Sr, III), if the Principal Investigator is a Covered Recipient Physician.</p> <p>3. The required field is: no, unless indicating multiple principal investigators</p>                    | Based on comments received additional data elements were added to allow applicable manufactures to report multiple principal investigators that are covered recipients. |

| DE# revised | DE#   | Data element name                                     | Action to be performed | Changes to the submission file specifications   | Reason for the Change   |
|-------------|-------|---|------------------------|---|---|
|             |       |   |                        | 4. The field size is: less than or equal to 5 characters.   |   |
| 96.         | ----- | Principal Investigator Business Street Address Line 1 | Addition               | <ol style="list-style-type: none"> <li>1. The data element name is: Principal Investigator Business Street Address Line 1</li> <li>2. The description is: The first line of the primary business street address of the Principal Investigator of the research study, if the Principal Investigator is a Covered Recipient Physician. If the Principal Investigator is the same as the Covered Recipient Physician receiving the payment (identified in data elements 10-13), it is not necessary to duplicate the information for the Principal Investigator fields (Data Elements 45-60).</li> <li>3. The required field is: no, unless indicating multiple principal investigators</li> <li>4. The field size is: less than or equal to 55 characters.</li> </ol> | Based on comments received additional data elements were added to allow applicable manufactures to report multiple principal investigators that are covered recipients. |
| 97.         | ----- | Principal Investigator Business Street Address Line 2 | Addition               | <ol style="list-style-type: none"> <li>1. The data element name is: Principal Investigator Business Street Address Line 2</li> <li>2. The description is: The first line of the primary business street address of the Principal Investigator of the research study, if the Principal Investigator is a Covered Recipient Physician. If the Principal Investigator is the same as the Covered Recipient Physician receiving the payment (identified in data</li> </ol>  | Based on comments received additional data elements were added to allow applicable manufactures to report multiple principal investigators that are covered recipients. |

| DE# revised | DE#   | Data element name            | Action to be performed | Changes to the submission file specifications   | Reason for the Change   |
|-------------|-------|------------------------------|------------------------|---|---|
|             |       |                              |                        | <p>elements 10-13), it is not necessary to duplicate the information for the Principal Investigator fields (Data Elements 45-60).</p> <p>3. The required field is: no, unless indicating multiple principal investigators</p> <p>4. The field size is: less than or equal to 55 characters.</p>   |   |
| 98.         | ----- | Principal Investigator City  | Addition               | <p>1. The data element name is: Principal Investigator City</p> <p>2. The description is: The primary business address city of the Principal investigator of the research study.</p> <p>3. The required field is: no, unless indicating multiple principal investigators</p> <p>4. The field size is: less than or equal to 40 characters</p>   | Based on comments received additional data elements were added to allow applicable manufactures to report multiple principal investigators that are covered recipients. |
| 99.         | ----- | Principal Investigator State | Addition               | <p>1. The data element name is: Principal Investigator State</p> <p>2. The description is: The primary business address state or territory abbreviation of the Principal investigator of the research study, if the primary practice address is in the United States.</p> <p>3. The required field is: no, unless indicating multiple principal investigators</p> <p>4. The field size is: 2 characters</p> | Based on comments received additional data elements were added to allow applicable manufactures to report multiple principal investigators that are covered recipients. |
| 100.        | ----- | Principal Investigator       | Addition               | <p>1. The data element name is: Principal Investigator Zip Code</p>   | Based on comments received additional data elements were added to allow applicable  |

| <b>DE# revised</b> | <b>DE#</b> | <b>Data element name</b>        | <b>Action to be performed</b> | <b>Changes to the submission file specifications</b>  | <b>Reason for the Change</b>  |
|--------------------|------------|---------------------------------|-------------------------------|---|---|
|                    |            | Zip Code                        |                               | <ol style="list-style-type: none"> <li>2. The description is: The 9 digit zip code of the primary business address location of the Principal investigator of the research study, if the primary practice address is in the United States.</li> <li>3. The required field is: no, unless indicating multiple principal investigators</li> <li>4. The field size is: less than or equal to 9 characters</li> </ol>  | manufactures to report multiple principal investigators that are covered recipients.  |
| 101.               | -----      | Principal Investigator Country  | Addition                      | <ol style="list-style-type: none"> <li>1. The data element name is: Principal Investigator Country</li> <li>2. The description is: The primary business address country name of the Principal investigator of the research study.</li> <li>3. The required field is: no, unless indicating multiple principal investigators</li> <li>4. The field size is: less than or equal to 40 characters</li> </ol>   | Based on comments received additional data elements were added to allow applicable manufactures to report multiple principal investigators that are covered recipients. |
| 102.               | -----      | Principal Investigator Province | Addition                      | <ol style="list-style-type: none"> <li>1. The data element name is: Principal Investigator Province</li> <li>2. The description is: The primary business address province name of the Principal investigator of the research study, if the primary practice address is outside the United States.</li> <li>3. The required field is: no, unless indicating multiple principal investigators</li> <li>4. The field size is: less than or equal to 20 characters</li> </ol> | Based on comments received additional data elements were added to allow applicable manufactures to report multiple principal investigators that are covered recipients. |



| <b>DE# revised</b> | <b>DE#</b> | <b>Data element name</b>                      | <b>Action to be performed</b> | <b>Changes to the submission file specifications</b>   | <b>Reason for the Change</b>  |
|--------------------|------------|---|-------------------------------|--|---|
| 103.               | -----      | Principal Investigator Postal Code            | Addition                      | <ol style="list-style-type: none"> <li>1. The data element name is: Principal Investigator Postal Code</li> <li>2. The description is: The international postal code of the primary business location of the Principal investigator of the research study if the primary practice address is outside the United States.</li> <li>3. The required field is: no, unless indicating multiple principal investigators</li> <li>4. The field size is: less than or equal to 20 characters.</li> </ol>   | Based on comments received additional data elements were added to allow applicable manufactures to report multiple principal investigators that are covered recipients. |
| 104.               | -----      | Principal Investigator Physician Primary Type | Addition                      | <ol style="list-style-type: none"> <li>1. The data element name is: Principal Investigator Physician Primary Type</li> <li>2. The description is: Primary type of medicine practiced by the Principal Investigator. If the Principal Investigator is the same as the Covered Recipient Physician receiving the payment (identified in data elements 10-13), it is not necessary to duplicate the information for the Principal Investigator fields (Data Elements 45-60).</li> <li>3. The required field is: no, unless indicating multiple principal investigators</li> <li>4. The field size is: 1 character.</li> </ol> | Based on comments received additional data elements were added to allow applicable manufactures to report multiple principal investigators that are covered recipients. |
| 105.               | -----      | Principal Investigator NPI                    | Addition                      | <ol style="list-style-type: none"> <li>1. The data element name is: Principal Investigator NPI</li> <li>2. The description is: Individual NPI for Physician (not NPI of any group</li> </ol>   | Based on comments received additional data elements were added to allow applicable manufactures to report multiple principal investigators that are covered recipients. |

| DE# revised | DE#   | Data element name                                | Action to be performed | Changes to the submission file specifications   | Reason for the Change   |
|-------------|-------|--|------------------------|---|---|
|             |       |  |                        | <p>physician belonging to) required, if applicable. If the Principal Investigator is the same as the Covered Recipient Physician receiving the payment (identified in data elements 10-13), it is not necessary to duplicate the information for the Principal Investigator fields (Data Elements 45-60).</p> <p>3. The required field is: no, unless indicating multiple principal investigators</p> <p>4. The field size is: 10 characters</p>  |   |
| 106.        | ----- | Principal Investigator Specialty                 | Addition               | <p>1. The data element name is: Principal Investigator Specialty</p> <p>2. The description is: Principal Investigator's single specialty chosen from "provider taxonomy" list. If the Principal Investigator is the same as the Covered Recipient Physician receiving the payment (identified in data elements 10-13), it is not necessary to duplicate the information for the Principal Investigator fields (Data Elements 45-60).</p> <p>3. The required field is: no, unless indicating multiple principal investigators</p> <p>4. The field size is: 10 characters</p> | Based on comments received additional data elements were added to allow applicable manufactures to report multiple principal investigators that are covered recipients. |
| 107.        | ----- | Principal Investigator License State and License | Addition               | <p>1. The data element name is: Principal Investigator License State and License Number</p> <p>2. The description is: Paired state and state</p>  | Based on comments received additional data elements were added to allow applicable manufactures to report multiple principal investigators that are covered recipients. |

| DE# revised | DE#   | Data element name                 | Action to be performed | Changes to the submission file specifications  | Reason for the Change   |
|-------------|-------|-----------------------------------|------------------------|--|---|
|             |       | Number                            |                        | <p>license number of the Principal Investigator, who is a physician covered recipient; the pairing includes the 2 letter state abbreviation, followed by a hyphen, followed by the state license number and may include up to 5 "Physician License State and License Number" pairs. If a Principal investigator is licensed in multiple states, provide only one state and license number pair.</p> <p>3. The required field is: no, unless indicating multiple principal investigators</p> <p>4. The field size is: less than or equal to 20 characters per state and license number.</p>             |   |
| 108.        | ----- | Principal Investigator First Name | Addition               | <p>1. The data element name is: Principal Investigator First Name</p> <p>2. The description is: Textual first name of the Principal Investigator(s) of the research study; required, if the Principal Investigator is a Covered Recipient Physician. If the Principal Investigator is the same as the Covered Recipient Physician receiving the payment (identified in data elements 10-13), it is not necessary to duplicate the information for the Principal Investigator fields (Data Elements 45-60).</p> <p>3. The required field is: no, unless indicating multiple principal investigators</p> | Based on comments received additional data elements were added to allow applicable manufactures to report multiple principal investigators that are covered recipients. |

| <b>DE# revised</b> | <b>DE#</b> | <b>Data element name</b>           | <b>Action to be performed</b> | <b>Changes to the submission file specifications</b>   | <b>Reason for the Change</b>  |
|--------------------|------------|------------------------------------|-------------------------------|--|---|
|                    |            |                                    |                               | 4. The field size is: less than or equal to 20 characters.   |   |
| 109.               | -----      | Principal Investigator Middle Name | Addition                      | <ol style="list-style-type: none"> <li>1. The data element name is: Principal Investigator Middle Name</li> <li>2. The description is: Textual middle initial or middle name of the Principal Investigator of the research study, if the Principal Investigator is a Covered Recipient Physician.</li> <li>3. The required field is: no, unless indicating multiple principal investigators</li> <li>4. The field size is: less than or equal to 20 characters.</li> </ol> | Based on comments received additional data elements were added to allow applicable manufactures to report multiple principal investigators that are covered recipients. |
| 110.               | -----      | Principal Investigator Last Name   | Addition                      | <ol style="list-style-type: none"> <li>1. The data element name is: Principal Investigator Last Name</li> <li>2. The description is: Textual last name of the Principal investigator of the research study; required if, the Principal Investigator is a Covered Recipient Physician.</li> <li>3. The required field is: no, unless indicating multiple principal investigators</li> <li>4. The field size is: less than or equal to 35 characters.</li> </ol>             | Based on comments received additional data elements were added to allow applicable manufactures to report multiple principal investigators that are covered recipients. |
| 111.               | -----      | Principal Investigator Name Suffix | Addition                      | <ol style="list-style-type: none"> <li>1. The data element name is: Principal Investigator Name Suffix</li> <li>2. The description is: Suffix of the Principal Investigator of the research study chosen from a constrained list of values (Examples: Jr., Sr, III), if the Principal Investigator is a Covered</li> </ol>   | Based on comments received additional data elements were added to allow applicable manufactures to report multiple principal investigators that are covered recipients. |

| DE# revised | DE#   | Data element name                                     | Action to be performed | Changes to the submission file specifications  | Reason for the Change   |
|-------------|-------|---|------------------------|--|---|
|             |       |   |                        | <p>Recipient Physician.</p> <p>3. The required field is: no, unless indicating multiple principal investigators</p> <p>4. The field size is: less than or equal to 5 characters.</p>   |   |
| 112.        | ----- | Principal Investigator Business Street Address Line 1 | Addition               | <p>1. The data element name is: Principal Investigator Business Street Address Line 1</p> <p>2. The description is: The first line of the primary business street address of the Principal Investigator of the research study, if the Principal Investigator is a Covered Recipient Physician. If the Principal Investigator is the same as the Covered Recipient Physician receiving the payment (identified in data elements 10-13), it is not necessary to duplicate the information for the Principal Investigator fields (Data Elements 45-60).</p> <p>3. The required field is: no, unless indicating multiple principal investigators</p> <p>4. The field size is: less than or equal to 55 characters.</p> | Based on comments received additional data elements were added to allow applicable manufactures to report multiple principal investigators that are covered recipients. |
| 113.        | ----- | Principal Investigator Business Street Address Line 2 | Addition               | <p>1. The data element name is: Principal Investigator Business Street Address Line 2</p> <p>2. The description is: The first line of the primary business street address of the Principal Investigator of the research study, if the Principal Investigator is a</p>  | Based on comments received additional data elements were added to allow applicable manufactures to report multiple principal investigators that are covered recipients. |

| DE# revised | DE#   | Data element name            | Action to be performed | Changes to the submission file specifications   | Reason for the Change   |
|-------------|-------|------------------------------|------------------------|---|---|
|             |       |                              |                        | <p>Covered Recipient Physician. If the Principal Investigator is the same as the Covered Recipient Physician receiving the payment (identified in data elements 10-13), it is not necessary to duplicate the information for the Principal Investigator fields (Data Elements 45-60).</p> <p>3. The required field is: no, unless indicating multiple principal investigators</p> <p>4. The field size is: less than or equal to 55 characters.</p> |   |
| 114.        | ----- | Principal Investigator City  | Addition               | <p>1. The data element name is: Principal Investigator City</p> <p>2. The description is: The primary business address city of the Principal investigator of the research study.</p> <p>3. The required field is: no, unless indicating multiple principal investigators</p> <p>4. The field size is: less than or equal to 40 characters</p>   | Based on comments received additional data elements were added to allow applicable manufactures to report multiple principal investigators that are covered recipients. |
| 115.        | ----- | Principal Investigator State | Addition               | <p>1. The data element name is: Principal Investigator State</p> <p>2. The description is: The primary business address state or territory abbreviation of the Principal investigator of the research study, if the primary practice address is in the United States.</p> <p>3. The required field is: no, unless indicating multiple principal</p>   | Based on comments received additional data elements were added to allow applicable manufactures to report multiple principal investigators that are covered recipients. |

| <b>DE# revised</b> | <b>DE#</b> | <b>Data element name</b>        | <b>Action to be performed</b> | <b>Changes to the submission file specifications</b>   | <b>Reason for the Change</b>  |
|--------------------|------------|---------------------------------|-------------------------------|--|---|
|                    |            |                                 |                               | investigators<br>4. The field size is: 2 characters  |   |
| 116.               | -----      | Principal Investigator Zip Code | Addition                      | <ol style="list-style-type: none"> <li>1. The data element name is: Principal Investigator Zip Code</li> <li>2. The description is: The 9 digit zip code of the primary business address location of the Principal investigator of the research study, if the primary practice address is in the United States.</li> <li>3. The required field is: no, unless indicating multiple principal investigators</li> <li>4. The field size is: less than or equal to 9 characters</li> </ol> | Based on comments received additional data elements were added to allow applicable manufactures to report multiple principal investigators that are covered recipients. |
| 117.               | -----      | Principal Investigator Country  | Addition                      | <ol style="list-style-type: none"> <li>1. The data element name is: Principal Investigator Country</li> <li>2. The description is: The primary business address country name of the Principal investigator of the research study.</li> <li>3. The required field is: no, unless indicating multiple principal investigators</li> <li>4. The field size is: less than or equal to 40 characters</li> </ol>  | Based on comments received additional data elements were added to allow applicable manufactures to report multiple principal investigators that are covered recipients. |
| 118.               | -----      | Principal Investigator Province | Addition                      | <ol style="list-style-type: none"> <li>1. The data element name is: Principal Investigator Province</li> <li>2. The description is: The primary business address province name of the Principal investigator of the research study, if the primary practice address is outside the United States.</li> <li>3. The required field is: no, unless</li> </ol>   | Based on comments received additional data elements were added to allow applicable manufactures to report multiple principal investigators that are covered recipients. |

| DE# revised | DE#   | Data element name                             | Action to be performed | Changes to the submission file specifications   | Reason for the Change   |
|-------------|-------|---|------------------------|---|---|
|             |       |   |                        | <p>indicating multiple principal investigators</p> <p>4. The field size is: less than or equal to 20 characters</p>   |   |
| 119.        | ----- | Principal Investigator Postal Code            | Addition               | <p>1. The data element name is: Principal Investigator Postal Code</p> <p>2. The description is: The international postal code of the primary business location of the Principal investigator of the research study if the primary practice address is outside the United States.</p> <p>3. The required field is: no, unless indicating multiple principal investigators</p> <p>4. The field size is: less than or equal to 20 characters.</p>   | Based on comments received additional data elements were added to allow applicable manufactures to report multiple principal investigators that are covered recipients. |
| 120.        | ----- | Principal Investigator Physician Primary Type | Addition               | <p>1. The data element name is: Principal Investigator Physician Primary Type</p> <p>2. The description is: Primary type of medicine practiced by the Principal Investigator. If the Principal Investigator is the same as the Covered Recipient Physician receiving the payment (identified in data elements 10-13), it is not necessary to duplicate the information for the Principal Investigator fields (Data Elements 45-60).</p> <p>3. The required field is: no, unless indicating multiple principal investigators</p> <p>4. The field size is: 1 character.</p> | Based on comments received additional data elements were added to allow applicable manufactures to report multiple principal investigators that are covered recipients. |



| <b>DE# revised</b> | <b>DE#</b> | <b>Data element name</b>         | <b>Action to be performed</b> | <b>Changes to the submission file specifications</b>   | <b>Reason for the Change</b>  |
|--------------------|------------|----------------------------------|-------------------------------|--|---|
| 121.               | -----      | Principal Investigator NPI       | Addition                      | <ol style="list-style-type: none"> <li>1. The data element name is: Principal Investigator NPI</li> <li>2. The description is: Individual NPI for Physician (not NPI of any group physician belonging to) required, if applicable. If the Principal Investigator is the same as the Covered Recipient Physician receiving the payment (identified in data elements 10-13), it is not necessary to duplicate the information for the Principal Investigator fields (Data Elements 45-60).</li> <li>3. The required field is: no, unless indicating multiple principal investigators</li> <li>4. The field size is: 10 characters</li> </ol> | Based on comments received additional data elements were added to allow applicable manufactures to report multiple principal investigators that are covered recipients. |
| 122.               | -----      | Principal Investigator Specialty | Addition                      | <ol style="list-style-type: none"> <li>1. The data element name is: Principal Investigator Specialty</li> <li>2. The description is: Principal Investigator's single specialty chosen from "provider taxonomy" list. If the Principal Investigator is the same as the Covered Recipient Physician receiving the payment (identified in data elements 10-13), it is not necessary to duplicate the information for the Principal Investigator fields (Data Elements 45-60).</li> <li>3. The required field is: no, unless indicating multiple principal investigators</li> <li>4. The field size is: 10 characters</li> </ol>               | Based on comments received additional data elements were added to allow applicable manufactures to report multiple principal investigators that are covered recipients. |

| <b>DE# revised</b>                           | <b>DE#</b> | <b>Data element name</b>  | <b>Action to be performed</b> | <b>Changes to the submission file specifications</b>  | <b>Reason for the Change</b>  |
|--|------------|---|-------------------------------|---|---|
| 123.   | -----      | Principal Investigator License State and License Number                   | Addition                      | <ol style="list-style-type: none"> <li>1. The data element name is: Principal Investigator License State and License Number</li> <li>2. The description is: Paired state and state license number of the Principal Investigator, who is a physician covered recipient; the pairing includes the 2 letter state abbreviation, followed by a hyphen, followed by the state license number and may include up to 5 "Physician License State and License Number" pairs. If a Principal investigator is licensed in multiple states, provide only one state and license number pair.</li> <li>3. The required field is: no, unless indicating multiple principal investigators</li> <li>4. The field size is: less than or equal to 20 characters per state and license number.</li> </ol> | Based on comments received additional data elements were added to allow applicable manufactures to report multiple principal investigators that are covered recipients.               |
| <b>Physician Ownership/Investment Record</b> |            |   |                               |   |   |
| 2.   | 2.         | Applicable manufacturer or applicable GPO registration ID submitting file | Edit                          | <ol style="list-style-type: none"> <li>1. The description field is edited to: Open Payments System generated identifier used to identify the Applicable Manufacturer or GPO (populated only with CMS provided identifier). If this file contains a single AM/GPO's set of payment/transfer of value records, this AM/GPO ID will be used for all records in the file.</li> <li>2. The field size is edited to: system generated.</li> </ol>   | The description is edited to provide guidance to collect the information required for to reporting. The field size is edited to reflect the registration ID will be system generated. |
| 6.   | 6.         | Ownership/  | Edit                          | 1. The description field is edited to: textual  | The description is edited to provide guidance to  |

| <b>DE# revised</b> | <b>DE#</b> | <b>Data element name</b>                      | <b>Action to be performed</b> | <b>Changes to the submission file specifications</b>   | <b>Reason for the Change</b>   |
|--------------------|------------|---|-------------------------------|--|--|
|                    |            | Investment Physician's Frist Name             |                               | <p>first name, as listed in the National Plan &amp; Provider Enumeration System (NPPES) of the physician (covered recipient) receiving the payment or transfer of value.</p> <p>2. The field size is limited to less than or equal to 20 characters.</p>   | collect the information required for to reporting. The field size is edited to be consistent with data collection in NPPES.  |
| 7.                 | 7.         | Ownership/ Investment Physician's Middle Name | Edit                          | <p>1. The description field is edited to: textual middle initial or middle name, as listed in the National Plan &amp; Provider Enumeration System (NPPES) of the physician (covered recipient) receiving the payment or transfer of value.</p> <p>2. The field size is limited to less than or equal to 20 characters.</p>   | The description is edited to provide guidance to collect the information required for to reporting. The field size is edited to be consistent with data collection in NPPES. |
| 8.                 | 8.         | Ownership/ Investment Physician's Last Name   | Edit                          | <p>1. The description field is edited to: textual last name, as listed in the National Plan &amp; Provider Enumeration System (NPPES) of the physician (covered recipient) receiving the payment or transfer of value.</p> <p>2. The field size is limited to less than or equal to 35 characters.</p>   | The description is edited to provide guidance to collect the information required for to reporting. The field size is edited to be consistent with data collection in NPPES. |
| 9.                 | 9.         | Ownership/ Investment Physician's Name Suffix | Edit                          | <p>1. The description field is edited to: suffix, as listed in the as listed in the National Plan &amp; Provider Enumeration System (NPPES) of the physician (covered recipient) receiving the payment or transfer of value chosen from a constrained list of values. (Examples: Jr., Sr., III).</p> <p>2. The field size is limited to less than or equal to five characters.</p> | The description is edited to provide guidance to collect the information required for to reporting. The field size is edited to be consistent with data collection in NPPES. |

| <b>DE# revised</b> | <b>DE#</b> | <b>Data element name</b>  | <b>Action to be performed</b> | <b>Changes to the submission file specifications</b>  | <b>Reason for the Change</b>   |
|--------------------|------------|---|-------------------------------|---|--|
| 10.                | 10.        | Ownership/<br>Investment<br>Physician's<br>Business<br>Street Address<br>Line 1 | Edit                          | 1. The field size is limited to less than or equal to 55 characters.  | The field size is edited to be consistent with data collection in NPPES.   |
| 11.                | 11.        | Ownership/<br>Investment<br>Physician's<br>Business<br>Street Address<br>Line 2 | Edit                          | 1. The field size is limited to less than or equal to 55 characters.  | The field size is edited to be consistent with data collection in NPPES.   |
| 12.                | 12.        | Ownership/<br>Investment<br>Physician's<br>City                                 | Edit                          | 1. The field size is limited to less than or equal 40 characters.   | The field size is edited to be consistent with data collection in NPPES.   |
| 14.                | 14.        | Ownership/<br>Investment<br>Physician's<br>Zip Code                             | Edit                          | 1. The description field is edited to: The 9 digit zip code for the primary practice location of the physician or teaching hospital (covered recipient) receiving the payment or transfer of value if the primary practice address is in the United States.<br>2. The field size is edited to less than or equal to 9 characters. | Based on comments received the field size is increased to accommodate a 5 digit zip code with an option to report the additional 4 digits. |
| 15.                | -----      | Ownership/<br>Investment<br>Physician's<br>Country                              | Addition                      | 1. The data element name is: Ownership/<br>Investment Physician's Country<br>2. The description field is: The primary practice/business address country name of the physician.<br>3. The required field is: yes<br>4. The field size is: less than or equal to 20 characters.   | This data element is added match information collected in general and research data specifications.  |

| <b>DE# revised</b> | <b>DE#</b> | <b>Data element name</b>                                 | <b>Action to be performed</b> | <b>Changes to the submission file specifications</b>   | <b>Reason for the Change</b>  |
|--------------------|------------|--|-------------------------------|--|---|
| 16.                | -----      | Ownership/<br>Investment<br>Physician's<br>Province      | Addition                      | <ol style="list-style-type: none"> <li>1. The data element name is: Ownership/<br/>Investment Physician's Province</li> <li>2. The description field is: The primary<br/>business address province name of the<br/>Physician Owner/Investor, if the primary<br/>practice address is outside the United<br/>States.</li> <li>3. The required field is: no</li> <li>4. The field size is: less than or equal to 20<br/>characters.</li> </ol>  | This data element is added match information<br>collected in general and research data specifications.                                    |
| 17.                | -----      | Ownership/<br>Investment<br>Postal Code                  | Addition                      | <ol style="list-style-type: none"> <li>1. The data element name is: Ownership/<br/>Investment Physician's Postal Code</li> <li>2. The description field is: The<br/>international postal code of the primary<br/>business location of the Principal<br/>investigator of the research study if the<br/>primary practice address is outside the<br/>United States.</li> <li>3. The required field is: yes, if country is<br/>not the United States.</li> <li>4. The field size is: less than or equal to 20<br/>characters.</li> </ol> | This data element is added match information<br>collected in general and research data specifications.                                    |
| 18.                | 15.        | Ownership/<br>Investment<br>Physician's<br>Email Address | Edit                          | <ol style="list-style-type: none"> <li>1. The field size is increased to less than or<br/>equal to 100 characters.</li> </ol>  | The field size is increased to allow applicable<br>manufacturers and applicable GPOs to accurately<br>report a recipient's email address. |
| 19.                | -----      | Ownership/<br>Investment<br>Physician's<br>Primary Type  | Addition                      | <ol style="list-style-type: none"> <li>1. The data element name is: Ownership/<br/>Investment Physician's Primary Type</li> <li>2. The description field is: Primary type of<br/>medicine practiced by the physician<br/>covered recipient.</li> <li>3. The required field is: yes</li> <li>4. The field size is: 1 character</li> </ol>   | This data element is added match information<br>collected in general and research data specifications.                                    |

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|--------------------|------------|---|-------------------------------|--|--|
| 20.                | 17.        | Ownership/<br>Investment<br>Physician's<br>NPI                                    | Edit                          | <ol style="list-style-type: none"> <li>1. The description field is edited to:<br/>Individual NPI for Physician (not NPI of any group physician belonging to), required if applicable.</li> <li>2. The required field is changed to: no.</li> </ol>   | The required field is changed to no because applicable manufacturers and applicable GPOs are only required to report a physician's NPI if applicable.  |
| 21.                | 16.        | Ownership/<br>Investment<br>Physician's<br>Specialty                              | Edit                          | <ol style="list-style-type: none"> <li>1. The description field is changed to:<br/>Physician's single specialty chosen from the standardized "provider taxonomy" code list.</li> <li>2. The field size is edited to be limited to 10 characters.</li> </ol>  | Based on comments received the "provider taxonomy" list from the Washington Publishing Company will be provided. This is the same list that can be retrieved through the NPPESS website. The field size is edited to accurately reflect the characters for collection. |
| 22.                | 18.        | Ownership/<br>Investment<br>Physician's<br>License State<br>and License<br>Number | Edit                          | <ol style="list-style-type: none"> <li>1. The data element name is changed to:<br/>Ownership/ Investment Physician's License State and License Number</li> <li>2. The description field is changed to:<br/>Paired state and state license number of the covered physician; the pairing includes the 2 letter state abbreviation followed by the state license number and may include up to 5 "Ownership/ Investment Physician License State and License Number" pairs.</li> <li>3. The field size is edited to: less than or equal to 20 characters per state and license number.</li> </ol> | The physician's license number and state are combined in order to reflect the appropriate state with the license number because multiple license numbers and states may be reported. The field size is edited to accurately reflect the characters for collection.     |
| -----              | 19.        | Ownership/<br>Investment<br>Physician's<br>License State                          | Delete                        | <ol style="list-style-type: none"> <li>1. This data element is deleted.</li> </ol>   | This data element was combined with Physician Licenses State(s) and License Number(s) for simplification.  |