

| Commenter | Template | Comment | Response |
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| AdvaMed | General | <p>1. Inaccurate Cross-References. Throughout the Data Templates, internal cross references inaccurately refer to previous Line numbers. For example, Lines 54, 55 and 56 on the Research Payment Template inaccurately cross reference Line 55 as the “Multi-year Payment Structure Indicator; the “Multi-year Payment Structure Indicator” is set forth in Line 53. We recommend that CMS revise the Data Templates to ensure that accurate cross- references are included.</p> | <p>The submission file specifications are edited to include accurate cross references.</p> |
| | General | <p>2. Data Element Size. The Data Templates currently include the column for “Data Element Size” information regarding the proposed number of characters available for each line item within the Data Templates. It is not clear how these character limits were determined and the character lengths also vary between Data Templates (e.g., Line 46 of the Non-Research Payment Template related to Contextual Information has a data element size of 200 characters, whereas the corresponding Line 59 in the Research Payment Template related to Context of Research has a data element size of 500 characters). We recommend that CMS standardize the character lengths between the Data Templates. CMS should also ensure that the character lengths are sufficient to allow appropriate reporting.</p> | <p>The field size for data elements has been edited to allow for appropriate reporting. Additionally, the field sizes in the data submission specifications are standardized throughout.</p> |
| | General | <p>3. Standardized Lists. Throughout the data Templates, CMS refers to certain standardized lists that may apply to particular fields. In order</p> | <p>Some standardized list will be provided as guidance for reporting. Required standardized lists will be provided allowing</p> |

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| | | <p>to allow manufacturers sufficient time to prepare for implementation, CMS should timely make such lists available for receive and comment by applicable manufacturers.</p> | <p>sufficient time for applicable manufacturers and applicable GPOs to implement, except for common lists such as country.</p> |
| <p>Non-Research and Research</p> | | <p>4. Associated covered products; Lines 27 and 29. Line 27 of both the Non-Research Payment Template and the Research Payment Template (Name of Associated Drug, Device, Biological, or Medical Supply) requires applicable manufacturers to report 91) the name of an associated covered product, (2) that the product is a “non-covered product,” or (3) that there is “none.” Line 29 of both the Non-Research Payment Template and the Research Payment Template (Therapeutic Area of Product Category), which is not required, allows manufacturers to report the therapeutic area or product category of the primary device or medical supply associated with the payment, if applicable. With respect to devices and medical supplies, under the Final Rule, manufacturers must report either the name under which the device is or was marketed or the therapeutic area or product category for the device. Therefore, Line 27 should not be “Required” as written unless “therapeutic area or product category” is an acceptable response as well.</p> <p>We also note that in Line 27 on the Research Payment Template, CMS indicates that the associated covered product should be selected from “Text of Standardized Selection based on validated industry lists,” or “None” or “Non-</p> | <p>The name of an associated covered device or medical supply is now a separate data element. This will allow applicable manufactures and applicable GPOs to report the marketed name or the therapeutic area or product category for covered devices or medical supplies that are associated with a payment or transfer of value. Name of Associated Covered Device or Medical Supply data element has been updated in both submission file specifications for consistent reporting.</p> |

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| | | <p>covered product” should be indicated. The corresponding Line 27 in the Non-Research Payment Template does not refer to the same three value options. The reason for the discrepancy between the two data Templates is unclear. Similarly, in Line 29 on both the Non-Research Payment Template and the Research Payment Template, CMS indicates that the Therapeutic Area or Product Category will be selected from “Text from Standardized Selection,” which will include two characters. The Final Rule does not reference such standardized lists, and any lists should be available for review and comment by applicable manufacturers. In addition, if standardized lists are not provided by CMS, two characters is likely insufficient for reporting on the therapeutic area or product category.</p> | |
| | <p>Non-Research and Research</p> | <p>5. Teaching hospital’s TIN; Line 8. For research and non-research payments to a teaching hospital, Line 8 of both the Non-Research Payment Template and the Research Payment Template requires manufacturers to report the teaching hospital’s TIN. The Final Rule does not require manufacturers to report this information. Accordingly, we recommend that CMS change the required field in both the Non-Research Payment Template and the Research Payment Template to indicate that such information is not required.</p> | <p>Applicable manufacturers are not required to collect teaching hospitals’ TINs. CMS will provide a teaching hospital list that will include the name, TIN, and business address of the teaching hospital. In order to assure accurate payment or other transfers of value are allocated to the correct teaching hospital applicable manufacturers need to report the information provided by CMS from the teaching hospital list.</p> |
| | <p>Non-Research and Research</p> | <p>6. Physician and principal investigator specialty; Lines 24 (non-research) and 45 (research), In Line 24 of the Non-Research Payment Template</p> | <p>The field size has been edited to account for the correct character limit.</p> |

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| | | <p>and Line 45 of the Research Payment Template related to physician specialty, manufacturers are provided only two characters to report the physician's or principal investigator's specialty. The Final Rule requires manufacturers to use the NPPEES provider taxonomy list as the list of accepted specialties. That list available from the Washington Publishing Company and the relevant codes are longer than two characters (e.g., the code for Adult Reconstructive Orthopedic Surgery is 207XS0114X). If manufacturers are required to conform physician specialty information to the NPEES, two characters are likely insufficient. Accordingly, we recommend that CMS revise the character limit.</p> | |
| Research | | <p>7. Research payments to individual non-covered recipients; Line 6, 9-12. Line 6 of the Research Payment Template requires manufacturers to identify whether the recipient of the research payment is a teaching hospital, physician, institutional non-covered recipient, or individual non-covered recipient. According to the "Required" Fields for Lines 8-12, manufacturers are only required to report the name of the physician covered recipient or individual non-covered recipient. By contrast, the "Definition/Description" Fields for Lines 7-12 imply that manufacturers are only required to report the name of the physician covered recipient. Because the name of an individual non-covered recipient, which must be reported under the regulations, we recommend that CMS</p> | <p>Line 6 of the Research submission file specification has been edited to allow applicable manufactures to indicate: (1) covered recipient physician, (2) covered recipient teaching hospital, (3) non-covered recipient entity, or (4) non-covered recipient individual. The required fields and definition/description fields have been edited to indicate what information is required.</p> |

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| | | revise the Definition/Description” Fields to align with the “Required” Fields and the regulations. | |
| Research | 8. | Research payments to institutional non-covered recipients and reporting TINs; Line 8. For research payments made to an institutional non-covered recipient, Line 8 of the Research Payment Template requires manufacturers to report the entity’s TIN. While the regulations require manufacturers to report the name of the research institutional, individual or entity receiving the payment or transfer of value, the regulations do not require manufacturers to report the TIN. Accordingly, we recommend that CMS change the required field in the Research Payment Template to indicate that such information is optional. | Line 8 has been edited to report a teaching hospital TIN. Applicable manufactures are not required to collected teaching hospital TINs. Teaching hospital TINs are available from the teaching hospital provided by CMS. |
| Research | 9. | Principal investigators; Lines 30-47. It is unclear how manufacturers will report a research payment that involves multiple principal investigators. Additionally, the Research Payment Template does not contemplate reportable payments to teaching hospitals for research where the principal investigator is not a physician. We recommend that CMS revise the Research Payment Template to address these issues. | The final rule requires reporting information about each physician covered recipient principal investigator (if applicable). Additional optional data elements have been added to allow applicable manufacturers to report information for multiple covered recipient principal investigators. Information regarding principal investigators that are not physician covered recipients is not required for reporting. |
| Research | 10. | Principal investigator’s zip code and state; Lines 39 and 40. Line 39 requires applicable manufacturers to report a principal investigator’s zip code if the applicable manufacturers previously indicated (1) the recipient of the research payment was a | The requirements for reporting zip codes and states have been edited throughout the submission file specifications. |

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| | | <p>physician covered recipient (Line 6); (2) the physician receiving the research payment is not the principal investigator (Line 32); and (3) the principal investigator’s country is the Unites States (line 40). By contrast, Line 40 requires applicable manufacturers to report a principal investigator’s state if the applicable manufacturers previously indicated (1) the recipient of the research payment was a physician covered recipient or an individual non-covered recipient (Line 6); (2) the physician receiving the research payment is not the principal investigator (Line 32); and (3) the principal investigator’s country is the Unites States (Line 40). The requirements for reporting a principal investigator’s zip code and state, should be consistent. Therefore, we recommend that CMS revise the requirement outlined in the “Required” fields for Lines 39-40. We also recommend that CMS review the “Required” fields generally to ensure that all requirements are accurate and consistent where necessary.</p> | |
| | <p>Research</p> | <p>11. Multi-year research payments; Line 53-56. Lines 53 through 56 of the Research Payment Template are identified as “Required” if a payment or transfer of value is part of a multi-year payment structure. Information to be reported includes: (1) total number of years for this research payment; (2) total number of years for this research project; and (3) the total budget of this research project. This information is outside the scope of the Final</p> | <p>Lines 53-56 are deleted.</p> |

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| | | <p>Rule and therefore not required to be reported. It is also unclear how to capture such information in an automated, physician-spend system. Accordingly, we recommend that CMS change the required field in the Research Payment Template to indicate that such information is optional.</p> | |
| Research | 12. | <p>Context of research; Line 59. Line 59 requires applicable manufacturers to provide a “Textual description of research context or research objectives.” The Final Rule, however, makes clear that CMS has “included an optional field allowing applicable manufacturers to provide additional contextual information on or the objectives of the research.” Therefore, we recommend that CMS revise Line 59 to be optional only.</p> | <p>Line 59 context of research is edited as an optional data element.</p> |
| Research | 13. | <p>Reason for delayed publications; Line 61. Line 61 of the research Payment Template requires manufacturers to report the reason a research payment is subject to delayed publication (if any). CMS provides the following options: (1) New Product; (2) Research on Medical Technology; (3) Clinical Investigation; or (4) None. These options are not consistent with the Final Rule, and it is not clear why this line is in the Research Payment Template when the Final Rule clearly states the criteria that must be met for a payment to be eligible for delayed publication. The Final Rule states that payments and other transfers of value related to research (excluding clinical investigations) of new products and new</p> | <p>Line 61 is edited to reflect reasons for delay in publication for research to align with the final rule, (1) research on or development of a new drug, device, biological, or medical supply, (2) clinical investigations regarding a new drug, device, biological, or medical supply or (3) not requesting a delay in publication. CMS will display payments or transfers of value after four years after the request for delay in publication research. The final rule also requires reporting to CMS if the new drug, device, biological or medical supply, to which the payment is related (or the new application of the existing drug, device, biological, or medical supply) is approved by the FDA, therefore</p> |

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| | | <p>applications of existing products and clinical investigations of new products will be eligible for delayed publication, at a manufacturer's discretion. If this line is kept in the Research Payment Template, we recommend changing the options to: (1) Research (Excluding Clinical Investigations); (2) Clinical Investigations; or (3) None.</p> | <p>upon FDA approval applicable manufactures are required to submit a correction to CMS indicating (3) not requesting a delay in publication. Applicable manufactures indicting a reason for delay in publication allows the OPEN PAYMENTS system to not publicly display the information.</p> |
| Research | | <p>14. Lift delay in publication indicator; Line 62. Line 62 requires applicable manufacturers to indicate whether a "delay in publication" should be lifted according to the requirements of the Final Rule (i.e., expiration of the four-year maximum time allotment of FDA approval, licensure or clearance). Line 62 also implies that CMS can change a "No" response to "Yes" as a result of FDA approval or expiration of the four-year time allotment. While the Final Rule provides that "[f]ailure to notify CMS when FDA approval occurs may be considered failure to report," the Final Rule does not provide that CMS may unilaterally report a payment identified as subject to delayed publication solely because FDA approval has occurred. By contrast, CMS may unilaterally report a payment identified as subject to a delay if the four-year maximum time allotment has expired. We recommend that CMS can only lift the delay in publication indicator in situation where the applicable payment or transfer of value has reached the four-year maximum time allotment.</p> | <p>Line 62 lift in delay in publication indicator is deleted. CMS will publish information regarding payments or other transfers of value four years after option (1) or (2) was selected for the data element Reasons for Delay in Publication. Additionally, applicable manufactures indicating a reason for delay in publication will attest that annually in their report that FDA approval, licensure, or clearance of the new drug, device, biological or medical supply to which the payment or other transfer of value is related is pending.</p> |

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| | Research | <p>15. Expenditure category; Line 64. Line 64 of the Research Payment Template is not required but allows manufacturers to report a contextual category for a research payment or transfer of value from an enumerated list to be provided by CMS at a later date. CMS provides the following examples: professional salary support, medical research writing or publication, patient care, non-patient care, overhead or other. Providing an enumerated list at some later date does not, however, afford manufacturers the opportunity to incorporate such information into their automated physician-spend systems. We therefore recommend that CMS provide the enumerated list with a reasonable time period with an opportunity for manufacturers and other stakeholders to comment on the same.</p> | <p>The data element expenditure category is optional. The enumerated list is: “1” = professional salary support “2” = medical research writing or publication “3” = patient care “4” = non-patient care “5” = overhead “6” = other. Applicable manufactures opting to indicate expenditure categories are required to report an applicable percentage associated with each category.</p> |
| | Non-Research | <p>16. Nature of payment – research; Line 39. Line 39 of the Non-Research Payment Template includes “09=Research” as an option for describing the nature of a payment. This option should be removed because such payments should be reported using the Research Payment Template.</p> | <p>The option “9” = research is deleted from the nature of payment or transfer of value data element.</p> |
| | Non-Research | <p>17. Indirect payments and payments at the request of or designated on behalf of covered recipient; Lines 32, 44, and 45. Line 32 requires applicable manufacturers to report that name of the third party entity involved in an indirect payment to a covered recipient. Line 45 requires the manufacturer to report the name of the entity that received a payment or</p> | <p>Line 32, requiring the reporting information regarding indirect payments is deleted. Indirect payments made by applicable manufacturers or applicable GPOs are required to be reported in the name of the covered recipient that received the indirect payment.</p> |

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| | | <p>other transfer of value if (a) the covered recipient directed the manufacturer to pay a third party, or (b) the fee was waived and the manufacturer donated the payment to an entity. Line 44 requires manufactures to report whether a payment or other transfer of value was (1) paid to the covered recipient, (2) paid to a third party at the covered recipient’s request, or (3) waived by the covered recipient. In effect, Lines 32, 44 and 45 require applicable manufacturers to distinguish between indirect payments and direct payments that involved third parties. Under the Final Rule, however, applicable manufacturers are not obligated to classify payments or transfers of value as either indirect or direct.</p> | |
| Covidien Mallinckrodt | | <p>18. Row #22 in the proposed template requires reporting of the “Physician Primary Type” if the Covered Recipient is a physician. The template provides “Allowed values”, such as “01” = Medical Doctor (MD), “02” = Doctor of Osteopathy, etc., but there is no indication whether the data in this row is intended to reflect specific data in the NPPES database for accuracy and consistency. Is there a corresponding data field in the NPPES database against which the data in row #22 will be matched or compared? If so, what data, specifically?</p> | <p>No there is a not corresponding data in the NPPES database. The primary types listed are equivalent to the definition of a physician according to the Social Security Act, which also defines a physician for OPEN PAYMENTS. These are the available enumerations for OPEN PAYMENTS.</p> |
| | | <p>19. There seems to be a data field size mismatch in Row # 24. The “Physician Specialty” data</p> | <p>The field size is edited to reflect 10 characters. CMS will provide a</p> |

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| | | <p>element for this row is defined in the template as consisting of two characters, but the corresponding Physician Specialty codes in the NPES “provider taxonomy” that appear to be the desired universe of options are 10 characters. Is the two character limitation correct? If so, then please be specific as to where to find the source data for the two character “Physician Specialty” codes.</p> | <p>standardized list for applicable manufacturers and applicable GPOs to provide a physician’s specialty. This list will be available for informal comments by applicable manufacturers and applicable GPOs.</p> |
| Non-research | 20. | <p>The Final Rule and Preamble are crystal clear that payments and transfers of value to physicians through third-parties and to third-parties on behalf of physicians are reportable to each physician. However, the Final Rule and Preamble also fairly clearly only require the disclosure of the third-party recipient of value on behalf of Physicians and not for third-parties who transfer value to physicians on behalf of the manufacturer. Is the template’s requirement to disclose the Third-party transferring the value on behalf of the manufacturer a new requirement? If so, I submit that it is potentially unfair to be instituting additional requirements not included in the Final Rule and not clearly disclosed as additional requirements if the expectation is that our systems will need to capture this information by 8/1/13. Please consider delaying this requirement for capturing the data for third-parties providing value on behalf of the manufacturer until 2014 data.</p> | <p>Line 32, requiring the reporting information regarding indirect payments is deleted. Indirect payments made by applicable manufacturers or applicable GPOs are required to be reported in the name of the covered recipient that received the indirect payment.</p> |

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| | Non-research | 21. There seems to be a disconnect between the described reportable information in the Final Rule and Preamble and that described in the template for Rows #27-29 for “Associated Drug, Device, Biological, or Medical Supply Information.” Specifically, the Final Rule indicates that manufacturers will be able to report up to 5 products being discussed/addressed for each payment, but the template characterizes this as just one. Can you clarify how many products will be able to be listed in the template, and, if it is more than one, how to do it? | The data element regarding reporting associated drugs, devices, biological and medical supplies has been edited to accurately reflect reporting requirements by applicable manufacturers and applicable GPOs. Applicable manufacturers and applicable GPOs have the option to report up to five covered drugs, devices, biologicals, or medical supplies that are related to the payment or other transfer of value provided to covered recipients, physicians owners or physician investors. |
| | | 22. In retrospect, when determining which “Form of Payment” to select for a specific transfer of value, what option should we select for instances in which we are reimbursing for properly documented expenses such as travel or meals? Should they be “cash or cash equivalents” since we are reimbursing by check, or should they be “in-kind items or services” because the ultimate value provided was the actual travel or meal substantiated by the receipt and reimbursed? Could this also be addressed through an assumptions document entry detailing our decision making process for these situations? | Providing a payment or transfer of value in the form of a check should be reported as “cash or cash equivalent” form of payment. An assumptions document can describe any assumptions and methodologies used regarding the information reported about a payment or transfer of value, as well, physician ownership or physician investments. |
| Biotechnology Industry Organization | General | 23. Recommend that CMS allow manufacturers the option to submit corrected rows, rather than an entire report. To make that possible, | Applicable manufacturers or applicable GPOs receiving errors for reports submitted are required to submit a report that |

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| | | <p>manufacturers should be given the flexibility to provide either a unique transaction identifier in the initial submission and any subsequent submissions, or the manufacturers should have the option of utilizing a unique line identified supplied by CMS for each record.</p> | <p>addresses all the errors for that report. Applicable manufacturers or applicable GPOs submitting data for a correction, omission, or dispute resolved will submit only corrected rows in a resubmitted report. CMS will provide a unique identifier in order to correctly associate the updated data with the initial report submitted.</p> |
| | Non-Research | <p>24. Row 27: Name of Associated Drug, Device, Biological, or Medical Supply. The definition/description does not describe how reporting entities should separate the names of multiple products when they are reported on this row. We recommend CMS specify how names should be separated from each other. Recommend that CMS clarify in the instructions for the name of devices and medical supplies to provide the name that does not apply to devices and medical supplies.</p> | <p>The data elements for reporting names of associated drugs, devices, biologicals, or medical supplies have been edited to clarify the reporting requirements. A format column has been added to the submission file specifications to describe how reporting of multiple products should be separated.</p> |
| | Non-Research | <p>25. Row 28: NDC of Associated Drug, Device, Biological, or Medical Supply. Recommend CMS omit this field since it is redundant, does not add value for consumers, and will not enable CMS to “roll up” or aggregated the data per covered product. We recommend that CMS modify this row to allow the inclusions of up to five NDCs, that CMS provide clear instructions on how the NDCs should be separated, and that the allowed number of characters be expanded to accommodate five NDCs, with whatever separating value that CMS requires.</p> | <p>The data element NDC of associated drug or biologicals is edited to provide instructions for reporting of NDC. Reporting of NDC is not a required data element. A format column has been added to the submission file specification indicating NDCs reported which is, maximum of 5 comma separated NDCs.</p> |
| | Non-Research | <p>26. Row 39; Nature of Payment or Transfer of</p> | <p>An “Other” category for nature of payment</p> |

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| | | Value. We recommend that CMS establish an “Other” category to capture such transfers of value. | or transfer of value was included in the proposed rule, however based on comments received for the proposed rule this category was not included in the final rule. Applicable manufacturers and applicable GPOs are required to report each payment under the nature of payment category that closely describes the payment. |
| Research | 27. Rows 53-56: Multiyear Payment Structure Indicator, Total of Years for this Research Payment, Total Number of Years for this Research Project, Total Research Budget of this Project. These fields were not included in the proposed rule; as such, there was no opportunity to review and provide comments. As written, the definition/description implies that CMS would like the global study budget included in this field, which seems to be beyond the scope of the relevant ACA provisions. We recommend that CMS omit these fields since they were not adequately proposed or reviewed during the notice and comment period. | Lines 53-56 are deleted. | |
| Research | 28. Row 58: Name of Study. We recommend that CMS modify this row to accommodate up to 500 characters, since many study titles far exceed 100 characters. | The field size for the Name of Study is edited to allow up to 500 characters. | |
| Research | 29. Row 64-65: Expenditure Category, Expenditure Category Percentage. Since companies may report a lump sum for research payments, these fields are extraneous, albeit option. We recommend that these fields be omitted. | The data element Expenditure Category Percentage is deleted. Applicable manufactures have the option to report research expenditures based on the categories provided and applicable percentage for each category selected. This | |

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| | | | data element allows applicable manufacturers to allocate percentages of lump sum research payment to increase transparency for consumers by indicating having the option to indicate how the payment was used for the research study. |
| Pew Trust | Research and Non-Research | 30. Row 27, associated drugs, devices, biological, and medical supplies. Listing more than one product in this field would make it difficult for consumers and other end-users to search for or sort by a specific product. We suggest that each data field contain only a single product, and that manufacturers be required to use more than one data field when a transfer of value is relevant to more than one product. | The Name of Associated Drugs, Devices, Biologicals, and Medical Supplies has been separated in two data elements, (1) Name of Associated Covered Drug or Biological, and (2) Name of Associated Covered Device or Medical Supply. The format column requires commas to separate the each name, which allows for the OPEN PAYMENTS system to report the products in a way that is user friendly and will allow consumers to search for a specific product. |
| Medtronic | Both | 31. We request clarification that the fields are in fact columns, not rows. | Row# has been edited to DE#, data element number. |
| | Non-research | 32. Row 19, because not all countries outside of the United States necessarily have provinces, we suggest that this field be optional. | The recipient provinces data field is edited to reflect that it is not a required field. |
| | Research | 33. Row 27 and 29, request clarification of the template such that product (specific for drug manufacturers) should be entered in row 27. Any standardized listing such as row 29 was not anticipated by manufacturers and should remain optional. | Row 27 has been edited to clarify that an applicable manufacturer may report the marketed name of up to five covered drugs, devices, biologicals, or medical supplies provided in either line 27 or line 29. |
| | Non-research and research | 34. Based on row 33 of the Non-Research Payment Template and row 50 of the research Payment Template, it appears that CMS will be assigning record IDs to each transaction. We respectfully request that either 1) CMS allow | The OPEN PAYMENTS system will assign a record ID to each transaction. We will work on ways to make the implementation of these IDs as simple as possible to accommodate Applicable Manufacturers' |

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| | <p>manufacturers to provide their own transaction ID with the manufacturer's ID or report ID), or</p> <p>2) CMS begin the transaction ID with the report ID on which the file was originally submitted. This would enable manufacturers to easily retrieve the records included on each report their reporting system if needed in the future.</p> | <p>and Group Purchasing Organization's feedback on how this ID is constructed.</p> |
| | <p>35. Could CMS clarify whether when a file is resubmitted, CMS expects that all transactions will be resubmitted or does CMS expect that only those transactions that are new or modified since the file was originally submitted will be resubmitted?</p> | <p>When a file is resubmitted only those transactions that are new or modified should be reported.</p> |
| | <p>36. We respectfully request CMS clarify how manufacturers should indicate that transaction should be removed from the report.</p> | <p>Applicable manufactures and applicable GPOs submitted a correction or update from a resolved dispute should indicate that the report is a resubmission with the Resubmission File Indicator and amend the payment or other transfer to the correct amount. Report zero (0) for payments or transfer of value that should not have been reported.</p> |
| | <p>37. There is no field in the template which could be used to indicate that a record is in dispute. We respectfully request such a field be added because manufacturers may have covered recipients review their transactions through the year. If a dispute is not resolved prior to the data being uploaded to the CMS website, manufacturers will need a method for indicating that the transaction is in dispute.</p> | <p>Covered recipients will use the CMS' OPEN PAYMENTS System to dispute a record submitted by an applicable manufacturers.</p> |
| Non-Research | <p>38. CMS eliminate row 32 and use row 45 to</p> | <p>Line 32, requiring the reporting information</p> |

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| | | <p>indicate the name of the third party receiving payment from the manufacturer whenever payment was not provided directly to the covered recipient. The selections in Row 44 should be: “01-Provided to covered recipient” and “02-Provided to third party”. We believe requiring manufacturers to distinguish between indirect payments and payments made at the request of or designated on behalf of provides little value and will only result in additional burden on manufacturers and significant confusion for the covered recipients. This could lead to potentially inconsistent posting and confusion for those looking at the website (patients, other stakeholders) as well as additional inquiries and disputes.</p> | <p>regarding indirect payments is deleted. Indirect payments made by applicable manufacturers or applicable GPOs are required to be reported in the name of the covered recipient that received the indirect payment.</p> |
| | <p>Research</p> | <p>39. Clarification of Row 27 which currently requires manufacturers enter the “Name of Associated Drug, Device, Biological, or Medical Supply”. The preamble to the regulations states that a product name is not required for pre-clinical research transaction and it is unclear if CMS expects a value of ‘Non-covered product’ or ‘none’ for these transactions. Further, the report template indicated the value in row 27 will be from a standardized selection. This is different that what is indicated in the Non-research Payment Template for this same field. In light of the guidance provided by the statute and the proposed regulations, manufacturers did not expect the product association to be from a predefined list. Thus, this will cause a problem</p> | <p>Applicable manufacturers reporting a research payment related to a pre-clinical study are only required to report: (1) research entity name, (2) total amount of research payment, and (3) principal investigators (if applicable). Therefore, with regard to a pre-clinical study applicable manufacturers should not be reported name(s) of related covered drugs, devices, biological, or medical supplies.</p> |

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| | | <p>for manufacturers who have already updated their systems to use a product listing which they specifically developed for their organization. In particular, it is likely to be problematic for medical device and supply companies who may have developed a list of therapeutic areas or product categories that may not align with the predefined list created by CMS. This is especially concerning because the template mentions “common device names” but the interactions of medical device and supply companies are rarely related to a product category, a product family or therapeutic area that are unique to each manufacturers. Accordingly, we respectfully request that this field not use a predefined list.</p> | |
| Research | 40. | <p>Request that the “principal investigator” field be relabeled to “principal investigator/researcher” or “principal investigator/research/physician”. We are concerned that the label ‘principal investigator’ for all research activities will cause confusion to those consuming the data.</p> | <p>Data elements collecting information related principal investigators have been labeled “Principal Investigator Physician Covered Recipient”. This should provide clarification that only principal investigators that are considered physician covered recipients are required for reporting.</p> |
| Research | 41. | <p>In row 30, the report template asks for a value of yes or no to indicate if the physician receiving the payment is a principal investigator of the research project. Because it requests a yes or no value, we believe it should be required for all records. If it is not required for all records, then we believe CMS may have intended it to be required when row 6 is equal to “01-physican covered recipient” and not”04-Individual non-covered recipient” as stated in</p> | <p>The data element “Principal Investigator Physician Covered Recipient Indicator” allows applicable manufacturer to indicate if the physician covered recipient that received the research related payment is also the physician covered recipient principal investigator, therefore preventing the applicable manufacturer to report the same information that was previously reported for the physician covered recipient.</p> |

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| | the template. | |
| Research | 42. The report template indicates rows 31, 33, and 35 are required if the recipient type in row 6 is “04-Individual non-covered recipient”. We believe CMS intends this field to be required whenever the payment was not made directly to a physician covered recipient who is the principal investigator. Therefore, we believe these rows should be required whenever the answer to row 30 is “No” or alternatively when row 6 is “02-Teaching Hospital Covered Recipient”, “03-Institutional Non-Covered Recipient”, “04-Individual Non-Covered recipient”, or “01-Physician Covered Recipient” and row 30 is equal to No. We believe rows 37, 38, 43, 44, 45, 46, and 47 which are used to enter information about the principal investigator, should be required whenever rows 31, 33, and 35, which also required information about the principal investigator are required. This template, however, currently has different and inconsistent criteria for determining when these are required. | The required fields for data element regarding collection information for covered recipient principal investigators have been edited throughout. |
| | 43. We respectfully request the criteria for when row 39, zip code, and row 40, state, are required only in cases where row 38 is equal to United States | The required fields for zip code and state have been edited accordingly. |
| | 44. We respectfully request that row 42, postal code, be required only in cases where row 38 is not equal to United States | The postal code is edited to reflect that it is only required when the country is not the United States. |
| | 45. We respectfully request clarification regarding the reporting of research records as it relates to | CMS will provide additional guidance for applicable manufacturers or applicable |

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| | | <p>row 50, Resubmitted Payment Record ID. Since research records that are eligible for delayed publication could appear in as many as four annual reports, will CMS assign a new record ID each year for a record that is eligible for delayed publication or will the same record ID be used each year?</p> | <p>GPOs reporting that a report is eligible for delayed publication.</p> |
| Research | | <p>46. Row 53 of the report template requires an indication if the payment is a part of a multiyear payment structure. It is not clear what is meant by multiyear payment structure. If the intent is for manufacturers to dictate if the payment made was related to a research project that is longer than 12 months in duration we believe this extends beyond the scope of the Federal Sunshine Act. This requirement was not mentioned in the regulations and most manufacturers do not have this as a datapoint that is easily captures for reporting purposes. Additionally, rows 54, 55, and 56, which are required when the answer to the multiyear payment question, row 53, is yes, ask for the total duration and estimated cost of the research project. We believe this information is also not covered by the regulations and is proprietary information that is outside the statutory scope of the Federal Sunshine Act. We respectfully request to have rows 53, 54, 55, and 56 removed from the template.</p> | <p>Lines 53-56 are deleted.</p> |
| Research | | <p>47. Row 59, context of research, is listed as a required field. This is contrary to the regulations which indicate that the context of</p> | <p>The requirement for the context of research data element is edited to reflect optional.</p> |

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| | | research is an optional field. We respectfully request it be modified accordingly. | |
| Research | 48. | Row 61 requires manufacturers to indicate the reasons a record is eligible for delayed publication. We believe the selections are not consistent with the regulations and may be confusing to manufacturers which will result in inconsistent usage across manufacturers. Instead, we recommend use of these selections: “None” which would be used if the record is not eligible for delay, ‘Clinical’ if it is a clinical transaction eligible for delay under the requirements set forth in the regulation, and ‘Pre-Clinical’. | This data element was edited to reflect reasons for a delay in publication to align with the final rule, (1) research on or development of a new drug, device, biological, or medical supply, (2) clinical investigations regarding a new drug, device, biological, or medical supply. Additionally (3) not requesting a delay in publication allows applicable manufacturers to indicate they are not requesting a delay. |
| Research | 49. | We request clarification regarding the use of row 62 in the report template. It is our understanding that records not eligible for delay will have “None” in Row 61. The template states row 62 should have a value of “Yes” if the record is no longer eligible for delayed publication and “No” if it is still eligible for delayed publication. We believe that row 62 is duplicative of row 61 because if row 61 has a value of “None”, that is the same as row 62 having a value of “Yes” and if row 61 has a value other than “None”, that is the same as row 62 having a value of “Yes” and if row 61 has a value other than “None”, it is the same as a value of “No” in row 62. If CMS intends for row 61 to have a value of “None” only if the record is not eligible for delayed publication the first year it is reported, we request CMS to provide clarification regarding | Line 62, Lift Delay in Publication Indicator, is deleted. Line 61, Delay in Publication Reason, is edited to accurately capture when an applicable manufacturer is requesting a delay in publication. |

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| | | <p>the uses of row 61 and 62, how manufacturers should populate them, and when, if ever, the value should change for a specific record.</p> | |
| | <p>Research</p> | <p>50. The regulations state that “an applicable manufacturer must notify CMS during subsequent annual submission, if the new drug, device, biological or medical supply, to which the payment is related (or the new application of the existing drug, device, biological, or medical supply), is approved by the FDA”. The template indicates in Row 62, however, that the Lift Delay in Publication Indicator can a) be reported by the manufacturers, b) be changed to Yes as result of the release of a drug by the FDA, or c) be changed to Yes as a result of the expiration of 4 year maximum time allotment. This implies that CMS may modify the Lift Delay in Publications Indicator based on the release of a drug by the FDA. We believe that this conflicts with the regulations which state it is the manufacturer’s responsibility to notify CMS when FDA approval occurs and a record previously state that only if “after 4 years from the date of a payment first appearing in a report to CMS, there is an indication in a report that the payment is subject to delayed reporting, it is reported regardless of the indication”. Accordingly, we respectfully request that CMS can modify the Lift Delay in publication indicator in situations where the payment has reached the four (4) year maximum time allotment.</p> | <p>The data element “Lift in Delay in Public Indicator” is deleted.</p> |

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| AstraZenca | Non-research | 51. Row 17 and throughout (ZIP Code): we recommend the optional use of a 9-digit ZIP Code number ("ZIP+4"), per standard practice in most address databases. | The recipient zip code data element has been edited to allow for a 9-digit zip code number. Including the additional 4 digits for the zip code is not required. |
| [REDACTED] | Research | 52. Rows 52-56 (payment date and multiyear payment information): we strongly suggest that rows 52-56 be converted from required to optional. This will align the template with the regulations and allow manufacturers to aggregate and report research payments annually by study and study site. When reported in this manner, information concerning the date of the first of multiple payments or transfers of value to a study site in a given year has limited to no value and is likely to mislead a reader into believing that the aggregate payment was made to the site on that date. Hence §403.904(f) does not include "date of payment" as a required field for research payments. Similarly, the detail about multiyear research payments in proposed rows 53-56 would be difficult to include in aggregate reporting since not all payments and transfers of value to a site would necessarily be included as part of a multiyear payment arrangement. Finally, any requirement that obligates manufacturers to include information relating to anticipated, as opposed to actual, payments and transfers of value presents implementation challenges and risks overstating or understating project costs and timelines. For these reasons, rows 52-56 should be marked optional. | Line 52, Date of Payment, is an optional data element. Lines 53-56 are deleted. |

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| | Research | 53. Row 59 (context of research): as is the case with the other "context" fields in the proposed templates, this should be optional as opposed to required. In most cases, the context of the research should be apparent from the study name. | The requirement for the context of research data element is edited to reflect optional. |
| | General | 54. We understand that PhRMA is submitting comments that include recommendations on revising data element sizes for many of the rows in the two proposed reports. We endorse PhRMA's recommendations. In addition, for Row 58 (name of study), we do not believe that the 100 character limit for this field is adequate for many study names (e.g., "A Randomised, Double-blind, Parallel-group, Multicentre, Phase III Study to Compare the Efficacy and Tolerability of Fulvestrant (FASLODEX) 500 mg With Anastrozole (ARIMIDEX) 1 mg as Hormonal Treatment for Postmenopausal Women With Hormone Receptor-Positive Locally Advanced or Metastatic Breast Cancer Who Have Not Previously Been Treated With Any Hormonal Therapy"). We recommend expanding the limit to 500 characters. | The data element Name of Study in the research Submission file specification is edited to allow the name of a study to be accurately reported. |
| AMA | General | 55. Limiting Mandatory Data Submissions. The AMA urges the agency to limit mandatory reporting to only that data required for accurate Sunshine Act reporting, while limiting the personally identifiable physician information beyond that which is required by statute and the final regulation. While we urge the agency to increase information that physicians and industry may voluntarily submit, we continue | Reporting a physician's email address allows CMS to alert physician's that an applicable manufacturer or applicable GPO reported data about the physician if that physician has not registered with the OPEN PAYMENTS system. If a physician has already registered with the OPEN PAYMENTS system then email address provided during registration will be used. |

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| | | <p>to have concerns that the public disclosures of information under the Freedom of Information Act would heighten the possibility of widespread physician identity theft. For example, allowing industry to submit physician e-mail addresses may create some confusion and undermine operation aspects of the Sunshine Act notification process as physicians may elect to have a third party, such as practice manager, oversee and manage information as it related to Sunshine Act disclosures. Since physicians will have the option to register for the Sunshine Act physician portal, the e-mails that the industry utilizes may be different than the e-mail specified by the physician for purposes of the Sunshine correspondence. For example, a third party, such as a practice manager, may handle Sunshine Act reporting for physicians and use an alternative email.</p> | |
| | <p>General</p> | <p>56. Expanding Voluntary Data Submission and Voluntary Context. The AMA urges CMS to include the option to add any contextual information to all of the templates and not limit it to the Non-Research Payment Template. Specifically, it has been proposed on the Non-Research Payment Template that industry may provide “[a]ny free text which the reporting entity deems helpful or appropriate regarding this payment or transfer of value.” When the agency issues the final templates, we strongly urge the agency to include this as an option for all three templates. Furthermore, we continue to urge CMS to exercise agency discretion to</p> | <p>The data element Context of Research in the research submission filed specifications provides an option for an applicable manufacturer to report a description of research context or research objectives. CMS will provide a proposed collection of information regarding registration.</p> |

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| | | <p>allow physicians to provide voluntarily context as Congress intended so that transparency reporting would be accurate, fair, and balanced. We will outline our support of the foregoing in our response to a Proposed Collection of physician information collected as part of the physician Sunshine Act secure portal registration (that has not yet been issued, but we expect would be forthcoming). Furthermore, the final regulations did not prohibit the inclusion of such information submitted voluntarily by physicians.</p> | |
| | <p>General</p> | <p>57. Allowing Physician to Designate A Third Party to Access Secure Database. We urge CMS to include functionality that allows physicians to designate and authorize a third party, such as a practice manager, to assist them with handling Sunshine Act registration, review, and challenging reports, and other administrative Sunshine functions. Other stakeholders have noted that CMS has prior experience with developing such an option (e.g., quality reporting, Medicare enrollment). The Sunshine Act has the potential to create significant administrative burdens for physicians, including the initial registration and any subsequent disputes that physicians may have with industry reporting. As a result, we strongly urge CMS to issue an Agency Information Collection Activities: Proposed Collection that outlines the information that physicians will submit to the registration portal as well as authorizing third parties.</p> | <p>CMS will provide a proposed collection of information regarding registration.</p> |

