

Document in CMS-10717 (version 09/2020)	Original Language	Clarification or Change	Revised Language
Supporting Statement A Section 8 Federal Register	<p>The 60-day notice published in the Federal Register on December 6, 2019 (84 FR 66912). CMS received 42 public submissions, which included 662 comments. We then combined the 662 comments into 329 unique comments and provided responses in the comment and response summary that is included in this collection request. We adopted many of the commenters’ suggestions and believe that those corresponding edits simplify and clarify the collection instruments. First, we removed the rejected claims transition record layout for the previous contract year from the FA Data Request, as well as the Part B Drugs record layout from the ODAG Data Request to further streamline our review and data collection. Then, we identified additional opportunities to clarify and standardize field definitions and locations within the FA, CDAG, and ODAG record layouts. Next, we redefined field descriptions within the SNPE record layout, as found in the SNPCC Data Request, to align our data collection and evaluation with the 2020 Part C Reporting Requirements. Finally, we renamed the CPE Program Audit Protocol and Data Request document for consistency and clarification of the audit scope, and spelled out frequently used acronyms to reduce confusion within the CPE questionnaires. Please refer to the Crosswalk of Changes for a complete summary of updates made to this collection request since the December 6, 2019 publication. The 30-day notice published in the Federal Register on [TBD] (85 FR INSERT).</p>	Updated to reflect changes resulting from public comment	<p>The 30-day notice published in the Federal Register on June 4, 2020 (85 FR 34450). CMS received 29 public submissions which included 192 comments. We then combined the 192 comments into 121 unique comments and provided responses in the comment and response summary that is included in this collection request. We adopted many of the commenters’ suggestions including adding the Attendance Log to the collection request and providing minor technical clarifications to the record layout field descriptions. We also further defined the Method of Evaluation for universe integrity testing and made minor formatting clarifications throughout. We believe that these edits simplify and clarify the collection instruments. Please refer to the Crosswalk of Changes for a complete summary of updates made to this collection request since the June 4, 2020 publication.</p>

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Supporting Statement A Section 12 Burden Estimates (Hours & Wages) Wage Estimates	We recognize that Sponsoring organizations will need to update systems to accommodate this collection request. Therefore, CMS has applied a one-time labor-related transition burden associated with reprogramming data extracts, developing new processes for quality assurance testing, general business owner testing, compliance review, etc. This burden is estimated at 340 hours per Sponsoring organization. To implement the changes, we estimate that each Sponsoring organization would require 50 hours of Program Director resources (\$118/hr x 50 = \$5,900); 40 hours of Compliance Officer resources (\$70/hr x 40 = \$2,800); 100 hours of Management Analyst resources (\$92/hr x 100 = \$9,200); 50 hours of Quality Assurance Specialist resources (\$77/hr x 50 = \$3,850); and 100 hours of Computer & Information Systems' Managers' resources (\$150/hr x 100 = \$15,000). In summary, the estimated average labor cost per organization is \$108/hour x 340 hours = \$36,720 x 190 Sponsoring organizations for an overall, one-time transition burden of \$6,976,800. Although we understand that First-Tier Downstream and Related Entities (FDRs) connected to the Sponsoring organizations would also incur a transition burden we have no way of estimating the number of impacted FDRs and welcome comment on that burden.	Deleted – comment period has closed	We recognize that Sponsoring organizations will need to update systems to accommodate this collection request. Therefore, CMS has applied a one-time labor-related transition burden associated with reprogramming data extracts, developing new processes for quality assurance testing, general business owner testing, compliance review, etc. This burden is estimated at 340 hours per Sponsoring organization. To implement the changes, we estimate that each Sponsoring organization would require 50 hours of Program Director resources (\$118/hr x 50 = \$5,900); 40 hours of Compliance Officer resources (\$70/hr x 40 = \$2,800); 100 hours of Management Analyst resources (\$92/hr x 100 = \$9,200); 50 hours of Quality Assurance Specialist resources (\$77/hr x 50 = \$3,850); and 100 hours of Computer & Information Systems' Managers' resources (\$150/hr x 100 = \$15,000). In summary, the estimated average labor cost per organization is \$108/hour x 340 hours = \$36,720 x 190 Sponsoring organizations for an overall, one-time transition burden of \$6,976,800.
Supporting Statement A Section 15 Changes to Burden	As indicated in Section 8 above, we adopted many of the technical changes that were suggested in public comment in the interest of simplifying and clarifying the collection instruments. First, we removed the rejected claims transition record layout for the previous contract year from the FA Data Request, as well as the Part B Drugs record layout from the ODAG Data Request to further streamline our review and data collection. Then, we identified additional opportunities to clarify and standardize field definitions and locations within the FA, CDAG, and ODAG record layouts. Next, we redefined field descriptions within the SNPE record layout, as found in the SNPCC Data Request, to align our data collection and evaluation with the 2020 Part C Reporting Requirements. Finally, we renamed the CPE Program Audit Protocol and Data Request document for consistency and clarification of the audit scope, and spelled out frequently used acronyms to reduce confusion within the CPE questionnaires. These changes resulted in no change to burden.	Updated to reflect changes resulting from public comment	As indicated in Section 8 above, we adopted many of the commenters' suggestions including adding the Attendance Log to the collection request and providing minor technical clarifications to the protocols' field descriptions. We also further defined the Method of Evaluation for universe integrity testing and made minor formatting clarifications throughout. We believe that these edits simplify and clarify the collection instruments. Please refer to the Crosswalk of Changes for a complete summary of updates made to this collection request since the June 4, 2020 publication. These changes resulted in no change to burden.
Attendance Log Template	NA	Addition	Attendance Log Template

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CPE Protocol Purpose	CMS may review factors not specifically addressed below if it is determined that there are other related CPE requirements not being met.	Technical Clarification – Removed Language	NA
CPE Protocol Compliance Standard Integrity Testing	Compare the data in Universe Table 1 to the information in the supplemental documentation via desk review. Determine any variance in oversight activities.	Technical Clarification	Review all supplemental documentation submitted with Universe Table 1. The integrity of the universe and supplemental documents will be questioned if the submissions are incomplete, were not prepared in accordance with Program Audit Data Request instructions, or a variance is discovered in oversight activities.
CPE Protocol Audit Element	[Compliance Standards 1.1-4.4] Prevention Controls and Activities Detection Controls and Activities All Audit Elements	Technical Clarification	[Compliance Standards 1.1-1.7] Prevention, Detection, or Correction
CPE Protocol Audit Element	4.1 1.2 4.2 2.1 4.3 4.4	Technical Clarification – Renumbered Compliance Standards	1.2 1.3 1.4 1.5 1.6 1.7
CPE Protocol Corrective Action Required Table 1 Column ID K	[Field Description] Enter “Yes” Enter “No” Enter “TBD”	Technical Clarification	[Field Description] Enter: Y (for Yes) N (for No) TBD
CPE Protocol Activity Results Shared? Table 1 Column ID L	[Field Description] ‘No’ ‘Yes’		[Field Description] N (for No) Y (for Yes)
FA Protocol Compliance Standard Universe Integrity Testing	NA	Technical Clarification – Added Language	Review all cases selected for universe integrity testing. The integrity of the universe will be questioned if data points specific to the sample case(s) are incomplete, do not match, or cannot be verified by viewing the Sponsoring organization’s systems and/or other supporting documentation.
FA Protocol Table 3: PDE Table Instructions	Include all final action PDEs accepted by CMS with dates of service in September –December of the contract year immediately prior to the audit year. Include PDEs only for the period requested for enrollees from the rejected claims transition universe Table 2 (including enrollees enrolled in employer plans and Medicare-Medicaid Plans (MMPs)).	Technical Clarification	Submit all final action PDEs accepted by CMS with dates of service September – December of the contract year immediately prior to the audit year, for enrollees in Table 2 and enrollees with effective enrollment dates of November and December of the contract year immediately prior to the audit year. Include enrollees in employer plans and Medicare- Medicaid Plans (MMPs).

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FA Protocol NDC Related Drug NDC Tables 1-3 & 2IA Column ID J or Column ID H or Column ID U	[Field Description] For multi-ingredient compound claims populate the field with the NDC as submitted on the associated PDE.	Technical Clarification	[Field Description] For multi-ingredient compound claims populate the field with the NDC as would be submitted on a paid claim's PDE.
FA Protocol Table 2IA Table Instructions	Inaccurate records (i.e. authorization, enrollment records) that may not be associated with a rejected claim. In this scenario, Sponsoring organizations should only complete the following fields: Enrollee ID, Contract ID, Plan Benefit Package (PBP), Enrollment Effective Date, Is enrollee currently enrolled, and Drug Name and Strength (if applicable).	Technical Clarification	Inaccurate records (i.e. authorization, enrollment records) that may not be associated with a rejected claim. In this scenario, Sponsoring organizations should only complete the following fields: Enrollee ID, Contract ID, Plan Benefit Package (PBP), Enrollment Effective Date, and Drug Name and Strength (if applicable).
FA Protocol Is enrollee currently enrolled? Table 2IA Column ID E	[Field Name] Is enrollee currently enrolled? [Field Type] CHAR Always Required [Field Length] 3 [Field Description] Was the enrollee enrolled at the time of submission of the claim? Enter: <ul style="list-style-type: none"> • Y for Yes • N for No 	Technical Clarification – Removed Field & Relettered Remaining Column IDs	NA
CDAG Protocol Compliance Standard Universe Integrity Testing	NA	Technical Clarification – Added Language	Review all cases selected for universe integrity testing. The integrity of the universe will be questioned if data points specific to the sample case(s) are incomplete, do not match, or cannot be verified by viewing the Sponsoring organization's systems and/or other supporting documentation.
CDAG Protocol Compliance Standard 4.1	For each case sampled, review case file documentation for proper initial written notice to the enrollee for at-risk determinations. Also review case file documentation to ensure Sponsoring organization made reasonable efforts to provide the beneficiary's prescriber(s) of frequently abused drugs with a copy of the notice.	Technical Clarification	For each case sampled, review case file documentation for proper initial written notice to the enrollee for at-risk determinations. Also review case file documentation to ensure Sponsoring organization made reasonable efforts to provide the enrollee's prescriber(s) of frequently abused drugs with a copy of the notice.
CDAG Protocol Compliance Standard 4.2	For each case sampled, review case file documentation to determine whether the enrollee submitted preferences for prescribers or pharmacies and review for proper second written notice to the enrollee for at-risk determinations. Also review case file documentation to ensure Sponsoring organization made reasonable efforts to provide the beneficiary's prescriber(s) of frequently abused drugs with a copy of the notice.	Technical Clarification	For each case sampled, wherein the Sponsoring organization determined the enrollee is an at-risk beneficiary, review case file documentation to determine whether the enrollee submitted preferences for prescribers or pharmacies and review for proper second written notice to the enrollee. Also review case file documentation to ensure Sponsoring organization made reasonable efforts to provide the enrollee's prescriber(s) of frequently abused drugs with a copy of the notice.

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CDAG Protocol Compliance Standard 4.3	For each case sampled, review case file documentation for proper alternate second written notice to the enrollee for at-risk determinations. Also review case file documentation to ensure Sponsoring organization made reasonable efforts to provide the beneficiary's prescriber(s) of frequently abused drugs with a copy of the notice.	Technical Clarification	For each case sampled, wherein the Sponsoring organization determined the enrollee is not an at-risk beneficiary, review case file documentation for proper alternate second written notice to the enrollee. Also review case file documentation to ensure Sponsoring organization made reasonable efforts to provide the enrollee's prescriber(s) of frequently abused drugs with a copy of the notice.
CDAG Protocol Universe Submissions	NA	Technical Clarification – Added Language	Sponsoring organizations may however enter the time within universes instead of ‘None’ if the time is not required per the field description.
CDAG Protocol Table 1: CD Table Instructions	Include all coverage determinations (including requests for Part B drugs) the Sponsoring organization approved, denied, re-opened approved, re-opened denied, auto-forwarded to the IRE or dismissed during the universe request period.	Technical Clarification	Include all coverage determinations the Sponsoring organization approved, denied, re-opened approved, re-opened denied, auto-forwarded to the IRE or dismissed for Part D coverage during the universe request period.
CDAG Protocol Table 2: CDER Table Instructions	Include all coverage determination exception requests (including requests for Part B drugs) the Sponsoring organization approved, denied, re-opened approved, re-opened denied, auto-forwarded to the IRE or dismissed during the universe request period.	Technical Clarification	Include all coverage determination exception requests the Sponsoring organization approved, denied, re-opened approved, re-opened denied, auto-forwarded to the IRE or dismissed for Part D coverage during the universe request period.
CDAG Protocol Table 2: CDER Table Instructions	NA	Technical Clarification – Added Language	Requests for a single drug involving multiple UM criteria and exception types must be entered as a single line item in Universe Table 2 only. If a request has multiple exception types and includes a tiering exception, enter the case as a tiering exception.
CDAG Protocol Table 3: PYMT_D Table Instructions	Include all payment coverage determinations and redeterminations (including requests for Part B drugs) the Sponsoring organization approved, denied, re-opened approved, re-opened denied, auto-forwarded to the IRE or dismissed during the universe request period.	Technical Clarification	Include all payment coverage determinations and redeterminations the Sponsoring organization approved, denied, re-opened approved, re-opened denied, auto-forwarded to the IRE or dismissed for Part D coverage during the universe request period.
CDAG Protocol Table 4: RD Table Instructions	Include all redeterminations (including requests for Part B drugs) the Sponsoring organization approved, denied, re-opened approved, re-opened denied, auto-forwarded to the IRE or dismissed during the universe request period. The date of the Sponsoring organization’s determination (Column ID W) must fall within the universe request period.	Technical Clarification	Include all redeterminations the Sponsoring organization approved, denied, re-opened approved, re-opened denied, auto-forwarded to the IRE or dismissed for Part D coverage during the universe request period. The date of the Sponsoring organization’s determination (Column ID X) must fall within the universe request period.
CDAG Protocol Table 4: RD Table Instructions	NA	Technical Clarification – Added Language	Requests for a single drug involving multiple UM criteria and exception types must be entered as a single line item. If a request has multiple exception types and includes a tiering exception, enter the case as a tiering exception.

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CDAG Protocol Table 6: GRV_D Table Instructions	NA	Technical Clarification – Added Language	Grievances with multiple issues must be entered as a single line item, unless the Sponsoring organization issued separate notifications.
CDAG Protocol Table 7: AR Table Instructions	NA	Technical Clarification – Added Language	(i.e. Sponsoring organization determinations that an enrollee is at-risk for prescription drug abuse and Sponsoring organization determinations that an enrollee is not at-risk for prescription drug abuse under 42 CFR § 423.153(f)). Each at-risk determination must be listed as its own line item in the submitted universe.
CDAG Protocol NDC Tables 1-5 Column ID G	[Field Description] For multi-ingredient compound claims populate the field with the NDC as submitted on the associated PDE.	Technical Clarification	[Field Description] For multi-ingredient compound claims populate the field with the NDC as would be submitted on a paid claim's PDE.
CDAG Protocol AOR/Equivalent notice Receipt Date Tables 1-4 Column ID L or Column ID K	[Field Description] Enter None for dismissed cases or if no AOR or equivalent written notice was received or required.	Technical Clarification	[Field Description] Enter None if no AOR or equivalent written notice was received or required.
CDAG Protocol AOR/Equivalent notice Receipt Time Tables 1, 2 & 4 Column ID M	[Field Description Tables 1&2] Enter None for dismissed cases or if no AOR or equivalent written notice was received or required. [Field Description Table 4] Enter None for standard cases, dismissed cases or if no AOR or equivalent written notice was received or required.	Technical Clarification	[Field Description Tables 1&2] Enter None if no AOR or equivalent written notice was received or required. [Field Description Table 4] Enter None for standard cases or if no AOR or equivalent written notice was received or required.
CDAG Protocol Formulary UM Type Table 1 Column ID T	NA	Technical Clarification – Added Language & Updated Field Length to 4	[Field Description] <ul style="list-style-type: none"> SE for Safety Edit Enter None if the enrollee did not satisfy or was not attempting to satisfy Prior Authorization and/or Step Therapy criteria.
CDAG Protocol Who made the request? Tables 1-4 Column ID AC or Column ID AG or Column ID X	[Field Description] <ul style="list-style-type: none"> ER for enrollee's representative 	Technical Clarification	[Field Description] <ul style="list-style-type: none"> ER for enrollee's representative or purported representative

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CDAG Protocol Exception Type Tables 2, 3 & 4 Column ID T or Column ID P or Column ID U	NA	Technical Clarification – Added Language	[Field Description] If multiple exception types apply, enter the exception type applicable based on the approval or denial reason.
CDAG Protocol UM Exception Type Tables 2, 3 & 4 Column ID U or Column ID Q or Column ID V	<p>[Field Name] Formulary UM Exception Type</p> <p>[Field Description] If the case was a formulary UM exception, indicate what criteria the enrollee was attempting to waive. Enter:</p> <ul style="list-style-type: none"> • PA for Prior Authorization • ST for Step Therapy • QL for Quantity Limit <p>If the case was a safety edit exception enter:</p> <ul style="list-style-type: none"> • SE for Safety Edit <p>Enter None if the request was not a formulary UM exception or safety edit exception.</p> <p>If multiple formulary UM exception criteria apply, enter the criteria applicable based on the approval or denial reason.</p>	Technical Clarification	<p>[Field Name] UM Exception Type</p> <p>[Field Description] If the case was a UM exception, indicate what criteria the enrollee was attempting to waive. Enter:</p> <ul style="list-style-type: none"> • PA for Prior Authorization • ST for Step Therapy • QL for Quantity Limit <p>If the case was a safety edit exception enter:</p> <ul style="list-style-type: none"> • SE for Safety Edit <p>Enter None if the request was not a UM exception or safety edit exception.</p> <p>If multiple UM exception criteria apply, enter the criteria applicable based on the approval or denial reason.</p>
CDAG Protocol Is this a protected class drug? Table 4 Column ID H	NA	Technical Clarification – Added Language & Updated Field Length to 4	<p>[Field Description]</p> <ul style="list-style-type: none"> • None if not applicable
CDAG Protocol Is this an appeal of an at-risk determination? Table 4 Column ID N	NA	Technical Clarification – Added Field & Relettered remaining Column IDs	<p>[Field Name] Is this an appeal of an at-risk determination?</p> <p>[Field Type] CHAR Always Required</p> <p>[Field Length] 1</p> <p>[Field Description] Enter whether it was an appeal of an at-risk determination (e.g. request for a change in pharmacy and/or prescriber limitations, request for a change in the enrollee's at-risk determination status):</p> <ul style="list-style-type: none"> • Y for Yes • N for No

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CDAG Protocol Drug Name, Strength, and Dosage Form Table 5 Column ID F	NA	Technical Clarification – Added Language	[Field Description] Enter None if not applicable.
CDAG Protocol Date reimbursement provided Table 5 Column ID O	NA	Technical Clarification – Added Language	[Field Description] Enter None if it was not a post-service (payment) request.
CDAG Protocol Who made the request? Table 6 Column ID T	NA	Technical Clarification – Added Field	<p>[Field Name] Who made the request? [Field Type] CHAR Always Required [Field Length] 2 [Field Description] Enter who made the request:</p> <ul style="list-style-type: none"> • E for enrollee • ER for enrollee’s representative or purported representative
CDAG Protocol Drug Name, Strength, and Dosage Form Table 7 Column ID F	<p>[Field Description] Enter the drug name, strength, and dosage form requested.</p> <p>Enter None if not related to a specific drug (e.g. pharmacy lock-in, prescriber lock-in) or if the at-risk determination is drug related, but is not specific to a single drug (e.g. beneficiary level edit blocking all opioid access, beneficiary level edit allowing a defined cumulative MME dosage).</p>	Technical Clarification	<p>[Field Description] Enter the drug name, strength, and dosage form applicable to the specific limitation the Sponsoring organization intends to place on the beneficiary's access to coverage for frequently abused drugs under the program.</p> <p>Enter Multiple if the intended limitation applies to more than one drug (e.g. beneficiary level edit blocking all opioid access, beneficiary level edit allowing a defined cumulative MME dosage).</p> <p>Enter None if the intended limitation is not related to a specific drug (e.g. pharmacy lock-in, prescriber lock-in).</p>
CDAG Protocol Date the At-Risk Determination was made Table 7 Column ID I	[Field Description] Enter the date the at-risk determination was made. Submit in CCYY/MM/DD format (e.g., 2020/01/01).	Technical Clarification – Added Language	[Field Description] Enter the date the at-risk or not at-risk determination was made. Submit in CCYY/MM/DD format (e.g., 2020/01/01).
ODAG Protocol	Column IDs followed format of A-Z followed by AA, BB, CC, etc.	Technical Clarification	Format of Column IDs updated to A-Z followed by AA, AB, AC, etc.

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ODAG Protocol Compliance Standard Universe Integrity Testing	NA	Technical Clarification – Added Language	Review all cases selected for universe integrity testing. The integrity of the universe will be questioned if data points specific to the sample case(s) are incomplete, do not match, or cannot be verified by viewing the Sponsoring organization’s systems and/or other supporting documentation.
ODAG Protocol Compliance Standard 1.20	Conduct timeliness test at the universe level on adverse integrated organization determinations to determine whether the DSNP-AIP notified the enrollee of the decision to terminate, suspend, or reduce services no later than 10 days prior to the action (that is, before the date on which a termination, suspension, or reduction of previously approved services becomes effective).	Technical Clarification	Conduct timeliness test at the universe level on adverse integrated organization determinations to determine whether the DSNP-AIP notified the enrollee of the decision to terminate, suspend, or reduce services no later than 10 calendar days prior to the action (that is, before the date on which a termination, suspension, or reduction of previously approved services becomes effective).
ODAG Protocol Universe Submissions	NA	Technical Clarification – Added Language	Sponsoring organizations may however enter the time within universes instead of ‘None’ if the time is not required per the field description.
ODAG Protocol Table 3: PYMT_C Table Instructions	Submit payment organization determinations (claims) based on the date the claim was paid (Column O) or notification of the denial to the provider (if provider submitted the claim - Column Q) or enrollee (if the enrollee submitted the claim – Column P). Submit payment reconsiderations based on the date the overturned reconsideration was paid or, for upheld reconsiderations, submit based on the date the case was forwarded to the IRE. Submit dismissed requests based on the date of the decision to dismiss (Column M).	Technical Clarification	Submit payment organization determinations (claims) based on the date the claim was paid (Column O) or notification of the denial to the provider (if provider submitted the claim - Column Q) or enrollee (if the enrollee submitted the claim – Column P). Submit payment reconsiderations based on the date the overturned reconsideration was paid or, for upheld reconsiderations, submit based on the date the case was forwarded to the IRE. Submit dismissed requests based on the date of the decision to dismiss (Column N).
ODAG Protocol Table 5: GRV_C Table Instructions	NA	Technical Clarification – Added Language	<p>Grievances with multiple issues must be entered as a single line item, unless the Sponsoring organization issued separate notifications.</p> <p>Sponsoring organizations determined to be an applicable integrated plan as defined by 42 CFR § 422.561 should populate the universe with grievances related to Medicare coverage only.</p>

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ODAG Protocol Table 6: AIP Table Instructions	<ul style="list-style-type: none"> •Include all integrated organization determination cases where a previously approved service is being reduced, suspended, or terminated by the DSNP-AIP. The date of the DSNP-AIP Integrated Denial Notification (Column ID G) must fall within the universe request period. •Populate this Table with requests involving Medicare-coverable benefits only. •Exclude all pre-service cases. 		<ul style="list-style-type: none"> •The AIP record layout must be submitted by all Sponsoring organizations determined to be an applicable integrated plan as defined by 42 CFR § 422.561 and have been notified by CMS of their status. • Include all integrated organization determination cases where a previously approved service is being reduced, suspended, or terminated by the DSNP-AIP. The date the DSNP-AIP notified the enrollee must fall within the universe request period (Column ID H). •Populate this Table with requests involving Medicare-coverable benefits only. •Exclude all pre-service cases.
ODAG Protocol Time the request was received Table 1 Column ID I	<p>[Field Description Table 1] For all expedited requests and standard Part B drug requests, enter the time the request was received. Submit in HH:MM:SS military time format (e.g., 23:59:59). If a standard request was upgraded to expedited, enter the time the request was upgraded. Enter None for standard and dismissed requests.</p>	Technical Clarification	<p>[Field Description Table 1] For all expedited requests and standard Part B drug requests, enter the time the request was received. Submit in HH:MM:SS military time format (e.g., 23:59:59). If a standard request was upgraded to expedited, enter the time the request was upgraded. Enter None for standard and dismissed requests.</p>
ODAG Protocol Part B Drug Request? Table 1 & 2 Column ID J	<p>[Field Description] Enter:</p> <ul style="list-style-type: none"> • Y for Yes • N for No <p>Sponsors must indicate ‘Y’ for any pre-service request that includes a Part B drug (primary or ancillary) or Part D drug that is part of a Sponsor’s step therapy requirement for a Part B drug.</p>	Technical Clarification	<p>[Field Description] Enter:</p> <ul style="list-style-type: none"> • Y for Yes • N for No

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<p>ODAG Protocol AOR/Equivalent notice Receipt Time Tables 1 - 2 Column ID L or Table 5 Column ID J</p>	<p>[Field Description Table 1] For all expedited requests and standard Part B drug requests, enter the time the Appointment of Representative (AOR) form or equivalent written notice was received by the Sponsoring organization. Submit in HH:MM:SS format (e.g., 23:59:59). Enter None for standard requests or if no AOR or equivalent written notice was received or required.</p> <p>[Field Description Table 2] For all expedited requests, enter the time the Appointment of Representative (AOR) form or equivalent written notice was received by the Sponsoring organization. Submit in HH:MM:SS format (e.g., 23:59:59). Enter None for dismissed requests or if no AOR or equivalent written notice was received or required.</p> <p>[Field Description Table 5] For expedited grievances, enter the time the Appointment of Representative (AOR) form or equivalent written notice was received by the Sponsoring organization. Submit in HH:MM:SS format (e.g., 23:59:59). Enter None for standard grievances, dismissed grievances, or if an AOR or equivalent written notice was not received or required.</p>	<p>Technical Clarification</p>	<p>[Field Description Table 1] For all expedited requests and standard Part B drug requests, enter the time the Appointment of Representative (AOR) form or equivalent written notice was received by the Sponsoring organization. Submit in HH:MM:SS format (e.g., 23:59:59). Enter None for standard service requests or if no AOR or equivalent written notice was received or required.</p> <p>[Field Description Table 2] For all expedited requests, enter the time the Appointment of Representative (AOR) form or equivalent written notice was received by the Sponsoring organization. Submit in HH:MM:SS format (e.g., 23:59:59). Enter None for standard requests or if no AOR or equivalent written notice was received or required.</p> <p>[Field Description Table 5] For expedited grievances, enter the time the Appointment of Representative (AOR) form or equivalent written notice was received by the Sponsoring organization. Submit in HH:MM:SS format (e.g., 23:59:59). Enter None for standard grievances or if an AOR or equivalent written notice was not received or required.</p>
<p>ODAG Protocol Date of Determination Table 1 Column ID P</p>	<p>[Field Description] Enter the date of the determination. Submit in CCYY/MM/DD format (e.g., 2020/01/01). For dismissed requests, enter the date the Sponsor dismissed the request.</p>	<p>Technical Clarification</p>	<p>[Field Description] Enter the date of the determination. Submit in CCYY/MM/DD format (e.g., 2020/01/01). For dismissed requests, enter the date the Sponsoring Organization dismissed the request.</p>
<p>ODAG Protocol Time of Determination Table 1 Column ID Q</p>	<p>[Field Description] For all expedited requests and standard Part B drug requests, enter the time of the determination. Submit in HH:MM:SS military time format (e.g., 23:59:59). Enter None for standard and dismissed requests.</p>	<p>Technical Clarification</p>	<p>[Field Description] For all expedited requests and standard Part B drug requests, enter the time of the determination. Submit in HH:MM:SS military time format (e.g., 23:59:59). Enter None for standard service requests and dismissed requests.</p>

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ODAG Protocol Time oral notification provided to enrollee Tables 1 & 2 Column ID S	<p>[Field Description Table 1] For all expedited requests and standard Part B drug requests, enter the time oral notification was provided to enrollee. Submit in HH:MM:SS military time format (e.g., 23:59:59). Enter None for standard requests, dismissed requests, or if no oral notification was provided.</p> <p>[Field Description Table 2] For expedited requests, including expedited Part B drug requests, enter the time oral notification was provided to enrollee. Submit in HH:MM:SS military time format (e.g., 23:59:59). Enter None for dismissed requests or if no oral notification was provided.</p>	Technical Clarification	<p>[Field Description Table 1] For all expedited requests and standard Part B drug requests, enter the time oral notification was provided to enrollee. Submit in HH:MM:SS military time format (e.g., 23:59:59). Enter None for standard service requests, dismissed requests, or if no oral notification was provided.</p> <p>[Field Description Table 2] For all expedited requests, enter the time oral notification was provided to enrollee. Submit in HH:MM:SS military time format (e.g., 23:59:59). Enter None for standard requests, dismissed requests, or if no oral notification was provided.</p>
ODAG Protocol Time written notification provided to enrollee Table 1 Column ID U	<p>[Field Description] For all expedited requests and standard Part B drug requests, enter the time written notification of determination was provided to enrollee. Do not enter the time a letter was generated or printed. Submit in HH:MM:SS military time format (e.g., 23:59:59). Enter None for standard requests, dismissed requests, or if no written notification was provided.</p>	Technical Clarification	<p>[Field Description] For all expedited requests and standard Part B drug requests, enter the time written notification of determination was provided to enrollee. Do not enter the time a letter was generated or printed. Submit in HH:MM:SS military time format (e.g., 23:59:59). Enter None for standard service requests, dismissed requests, or if no written notification was provided.</p>

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<p>ODAG Protocol Who made the request? Tables 1 – 3, 6 Column ID V or Column ID Z or Column ID S or Column ID K</p>	<p>[Field Description Table 1] Enter who made the request:</p> <ul style="list-style-type: none"> • E for enrollee • ER for enrollee’s representative • CP for requests by a contract provider • NCP for requests by a non-contract provider <p>“Provider” includes physicians and facilities.</p> <p>[Field Description Table 2] Enter the person who made the request:</p> <ul style="list-style-type: none"> • E for enrollee • ER for enrollee’s representative • CP for requests by a contract provider/facility • NCP for requests by a non- contract provider/facility <p>[Field Description Table 3] Enter who made the request:</p> <ul style="list-style-type: none"> • E for enrollee • ER for enrollee’s representative • NCP for requests by a non- contract provider <p>NCP includes non-contract pharmacies.</p> <p>[Field Description Table 6] Enter who made the plan level appeal:</p> <ul style="list-style-type: none"> • E for enrollee • ER for enrollee’s representative • CP for requests by a contract provider • NCP for requests by a non-contract provider <p>“Provider” includes physicians and facilities. Enter None if the decision was not appealed as indicated by N in column ID J.</p>	<p>Technical Clarification</p>	<p>[Field Description Table 1] Enter who made the request:</p> <ul style="list-style-type: none"> • E for enrollee • ER for enrollee’s representative or purported representative • CP for requests by a contract provider/facility • NCP for requests by a non-contract provider/facility <p>[Field Description Table 2] Enter the person who made the request:</p> <ul style="list-style-type: none"> • E for enrollee • ER for enrollee’s representative or purported representative • CP for requests by a contract provider/facility • NCP for requests by a non- contract provider/facility <p>[Field Description Table 3] Enter who made the request:</p> <ul style="list-style-type: none"> • E for enrollee • ER for enrollee’s representative or purported representative • NCP for requests by a non- contract provider/pharmacy <p>[Field Description Table 6] Enter who made the plan level appeal:</p> <ul style="list-style-type: none"> • E for enrollee • ER for enrollee’s representative or purported representative • CP for requests by a contract provider/facility • NCP for requests by a non-contract provider/facility <p>Enter None if the decision was not appealed as indicated by N in column ID J.</p>

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ODAG Protocol Issue description and type of service Table 1 - 3 Column ID W or Column ID AA or Column ID T	<p>[Field Description Table 1 & 2] Provide a description of the service or item requested and why it was requested (if known). For denials, also provide an explanation of why the pre-service request was denied. For dismissed requests, provide the reason for dismissal. For Part B drugs requests, include the J- Code, National Drug Code (NDC), or both.</p> <p>[Field Description Table 3] Provide a description of the service or item requested and why it was requested (if known). For denials, also provide an explanation of why the payment organization determination or payment reconsideration request was denied. For dismissed requests, please provide the reason for dismissal. For Part B drugs requests, include the J-Code, National Drug Code (NDC), or both.</p>	Technical Clarification	<p>[Field Description Table 1 & 2] Provide a description of the service or item requested and why it was requested (if known). For denials, also provide an explanation of why the pre-service request was denied. For dismissed requests, provide the reason for dismissal.</p> <p>[Field Description Table 3] Provide a description of the service or item requested and why it was requested (if known). For denials, also provide an explanation of why the payment organization determination or payment reconsideration request was denied. For dismissed requests, please provide the reason for dismissal.</p>
ODAG Protocol AOR/Equivalent Notice Receipt Date Tables 2 Column ID K	<p>[Field Description] Enter the date the Appointment of Representative (AOR) form or equivalent written notice was received by the Sponsoring organization. Submit in CCYY/MM/DD format (e.g., 2020/01/01). Enter None for dismissed requests or if no AOR or equivalent written notice was received or required.</p>	Technical Clarification	<p>[Field Description] Enter the date the Appointment of Representative (AOR) form or equivalent written notice was received by the Sponsoring organization. Submit in CCYY/MM/DD format (e.g., 2020/01/01). Enter None if no AOR or equivalent written notice was received or required.</p>
ODAG Protocol Request Determination Table 2 Column ID M	<p>[Field Description] Enter:</p> <ul style="list-style-type: none"> • Approved • Denied 	Technical Clarification	<p>[Field Description] Enter:</p> <ul style="list-style-type: none"> • Approved • Denied • Dismissed
ODAG Protocol Date Forwarded to IRE Table 2 Column ID X	<p>Enter the date the request was forwarded to the IRE. Submit in CCYY/MM/DD format (e.g., 2020/01/01).</p> <p>Enter None if the beneficiary was notified of the approved reconsideration, or if the request was not forwarded to the IRE.</p>	Technical Clarification	<p>Enter the date the request was forwarded to the IRE. Submit in CCYY/MM/DD format (e.g., 2020/01/01).</p> <p>Enter None if the enrollee was notified of the approved reconsideration, or if the request was not forwarded to the IRE.</p>
ODAG Protocol Time Forwarded to IRE Table 2 Column ID Y	<p>[Field Description] For all expedited requests, enter the time the request was forwarded to the IRE. Submit in HH:MM:SS military time format (e.g., 23:59:59).</p> <p>Enter None if the beneficiary was notified of the approved reconsideration, or if the request was not forwarded to the IRE.</p>	Technical Clarification	<p>[Field Description] For all expedited requests, enter the time the request was forwarded to the IRE. Submit in HH:MM:SS military time format (e.g., 23:59:59).</p> <p>Enter None if the enrollee was notified of the approved reconsideration, if the request was not forwarded to the IRE, or for standard requests.</p>

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ODAG Protocol Was an expedited request made but processed as standard? Table 2 Column AB	[Field Description] Enter: <ul style="list-style-type: none"> Y for Yes if an expedited request was received but downgraded to standard None for all other cases (e.g. the request was received as expedited and processed as expedited, the request was received as standard.) For dismissed requests, populate based on how the request was received. 	Technical Clarification	[Field Description] Enter: <ul style="list-style-type: none"> Y for Yes if an expedited request was received but downgraded to standard None for all other cases (e.g. the request was received as expedited and processed as expedited, the request was received as standard, or the request was dismissed).
ODAG Protocol Date of Determination Table 3 Column N	[Field Description] For dismissed requests, enter the date the Sponsor dismissed the request.	Technical Clarification	[Field Description] For dismissed requests, enter the date the Sponsoring organization dismissed the request.
ODAG Protocol Part B Drug Request? Table 4 Column L	NA	Technical Clarification – Added Field & Relettered remaining Column IDs	[Field Name] Part B Drug Request? [Field Type] CHAR Always Required [Field Length] 1 [Field Description] Enter: <ul style="list-style-type: none"> Y for Yes N for No
ODAG Protocol Time overturned decision or payment effectuated in the system Table 4 Column N	[Column ID] M [Field Description] For expedited requests and Part B drug requests, enter the time the overturned decision was effectuated in the system. Submit in HH:MM:SS military time format (e.g., 23:59:59). Enter None for Standard (pre-service) and Payment reconsideration cases, or if the overturned decision was not effectuated.		[Column ID] N [Field Description] For expedited requests and Part B drug requests, enter the time the overturned decision was effectuated in the system. Submit in HH:MM:SS military time format (e.g., 23:59:59). Enter None for standard service requests and payment reconsideration cases, or if the overturned decision was not effectuated.
ODAG Protocol Who made the request? Table 5 Column U	NA	Technical Clarification – Added Field	[Field Name] Who made the request? [Field Type] CHAR Always Required [Field Length] 2 [Field Description] Enter who made the request: <ul style="list-style-type: none"> E for Enrollee ER for enrollee’s representative or purported representative

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ODAG Protocol Table 6: AIP Prior to table	NA	Technical Clarification	Please use the guidance below for the following record layout:
ODAG Protocol If an extension was taken, did the DSNP-AIP notify the enrollee of the reason(s) for the delay and of their right to file an expedited grievance? Table 6 Column Q	[Field Name] If an extension was taken, did the DSNP-AIP notify the enrollee of the reason(s) for the delay and of their right to file an expedited grievance? [Field Type] CHAR Always Required [Field Length] 4 [Field Description] Yes (Y)/No (N) indicator of whether the DSNP-AIP notified the enrollee of the delay. Enter None if no extension was taken or if the decision was not appealed as indicated by N in column ID J.	Technical Clarification – Removed Field & Relettered Remaining Column IDs	NA
ODAG Protocol If request denied, date services were terminated, reduced, suspended Table 6: AIP Column Z	[Column ID] Z [Field Description] Enter None if the decision was not appealed as indicated by N in Column ID J.	Technical Clarification	[Column ID] Y [Field Description] Enter None if the reconsideration was approved or if the decision was not appealed as indicated by N in Column ID J.
SNPCC Protocol Compliance Standard Universe Integrity Testing	NA	Technical Clarification – Added Language	Review all cases selected for universe integrity testing. The integrity of the universe will be questioned if data points specific to the sample case(s) are incomplete, do not match, or cannot be verified by viewing the Sponsoring organization’s systems and/or other supporting documentation.
SNPCC Protocol Compliance Standard 1.1	Conduct a timeliness test at the universe level of enrollees who have been continuously enrolled for at least 90 days, to determine whether the Sponsoring organization conducted a timely initial health risk assessments (IHRAs) within 90 days (before or after) the effective date of enrollment. Request an impact analysis for any enrollee identified as having an untimely IHRA to quantify the outreach made by the Sponsoring organization in an attempt to conduct the IHRA within 90 days of enrollment. Impact analysis review period is limited to the 12-month period prior to date of the engagement letter, to align with the timeliness test.	Technical Clarification	Conduct a timeliness test at the universe level of enrollees who have been continuously enrolled for at least 90 days, to determine whether the Sponsoring organization conducted initial health risk assessments (IHRAs) within 90 days (before or after) enrollees’ effective date of enrollment. IHRA Timeliness assessments will be conducted using current enrollments, from Table 1. Request an impact analysis for any enrollee identified as not having an IHRA conducted to quantify the outreach made by the Sponsoring organization in an attempt to conduct the IHRA within 90 days of enrollment. Impact analysis review period is limited to the 12-month period prior to date of the engagement letter, to align with the timeliness test.

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SNPCC Protocol Compliance Standard 1.4	<p>[Method of Evaluation] Consider whether the ICP includes the following, in accordance with the MOC:</p> <ul style="list-style-type: none"> The beneficiary’s self-management goals and objectives. The beneficiary’s personal healthcare preferences. A description of services specifically tailored to the beneficiary’s needs. <p>Identification of goals (met or not met).</p>	Technical Clarification	<p>[Method of Evaluation] Consider whether the ICP includes the following, in accordance with the MOC:</p> <ul style="list-style-type: none"> The enrollee’s self-management goals and objectives. The enrollee’s personal healthcare preferences. A description of services specifically tailored to the enrollee’s needs. <p>Identification of goals (met or not met).</p>
SNPCC Protocol Compliance Standard 1.9	NA	Technical Clarification – Added Language	[Method of Evaluation] (e.g., ICT meeting attendee lists or other documentation reflecting PCP interaction with ICT members).
SNPCC Protocol Was an Interdisciplinary Care Team (ICT) created/identified? Table 1 Column ID N	<p>[Field Length] 3</p> <p>[Field Description] Enter Yes Enter No</p>	Technical Clarification	<p>[Field Length] 1</p> <p>[Field Description] Enter Y (for Yes) Enter N (for No)</p>
SNPCC Supplemental Questionnaire	NA	Technical Clarification	We defined PBP as Plan Benefit Package, HRAs as Health Risk Assessments, ICPs as Individualized Care Plans, ICT as Interdisciplinary Care Team, and FDRs as First Tier, Downstream, and Related Entities.
SNPCC Supplemental Questionnaire Question 7	7. Describe the outreach policy pertaining to HRA administration and ICP development. Describe the process for beneficiaries that cannot or do not want to be contacted.	Technical Clarification	7. Describe the outreach policy pertaining to HRA administration and ICP development. Describe the process for enrollees that cannot or do not want to be contacted.