

Applications for Part C Medicare Advantage, 1876 Cost Plans, and Employer Group Waiver Plans to Provide Part C Benefits as defined in Part 417 & 422 of 42 C.F. R. CMS-10237, OMB 0938-0935

CMS Responses to 60-Day Comments on the Contract Year 2019 PART C - Medicare Advantage and 1876 Cost Plan Expansion Application

| # | Topic | Comment Text | CMS Response | CMS Action (Requirements/ Attachments/Burden Change) |
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| 1 | HSD | We would support the removal of HSD submissions from the 2019 applications if CMS is able to provide clear and concrete information regarding the timeline and process flow around what activities are due and when they are due. However, until there is more predictability around the CMS disposition of a network adequacy review and exception requests, we recommend CMS continue to include network adequacy as part of the application process. From a timing and resource perspective, conducting the network adequacy review as part of the application process works well. If the review is conducted later in the year, we have concerns with the availability of time and plan resources because CMS has released no details about how quickly a review would begin under a triggering event. | CMS appreciates the concern and would like to clarify that this is simply a procedural change, and an organization’s first review would occur after their application is approved, but prior to the start of the first year in which the plan is offered. This gives new plans and existing plans that are expanding their service area additional time to secure a compliant network prior to the start of the year. CMS will give careful thought to the compliance approach when an initial applicant is found to have network deficiencies or when an existing applicant applying for a service area expansion has deficiencies. CMS is currently discussing these details internally and will release guidance to the industry as soon as possible. | None. CMS has not revised any requirements, attachments, or burden estimates as a result of this comment. |
| 2 | CMS Supply File | We have observed discrepancies in the CMS Supply File, CMS online FFS provider search tools and Quest Analytics software, especially for counties with rural areas as those have resulted in unexpected disapprovals of exception requests. The CMS Supply File in HPMS needs to have information that is complete and consistent across all states. For example, in the MN file some zip codes are missing. We also strongly urge CMS to add the county code and/or county name to the file as well as release the file more frequently throughout the year (last updated 4/27/17). CMS must also be better at informing plans when a new Supply File is available in HPMS. | Per the Medicare Advantage Network Adequacy Criteria Guidance, “given the dynamic nature of the market, the database may not be a complete depiction of the provider and facility supply available in real-time. Additionally, the supply file is limited to CMS data sources – organizations may have additional data sources that identify providers/facilities not included in the supply file used as the basis of CMS’s network adequacy criteria. As a result, organizations should not rely solely on the supply file when establishing networks, as additional providers and facilities may be available. CMS uses the supply file when validating information submitted on Exception Requests. Therefore, CMS and its contractor may update the supply file periodically to reflect updated provider and facility information and to capture information associated with Exception Request submissions.” This updated supply file and additional organization-provided information is used in the acquisition of the Exception Requests. As CMS makes the procedural change of removing network reviews from the application process, it will look to improve policies and procedures surrounding the supply file in order to increase efficiency and data accuracy. | None. CMS has not revised any requirements, attachments, or burden estimates as a result of this comment. |

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| 3 | CMS Supply File | We seek to understand how CMS is defining hospitals in the supply file as having Critical Care Services - ICU services and where we can get the ICU bed counts. For example, Sanford Sheldon Medical Center hospital in Spencer, IA is a hospital listed with services for Cardiac Catheterization Services and Cardiac Surgery Program, but does not list the service for Critical Care Services - ICU. Meanwhile a small town hospital like, Boone County Hospital has Critical Care Services - ICU but that location only has the typical hospital services of Acute Care Hospital, Diagnostic Radiology, Mammography, Outpatient Infusion/Chemotherapy and Surgical Services. We do not understand why a hospital that has Cardiac Catheterization Services and a Cardiac Surgery Program is not listed with ICU services on the supply file? Additionally, the CMS POS data file does not have ICU bed count and we've seen that the identification of hospitals with ICU on that file are not matching up with the supply file either. If plans are required to provide bed counts for ICUs in the HSD facility tables, we strongly urge CMS to include a definition for ICU population on the supply file and provide a way for plans to access that information more readily, either from the CMS POS or the supply file. We have historically spent a lot of time on ICU and will continue to spend a lot of time if we have to get ICU bed counts for hospitals that don't have a separate ICU. | CMS recommends that the commenter submit their specific questions to the CMS mailbox, located at: https://dmao.lmi.org . | None. CMS has not revised any requirements, attachments, or burden estimates as a result of this comment. |
| 4 | HSD | CMS needs to issue the Exception Request form in Excel or Word format that will allow plans to merge data and information already written, organized and validated into the form. The current Exception Request PDF fillable form is not user friendly and quite cumbersome to use. In the free text sections, the font size is not readable as it shrinks when populated with more than 100 characters. The only way we can view the information entered in the fields is to copy/paste the text into a Word document. This is an unnecessary and burdensome step for plans to have to take when completing the exception form. | Thank you for your comment regarding CMS's exception request policy. Consistent with the Supporting Statement, CMS removed the Exception Request template from this information collection. CMS will consider this comment as it develops the details surrounding the information collection for CMS-10636, OMB 0938-New. | None. CMS has not revised any requirements, attachments, or burden estimates as a result of this comment. |

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| 5 | HSD | The annual hours and resources needed to complete an entire network submission for one contract (see Table 4 of the Supporting Statement - Part A, proposed Three-Year Network Adequacy) are grossly underestimated. Based on our recent experience, we estimate three times what CMS lists for each activity required. Multiple staff are required, gaps need to be researched, provider contracting may be needed, new reports run, staff analysis completed, etc. These activities account for many more hours than what is represented in the table. | CMS considered the feedback from organizations concerning the methodology for estimating the hour burden for submitting Health Service Delivery (HSD) tables and Exception Requests to CMS, but after further review of its internal process, CMS is confident in its estimation. There may be minimal burden associated with this change for those contracts that have never expanded beyond their original footprint or experienced an event that would trigger a full network review since they joined the program. In the case of an SAE, CMS would review only the new service area's network (i.e., the expansion counties), and the entire network review would occur at the contract's three-year anniversary. With regard to burden on the federal government, as CMS makes the procedural change to move the network review out of the application and into this three-year review, CMS has simply shifted the annualized cost to the federal government from the application PRA package to this new PRA package. Therefore, no new cost to CMS has been added. | None. CMS has not revised any requirements, attachments, or burden estimates as a result of this comment. |
| 6 | HSD | We are requesting CMS to clarify the process and timing for removing from the service area pending counties versus existing counties. Based on the April 11, 2017, CMS memo, the date to remove EXISTING counties from the service area was Monday, June 5, 2017. However, CMS staff informed us that the date to remove EXISTING counties was actually May 22, 2017 (the same time to remove pending counties from the service area). The guidance does not align with the information provided by CMS staff and caused much confusion due to lack of consistency. | CMS recommends that the commenter submit their specific questions to the CMS mailbox, located at: https://dmao.lmi.org . | None. CMS has not revised any requirements, attachments, or burden estimates as a result of this comment. |
| 7 | HSD | During the 2018 application process, directions from CMS and Quest Analytics about time standards enforcement were inconsistent. Both CMS' Medicare Adv and Cost Plan Network Adequacy Criteria (1.18.17) and CMS' HSD Reference File (1.10.2017) indicate time standards apply across all specialty/county combinations. However, CMS approved without explanation 2 specialty areas in a CEAC county where internal analyses showed non-passing time results. Quest Analytics executives have directed our plan to always run 'Distance Only' reports and stated that CMS only applies time standards to Large Metro counties. We want to allocate resources only where needed. We want to mirror CMS' use of Quest. During the 2019 application process, will CMS always apply all the time standards in CMS' HSD Reference File when testing HSD tables? | Thank you for your comment regarding CMS's exception request policy and network adequacy criteria. Consistent with the Supporting Statement, CMS removed the Health Services Delivery tables and Exception Request template from this information collection. CMS will consider this comment as it develops the details surrounding the information collection for CMS-10636, OMB 0938-New. CMS also recommends that the commenter submit their specific question related to the automated review of network adequacy in HPMS (via Quest) to the CMS mailbox, located at: https://dmao.lmi.org . | None. CMS has not revised any requirements, attachments, or burden estimates as a result of this comment. |

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| 8 | HSD | We strongly support the application changes proposed in CMS-10237. Network Adequacy is an operational area and, like other operational areas for MAOs (ODAG, CDAG, etc.), it should be reviewed in its proper operational context and time frame. The goal of tying a Plan's network to its proposed SAE expansion to assure a Plan can properly provide for its members on day one is a good one. But there are better ways to test this, especially since the application time frame and data used to support an application can be up to one year out of date as of day one of a Plan's go live into its new area. | CMS appreciates the positive feedback and support. CMS will strive for appropriate, equitable implementation of this information collection. | None. CMS has not revised any requirements, attachments, or burden estimates as a result of this comment. |
| 9 | HSD | We greatly appreciate CMS' efforts to streamline the service area expansion process by separating network adequacy reviews from the application process. We understand the need for CMS to conduct oversight monitoring to ensure that MA plans continue to maintain adequate networks. As such, we support the proposal to conduct three year network adequacy reviews and support the proposal to remove the Health Service Delivery (HSD) tables from the MA application. We believe that these changes will reduce burden on plans as well as CMS staff, while establishing a transparent, predictable process for comprehensive network reviews. | CMS appreciates the positive feedback and support. CMS will strive for appropriate, equitable implementation of this information collection. | None. CMS has not revised any requirements, attachments, or burden estimates as a result of this comment. |
| 10 | HSD | Exceptions: We respectfully request CMS reconsider the requirement that all network adequacy exceptions be re-reviewed annually. Exceptions are often the result of a lack of provider specialties in a given geographic area, which presents a challenge to Medicare broadly. Thus we recommend CMS retain previously approved exception requests in between the three year review cycle as long as there were no negative changes to the network from the approved contract year. | Thank you for your comment regarding CMS's exception request policy. Consistent with the Supporting Statement, CMS removed the Exception Request template from this information collection. CMS will consider this comment as it develops the details surrounding the information collection for CMS-10636, OMB 0938-New. | None. CMS has not revised any requirements, attachments, or burden estimates as a result of this comment. |
| 11 | HSD | Provider-Specific Plans (PSPs): CMS did not address how review of PSP networks will be handled. We recommend they be included as part of the three year review cycle. If CMS continues to review PSP networks annually, we strongly suggest that CMS limit their review to the affected service areas. | Thank you for your comment regarding the information collection for CMS-10636, OMB 0938-New. CMS will consider this comment as it develops the details related to the three year network review cycle. | None. CMS has not revised any requirements, attachments, or burden estimates as a result of this comment. |

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| 12 | Service Area | <p>We recommend CMS transition the Orthotics and Prosthetics specialty to monitoring through an attestation.</p> <p>Similar to Home Health and Durable Medical Equipment, care provided by the Orthotics and Prosthetics specialty is not bound to a facility or office location, as services are provided at a patient's home or local hospital or clinic. For this reason, time and distance requirements are not appropriate for this specialty.</p> <p>Other specialties for which the time and distance requirements are not appropriate are currently monitored through attestation.</p> <p>To operationalize this recommendation, we propose the addition of the following language to 3.8.6: "Applicant agrees that it will provide all medically necessary durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS), including access to providers qualified to fit these devices, to its Medicare enrollees in full agreement with Chapter 4 of the MMCM."</p> <p>The proposed modification will ensure that prosthetics and orthotics are included in the application process as an attestation, similar to the other monitored programs and services.</p> | <p>CMS agrees with this comment. Recent analysis of claims data and industry trends demonstrates that Medicare Advantage (MA) enrollees often receive Orthotics and Prosthetics services in the home or a hospital. Therefore, CMS does not believe time and distance criteria standards are unrealistic for this specialty type.</p> <p>While CMS removed the health service delivery tables from this application (see Supporting Statement), CMS does include several attestations under the Service Area section of the application. CMS agrees with the recommendation to include an attestation for orthotics and prosthetics coverage in the attestation, consistent with the attestations included for home health, transplant facilities, and durable medical equipment.</p> | <p>Requirements. CMS modified attestation 3.8.6 as follows: Applicant agrees that it will provide all medically necessary durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS), including access to providers qualified to fit these devices, to its Medicare enrollees in full agreement with Chapter 4 of the MMCM.</p> <p>Attachment and Burden. CMS has not revised any attachments or burden estimates as a result of this comment.</p> |
| 13 | SMAC | <p>The SMAC and FIDE submission dates are listed as July 5, 2018. Previously the SMAC and FIDE submissions were due the first Monday in July which would be July 2, 2018. Could CMS please clarify if this changed?</p> | <p>CMS agrees with this comment. SMAC and FIDE submissions are due on the first Monday in July, or on July 2, 2018. CMS modified the instructions under 5.4 of the application based on this comment.</p> | <p>Requirements. CMS modified section 5.4 of the application as follows: The SMAC documents will be due by July 2, 2018.</p> <p>Attachment and Burden. CMS has not revised any attachments or burden estimates as a result of this comment.</p> |
| 14 | I-SNP | <p>The intent of the language in Attestation No. 1 (Section 5.5 "I-SNP: Attestations and Uploads") is somewhat confusing and appears to conflict with other guidance regarding requirements of I-SNPs to be under contract with and operate LTC facilities. The attestation states: "Applicant will only enroll institutionalized individuals residing in a long-term care (LTC) facility under contract with and owned by the SNP, or if no ownership, a contract exists between the I-SNP and LTC." We propose that this attestation be modified as follows:</p> <p>"Applicant will only enroll institutionalized individuals residing in a long-term care (LTC) facility under contract with or owned and operated by the SNP."</p> | <p>CMS agrees with this comment. CMS modified 5.5 of the application for I-SNP Individuals Residing ONLY in Institutions consistent with the commentator's suggestion.</p> | <p>Requirements. CMS modified one attestation for I-SNP Individuals Residing ONLY in Institutions under section 5.5 of the application as follows: Applicant will only enroll institutionalized individuals residing in a long-term care (LTC) facility under contract with or owned and operated by the SNP.</p> <p>Attachments and Burden. CMS has not revised any attachments or burden estimates as a result of this comment.</p> |

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| 15 | I-SNP | Our understanding is that I-SNPs may, but are not required, to contract with Assisted living facilities (ALF). Question 4.a. of the I-SNP Individuals Residing in Both Institutions and the Community Upload Document reads: "Applicant is contracting with assisted living facilities or other residential facilities." We believe this question should be re-worded to be clear that I-SNP applicants that intend to serve individuals that reside in both institutions and the community have the option to contract with ALFs, and suggest that the question be modified as follows: "For institutional equivalent individuals residing in the community, provide a list of applicable assisted living facilities or other residential facilities, e.g., continuing care communities. (Note use of ALF or other residential facilities is optional for I-SNPs that serve institutional equivalent individuals in the community.)" | CMS agrees with this comment. CMS modified 5.13.3 of the application consistent with the commentor's suggestion. | Requirements. CMS modified one attestation in the upload document under section 5.13.3 of the application as follows: 4.a. For institutional equivalent individuals residing in the community, provide a list of applicable assisted living facilities or other residential facilities, e.g., continuing care communities. (Note: The use of Assisted Living Facilities or other residential facilities is optional for I-SNPs that serve institutional equivalent individuals in the community.) Attachments and Burden. CMS has not revised any attachments or burden estimates as a result of this comment. |
| 16 | MSA | Compliance Crosswalk: On page 24 of the 2019 Part C Application, section 3.5.C., there is a request to complete and upload the crosswalk for Part C compliance plan document. No crosswalk template is provided in the 2019 (or CY2018) application information. Inform Health recommends that CMS either eliminate the crosswalk requirement or provide the desired template for submission. | Thank you for your comment. Under attestation 3.5.1, CMS requires that organizations respond yes or no to the following attestation: <i>Applicant will adhere to all compliance regulations in accordance with but not limited to 42 CFR 422.503(b)(4)(vi).</i> Under 3.5.B and 3.5.C, CMS required that MA-only non-network (Private Fee-for-Service and Medical Savings Account) applicants upload a compliance plan and compliance plan crosswalk in addition to the attestation. Upon review, CMS will remove both 3.5.B and 3.5.C from the application requirements. CMS believes that the response to attestation 3.5.1 provides the necessary assurances for CMS to determine the MA-only non-network applicants adherence to CMS's compliance requirements for the purpose of 42 CFR Subpart K. | Requirements. CMS will only require that MA-only non-network PFFS and MSA plans complete the compliance attestation under 3.5.1. CMS will no longer require uploads of the compliance plan and supporting matrix documents. CMS deleted 3.5.B and 3.5.C from the application. Burden. CMS anticipates a reduction of two hours based on this change for the MA-only non-network MSA and PFFS initial and SAE applications only. Attachments. CMS modified the Summary Statement to account for the burden reduction associated with this removal. |

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| 17 | MSA | <p>Banking Contract: On page 43 of the 2019 Part C Application, sections 3.25.6 and 3.25.B., the application requires uploading an executed banking contract. Section 3.25.B. is very clear on the required CMS direct and/or delegated contracting requirements are included in the contract, but does not provide any additional guidance on banking contract requirements. Inform Health recommends that CMS state any specific MSA banking requirements outside of those currently articulated in section 3.25.B. that need to be included in the MSA banking executed contract.</p> <p>Inform Health also recommends that CMS offer a standard MSA banking contract template in the 2019 Part C Application to ensure all requirements are clear and included by MSA applicants.</p> | <p>Thank you for your comment. Under attestation 3.25.B, CMS requires that organizations respond yes or no to the following attestation:</p> <p>Applicant will adhere to all compliance regulations in accordance with but not limited to 42 CFR 422.503(b)(4)(vi).</p> <p>Under 3.5.B and 3.5.C, CMS required that MA-only non-network (Private Fee-for-Service and Medical Savings Account) applicants upload a compliance plan and compliance plan crosswalk in addition to the attestation.</p> <p>Upon review, CMS will remove both 3.5.B and 3.5.C from the application requirements. CMS believes that the response to attestation 3.5.1 provides the necessary assurances for CMS to determine the MA-only non-network applicants adherence to CMS's compliance requirements for the purpose of 42 CFR Subpart K.</p> | <p>Requirements. CMS modified attestation C.25.6 as follows: Applicant will establish a relationship with a banking partner that meets the Internal Revenue Service (IRS) requirements (as a bank, insurance company or other entity) as set out in Treasury Reg. Secs. 1.408-2(e)(2) through (e)(5). Applicant will establish policies and procedures with its banking partner that include the services provided by the banking partner, including how members access funds, how spending is tracked and applied to the deductible, and how claims are processed. Burden.</p> <p>CMS also removed the requirement for MSAs to upload an executed banking contract. In removing this requirement, CMS renumbered the remaining MSA-only upload documents.</p> <p>Attachments and Burden. CMS has not revised any attachments or burden estimates as a result of this comment. CMS did not include a burden estimate for the banking contract upload in the initial Supporting Statement. CMS notes that MSA banking contract/reporting requirements are discussed in the information collection under OMB control number 0938-0753, CMS-R-267.</p> |

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| 18 | HSD | Removal of Health Services Delivery (HSD) Tables. CMS is proposing to remove the submission and review of the provider and facility Health Services Delivery (HSD) tables and related exceptions requests from the MA application process beginning with the CY 2019 application cycle. Under the proposal, CMS would no longer evaluate and review MA provider and facility networks with the application, and would instead create a separate and distinct process to conduct network reviews as part of contract operations (i.e., an operational function). CMS has published a related information collection entitled, "Three-Year Network Adequacy Review for Medicare Advantage Organizations" that proposes to establish this new operational function. The proposed approach would require organizations to upload HSD tables to the HPMS Network Management Module (NMM) for any contract that has not had an entire network review performed by the agency in the previous three-years of contract operation. HCSC has expressed general support for the Three-Year Network Adequacy Review proposal, which we believe could permit CMS to take a more balanced and uniform approach to evaluating and determining MA organization compliance with network adequacy requirements as all contracts will be subject to the three-year review cycle. This approach also may better position CMS to determine whether there is potential for beneficiary harm related to undetected network deficiencies in a manner that is consistent across all, rather than a subset of contracts. | CMS appreciates the positive feedback and support. CMS will strive for appropriate, equitable implementation of this information collection. | None. CMS has not revised any requirements, attachments, or burden estimates as a result of this comment. |
| 19 | HSD | Transparency in the Development Process. As CMS continues to consider removing the HSD review and submission process from the MA application, and further refines the new proposed operational approach (e.g., identifying needed systems and other modifications), HCSC recommends that the agency work in close and ongoing collaboration with MA organizations in a transparent manner. These steps will allow CMS to benefit from the range of MA organization practical experience and knowledge, and ensure any operational issues or considerations are identified as early as possible in the development process and well in advance of implementation. In addition, given the increased scale and scope of the proposed approach in comparison to the current review process, it will be important for CMS to take a flexible approach to initial implementation of the new process to accommodate the significant system, administrative, and timing resources that will be required on the part of the agency and plans. | CMS appreciates the positive feedback and support. CMS will strive for appropriate, equitable implementation of this information collection. | None. CMS has not revised any requirements, attachments, or burden estimates as a result of this comment. |

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| 20 | HSD | Implementation Timing. The CMS Supporting Statement indicates that the agency's goal is to remove the HSD submission and review process from the MA applications beginning with the CY 2019 applications. However, the timing of when CMS envisions the initial 3-year network reviews would begin under a new process is unclear. For clarity, we recommend that CMS confirm when the agency will begin the network adequacy reviews under the revised approach, as well as the timing of when and how impacted organizations will be notified of requests to upload HSD tables in the initial and subsequent years of implementation. As a practical consideration, we encourage CMS to establish a timeline that avoids implementation early in the year, and to ensure that the sample beneficiary file against which an organization's networks must be compared is available well in advance of that timing. | Thank you for your comment regarding the information collection for CMS-10636, OMB 0938-New. CMS is currently discussing a proposed timeline for reviews internally and will release guidance to the industry as soon as review timeframes and activities are defined. | None. CMS has not revised any requirements, attachments, or burden estimates as a result of this comment. |
| 21 | HSD | Exception Requests. HSCS believes it is important that MA organizations have the ability to submit requests when an exception to the current network adequacy criteria is warranted, especially given the continuously evolving patterns of care in certain service areas, and we appreciate that CMS is proposing to maintain this process under the revised network adequacy review approach. We recommend that CMS also consider implementing a process to make available to all organizations in a given service area, information regarding all approved Exception Requests for certain provider types in the service area in an effort to increase transparency and consistency in the review process. | Thank you for your comment regarding CMS's exception request policy. Consistent with the Supporting Statement, CMS removed the Exception Request template from this information collection. CMS will consider this comment as it develops the details surrounding the information collection for CMS-10636, OMB 0938-New. | None. CMS has not revised any requirements, attachments, or burden estimates as a result of this comment. |

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| 22 | HSD | Significant Network Changes. CMS requires MA organizations to notify the agency of any no-cause provider termination that the organization deems to be a “significant” change to the provider network, at least 90-days prior to the effective date of the change (See https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/mc86c04.pdf). The agency believes that MA organizations “may be in the best position to determine whether or not a provider termination without cause is significant” and expects organizations to take a conservative approach in making such determinations and notifying CMS accordingly. The agency notes that an organization that does not notify CMS of network changes that are ultimately determined by CMS to be significant will be subject to appropriate compliance actions. CMS guidance broadly defines “significant” changes as those changes to provider networks that go beyond individual or limited provider terminations that occur during the routine course of plan operations and affect, or have the potential to affect, a large number of enrollees. Consistent with previous comments we have submitted on this topic, we recommend that CMS further clarify and refine the definition of “significant” network changes, for example, by providing guidelines and/or criteria organizations may use to make determinations. We believe this step would promote a common understanding across MA organizations of the agency’s expectations, as well as support compliance with CMS’ requirements. | CMS recommends that the commenter submit their specific questions to the CMS mailbox, located at: https://dpap.lmi.org . | None. CMS has not revised any requirements, attachments, or burden estimates as a result of this comment. |
| 23 | HSD | Changes to Application. We note that along with the draft application, CMS issued a document that provides a high-level summary/crosswalk of changes the agency is proposing. We appreciate that CMS has made the document available and recommend that the agency consider providing a similar crosswalk when the final versions of the applications are released to help applicants more efficiently identify and navigate the year-over-year application changes. | Thank you for your feedback regarding the high-level summary/crosswalk of changes proposed through this information collection. CMS has modified this summary of changes document to include the sections impacted during the 60-day comment process. | None. CMS has not revised any requirements, attachments, or burden estimates as a result of this comment. |