Washington State Health Care Authority

Solicitation Amendment

COE for Spinal Fusion Bundle

RFP No. 2613

Amendment No. 4

Date Issued: March 22, 2018

Purpose: Questions and Answers - Continued

Amendment need not be submitted with Proposal. All other Terms, Conditions, and Specifications remain unchanged.

The following are the remaining questions HCA received during the bidder question period, and the associated answers. Any questions going forward will be addressed on a case-by-case basis at HCA's discretion.

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#	Section	Bidder Questions	HCA Answers
28	N/A	Bree is currently updating the 2014 Lumbar Fusion Bundle. How will the RFP align with the updated Bree bundle? Does the HCA have an interest in alignment of the updated Bree bundle with the requirements of the RFP? If so, how might this be accomplished?	HCA monitors updates of Bree recommendations, and as appropriate and in a collaborative manner, will incorporate updates in the bundle.
29	N/A	Will the state sponsor any shared decision-making tools for lumbar fusion similar to those offered for total joint replacement?	The HCA anticipates certifying shared decision-making tools for lumbar fusion; however, since this has not yet occurred, decision aid selection is at the discretion of the provider/facility.
30	N/A	One of the goals associated with Paying for Value is cost savings, to ensure that Bidders provide a Cost Proposal that will ensure cost savings. Will the HCA be providing historical claims data in addition to volume information?	The HCA will not be supplying historical cost data from claims. Applicants are encouraged to identify their actual costs of care for the bundle and put forward their pricing based on that methodology.
31	N/A	Surgeons sometimes are asked to repair lumbar fusions that were not done well at other locations. Will these be included in the bundle?	No, these will not be included.
32	N/A	Does HCA consider conservative treatment, such as fluoro injections, as part of a spinal fusion bundle?	Yes, when provided consistent with the Washington State Health Technology Clinical Committee coverage decisions.
33	N/A	Single and multi-level fusions have different codes, what specific ICD-10 codes does the HCA want included in the bundle?	The Bree Criteria used the existing ICD-9 codes since at the time of the bundle development, ICD-10 was not yet implemented. Please list the ICD-10 codes that you believe would be included in the warranty, based on the Bree Warranty.

34	N/A	Can the HCA please confirm the specific DRGs that are encompassed under this RFP?	The DRG for the bundle is limited to DRG 460. HCA intends to negotiate a price for DRG 459 during contract negotiations.
35	N/A	The data provided by the HCA for Total Joint Replacement Bundle RFP included volume by county and provider. Will the HCA be providing this level of detail for the Lumbar Fusion volume? Two additional related questions: -Will we be provided the volumes for two-level fusions separate from other multi-level fusions? -Can you please provide the logic used to pull the data provided (we are assuming Regence supported via claims data)?	PEBB Member demographic utilization data has been distributed via email to Bidders that provided a signed Non-Disclosure Agreement as part of the Letter of Intent (LOI) requirement. HCA anticipates providing additional data to the ASBs as part of contract negotiations. <u>Methodology:</u> Milliman reviewed and summarized spinal fusion surgery procedures performed between 2014 and 2016 calendar years for Non-Medicare enrollees within the Uniform Medical Plan (UMP) Plans. Identification of spinal fusion procedures was based on the Bree collaborative Healthcare Common Procedure Coding System (HCPCS) procedure codes, Diagnosis-related group (DRG) and HCPCS procedure codes, and the AAPC (previously known as the American Academy of Professional Coders). There were 665 members included in this study who had spinal fusion surgery between calendar years 2014 and 2016. Of these surgeries, 307 were for a single spinal fusion, and the remaining 358 surgeries were for multiple spinal fusions.

<table>
<tr>
<td>36</td>
<td>N/A</td>
<td>Are the proposed deviations for Fitness of Surgery, Bree Requirement, acceptable?

<u>FITNESS FOR SURGERY</u>
<table>
<tr><th>Bree Requirement</th><th>Proposed Deviation</th></tr>
<tr><td>Minimum requirement prior to surgery:
Body mass index less than 40</td><td>Some patients may fail in their attempts to lose weight, particularly if their spine condition prohibits them from being active. In such cases, performing the surgery may help patients be successful in weight loss efforts after recovery.</td></tr>
<tr><td>Minimum requirement prior to surgery: Hemoglobin A1c less than 8% in patients with diabetes</td><td>Studies show a weak correlation between pre-operative Hemoglobin A1c levels and post-operative surgical site infections and a far stronger correlation between high post-operative serum glucose levels and post-operative surgical site infections. [1,2] It can take 30 days of treatment to affect Hemoglobin A1c values so has the potential to delay surgery with little benefit. The recommendation is to manage diabetes through measurement of blood glucose values over time, throughout the peri-operative and post-operative periods with the goal of maintaining blood glucose at 180 mg/dL or less.</td></tr>
<tr><td>Patient must designate a personal care partner</td><td>The absence of a designated care partner should not preclude someone from having surgery, unless the patient has cognitive impairment or other functional impairment issues and thus will require extra assistance during the pre- or post-operative care.</td></tr>
</table></td>
<td>Bree has already made modifications in its joint replacement bundle to the designated care partner requirement. Exceptions to the Bree Criteria, if any, will be discussed as part of the contract negotiations.</td>
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<td>37</td>
<td>1.1, Purpose & Scope</td>
<td>The RFP states the HCA anticipates an additional RFP in 2019 for additional Members to participate in the Spinal Fusion Bundle. Can the HCA expand on the thought process for releasing an additional RFP rather than contracting with the ASB(s) for the ability to add additional Plans?</td>
<td>To clarify, the HCA anticipates releasing a second RFP in 2019, to give providers another opportunity to become a COE for the Spinal Fusion bundle program. This would allow respondents who were not successful in being awarded a contract to apply again.</td>
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38	1.1, Purpose & Scope	The RFP states the requirement any ASB(s) has a "dedicated care team that, at a minimum, includes physiatrist, surgeon, primary care provider (PCP) and physical therapist". Please clarify the expectation of this multi-disciplinary team in terms of the Lumbar Fusion Bundle. Please clarify if the HCA wishes consultation with a PCP included in the bundle or to simply have the PCP engaged with the care being provided to their patient.	The PCP should be engaged with the care being provided to the patient.
39	1.4, Scope of Work	The RFP states the scope of the bundle is limited to one- and two- level fusions. What was the HCA's decision around expanding from one- to two- level fusion but not beyond two levels? What is the process when a patient is recommended for more than a two-level lumbar fusion?	Most fusions in the UMP population are single or two level. If it is clinically appropriate for an individual to have more than a two-level fusion, this would be done outside of the bundle contract.
40	1.4, Scope of Work	If the Bree changes the scope of the procedures covered through the Lumbar Fusion Bundle beyond two levels, with the current refresh of the spine bundle, will the HCA also include those covered procedures?	If the Bree revises its criteria, including the scope of the bundle, the HCA will engage in discussions with the contracted COE regarding how to revise the services offered to patients through the bundle.
41	1.4, Scope of Work	The current Bree Lumbar Fusion states providers "should" participant in SCOAP under cycle 3C. Can the HCA clarify whether participation in SCOAP is a requirement?	Yes, participation in SCOAP is a requirement.
42	1.4, Scope of Work	The RFP states reporting requirements include single and multi-level fusion. Please clarify if multi-level fusion is limited to two-level fusion.	Data being requested is for single and two level fusion only.
43	1.4.A., Evaluation Only Bundle	The RFP states the ASB will be required to provide a comprehensive evaluation to all participants and this evaluation is to determine the most appropriate care plan. Is the HCA open to an evaluation bundle that includes additional non-surgical treatment such as injections or other non-surgical therapies that might be recommended in Bree's revision of the 2014 bundle?	Yes, when provided consistent with the Washington State Health Technology Clinical Committee coverage decisions.

44	3.9, Proprietary or Confidential Information	Can the HCA provide further clarification: “The HCA may not honor designations by the Bidder where pricing is marked proprietary or confidential.”? This language was not in RFP 15-023 Total Joint Replacement Bundle Episode of Care; can the HCA speak to why this language has been included in RFP 2613?	The Public Records Act (PRA) only allows an agency to withhold public records if there is law that exempts the information. Most information contained within bid submissions are not considered exempt by law. The PRA does allow for an agency to provide third party notification of a public disclosure request with an opportunity of time seek enjoinment of the records. We allow vendors to clearly identify sections of their bids they feel are confidential in an effort to protect their information and we will provide them notification if a request is received. However, as a state agency we also have other laws we must follow which in certain scenarios may include demonstrating why a vendor was chosen as the successful bidder. Often times, the price an agency pays a contractor is a key component of how the scoring is determined. If there are questions relating to the criterion used to calculate the scores, it might be necessary for an agency to demonstrate how they were able to determine the price each vendor was offering. If a bidder were to try to designate all of their pricing information as confidential, there would be no way for an agency to justify how they came up with the price. This does not mean all of the pricing details or the methodology behind the pricing must be provided which is why we state, “may not.”

45	4.2.B.2 & Appendix A, Section 8	Can the HCA please clarify the outlier cost proposal and cost scoring and provide an example? How is the HCA defining outlier threshold? Is the HCA defining outlier threshold based on billed charges? If so, how does HCA intend to account for significant differences in billed charges from bidder to bidder? Will the HCA use Medicare's Cost to Charge Ratio to compare facilities on a consistent basis? Additionally, can you please indicate how claims in excess of the outlier threshold will be paid? All of these issues affect the cost proposal.	HCA has decided to remove the outlier portion of the Cost Proposal in section 8 of the Appendix A Submittal Document. Instead, outlier thresholds and the associated warranty rates will be negotiated during the contracting phase. For purposes of the bundled payment, an outlier threshold is reached when the billed charges of an episode of care exceed a previously agreed upon dollar amount. After the threshold is reached, charges are paid according to a negotiated rate. This change will be documented in a subsequent amendment to be posted soon.
46	4.2.B.2 & Appendix A, Section 8	In RFP 15-023, Total Joint Replacement Bundle Episode of Care, the majority of the bundle cost used to develop the Cost Proposal was included in the DRG. The Cost Proposal requested in this RFP appears broadened, asking Bidders to define, and cost, components in the bundle. The way the Cost Scoring is outlined, the Lowest Cost will result in the highest Bidder Score. In evaluating pricing proposals, how will the HCA account for the differences in the scope of services being offered in the bundle?	HCA is amending the Cost Proposal section to include the DRG allowed under this program, DRG 460. Please indicate the ICD-10/CPT codes under the DRG for the two spinal fusion bundles (single and 2-level fusions) that you are proposing to include in your bundled episode of care.This change will be documented in a subsequent amendment to be posted soon.
47	4.2.B.2 & Appendix A, Section 8	Part of the Cost Proposal is understanding the potential volume associated with the Lumbar Fusion Bundle. Would the HCA be open to two Cost Proposals, one if the Bidder was the only COE chosen and another if there were to be multiple COEs?	If HCA is considering more than one COE when it comes time for the Best and Final Offer phase of the evaluation (Part 4), the phase will become a mandatory step in the evaluation. In this scenario, the remaining bidders will be given the opportunity to submit an updated Cost Proposal as part of the "best and final offer". This change will be documented in a subsequent amendment to be posted soon.
48	Exhibit 2, I.B. & II.A.	Exhibit 2 (I.B. and II.A.) state imaging standards not included in the 2014 Bree bundle. Other Bree standards have corresponding citations from the medical literature. Is there a source citation, guideline, or policy document in support of the stated standard?	See the Washington State Department of Labor & Industries Surgical Guideline for Lumbar Fusion - Updated March 7, 2016. http://www.lni.wa.gov/ClaimsIns/Files/OMD/MedTreat/LumbarfusionUpdate020216.pdf

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<tr><td>49</td><td>Exhibit 2, II</td><td>Are there citations or standards to support the surgical criteria outlined in the RFP for Members with previous spine surgery?</td><td>See the Washington State Department of Labor & Industries Surgical Guideline for Lumbar Fusion - Updated March 7, 2016. http://www.lni.wa.gov/ClaimsIns/Files/OMD/MedTreat/LumbarfusionUpdate020216.pdf</td></tr>
<tr><td>50</td><td>Exhibit 2, III</td><td>Is the proposed deviation to contraindications acceptable?
<table><tr><th>Contraindications for lumbar fusion</th><th>Proposed Deviation</th></tr><tr><td>There are important contraindications for lumbar fusions, even when patients meet the criteria described in the previous sections:
A. Absolute contraindication
1. Lumbar fusion is not indicated with an initial laminectomy/discectomy related to unilateral compression of a lumbar nerve root.</td><td>Lumbar fusion can be performed when any of the following is met:
A. Decompression is performed in an area of segmental instability as manifested by gross movement on flexion-extension radiographs; or
B. Decompression coincides with an area of significant degenerative instability (e.g., scoliosis or any degree of spondylolisthesis (grades I, II, III, IV or V); or
C. Decompression creates an iatrogenic instability by the disruption of the posterior elements where facet joint excision exceed 50% bilaterally or complete excision of one facet is performed."</td></tr></table></td><td>Modifications to criteria, if any, will be negotiated as part of the contract negotiations.</td></tr>
<tr><td>51</td><td>Appendix A, Section 7, A3</td><td>Regarding Questions 21 and 26 in Amendment 3: the HCA answer indicates that the data being requested in Appendix A2 and Appendix A3 is for single and two level fusions only. Would this also apply to the request for multi-level fusion volume in question A3 of the submittal document?</td><td>No. Question A3 of the Submittal document should include volumes for single and multi-level fusions as stated in the document.</td></tr>
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52	Appendix A, Section 7.B	Section B is dedicated to Bundle and Risk-Based Contract Experience. With this in mind, is the HCA seeking volume and adverse event data by surgeon (in question B5), only for those procedures performed under a bundled episode of care? Or for all procedures, even those performed outside of a care bundle? Similarly, if a surgeon practices at multiple facilities, should we provide this data only for those procedures performed at our proposed COE, or for all facilities where the surgeon operates?	The HCA is seeking volume and adverse event data by surgeon for all spinal fusion procedures, whether or not they were performed within a care bundle. If a surgeon practices at multiple facilities, please provide data only for those procedures performed at the proposed COE.
53	Appendix A, Section 7.B, 5	In the Written Proposal of the RFP Section B Question 5, the State asks for volume by surgeon. In the Bree Lumbar Fusion Bundle, the criteria for surgeon participation is "the spine surgeon should perform a minimum of twenty lumbar fusion surgeries in the previous twelve months". The Bree bundle does not specify the volume should be limited to single level fusions. It is our understanding that if a surgeon can perform a multi-level fusion, they have the sufficient experience to perform a single level fusion. Please clarify if surgical volume standards include only single- and two- level lumbar fusion, or if additional multilevel fusions may be included in the volume requirements. Additionally, if there are two surgeons in the room, would that surgery count towards for both surgeons or just one?	Volume is the total number of fusions performed, single, two level and multilevel. With respect to attributing surgeon volume: The Bree recommendation is based on literature that demonstrates an association between the number of surgeries a surgeon has done in a given time period and clinical outcome. From HCA's perspective, whether or not a surgery is counted toward a surgeon's volume is up to the bidder. However, if a facility counts surgeries toward a surgeon's volume where the surgeon is one of 2 surgeons in the operating room, it should provide a rationale for how this approach to attributing surgical volume meets the intent of the Bree recommendation.
54	Appendix A, Section 7.B, 5 (d & e)	Regarding Questions 21 and 26 in Amendment 3: the HCA answer indicates that the data being requested in Appendix A2 and Appendix A3 is for single and two level fusions only. Would this also apply to the request for multi-level fusion volume by surgeon in question B5 (d & e) of the submittal document? If so, is the HCA seeking information on adverse events (f) only for single-level and two-level fusions, or for all multi-level fusions?	Question B5 (d & e) should include data on multi-level lumbar fusions as indicated. In Question B5 (f) the HCA is seeking information on adverse events only for single and two-level fusions.
55	Appendix A, Section 7.E, 1 & 2	In the Written Proposal of the RFP Section E, Questions 1 and 2 specially calls out non-Medicare patients. We are concerned with insufficient volume of non-Medicare one- and two- level fusion to establish a statistically relevant denominator. We request that the HCA help us understand the reasoning behind excluding Medicare patients.	We understand your concern regarding the statistical relevance of a denominator with low volumes. Therefore, we will amend this to include both non-Medicare and Medicare volumes in your response. This change will be documented in a subsequent amendment to be posted soon.

56	Appendix A2, Section 4, 4a & 4c	In Appendix A2 Section 4, please clarify the difference in question 4a and 4c?	Use 4a if you have insufficient HCAHPs results for spinal fusion patients and need to report your results for all patients. Use 4c if you have been able to survey sufficient numbers of spinal fusion patients to provide statistically significant results.
57	Appendix A2, Section 5 5b	In Appendix A2, Section 5, Question 5b asks for warranty complications resulting in the first 30 days post-operatively. The Bree Lumbar Fusion Warranty has three warranty periods: 7 days, 30 days and 90 days, depending on the specific complication and the statistical window in which it is most likely to occur. Please clarify the quality metric.	For this specific question, we are referring to the 30-day warranty.