



STATE OF TENNESSEE
 DEPARTMENT OF FINANCE AND ADMINISTRATION
 DIVISION OF HEALTH CARE FINANCE AND ADMINISTRATION
 BUREAU OF TENNCARE

**REQUEST FOR PROPOSALS # 31865-00465
 AMENDMENT # 2
 FOR PHARMACY BENEFITS MANAGEMENT**

DATE: July 14, 2017

RFP # 31865-00465 IS AMENDED AS FOLLOWS:

1. This RFP Schedule of Events updates and confirms scheduled RFP dates. Any event, time, or date containing revised or new text is highlighted.

EVENT	TIME (central time zone)	DATE	CONFIRMED/ UPDATED
1. RFP Issued		June 13, 2017	CONFIRMED
2. Disability Accommodation Request Deadline		June 20, 2017	CONFIRMED
3. Pre-response Conference	10:30 a.m.	June 26, 2017	CONFIRMED
4. Notice of Intent to Respond Deadline	2:00 p.m.	June 27, 2017	CONFIRMED
5. Written "Questions & Comments" Deadline	11:00 a.m.	July 3, 2017	CONFIRMED
6. State Response to Written "Questions & Comments"		July 14, 2017	CONFIRMED
7. Response Deadline	10:00 a.m.	August 11, 2017	CONFIRMED
8. State Completion of Technical Response Evaluations		August 21, 2017	CONFIRMED
9. State Opening & Scoring of Cost Proposals	1:00 p.m.	August 22, 2017	CONFIRMED
10. State Notice of Intent to Award Released and RFP Files Opened for Public Inspection	2:00 p.m.	August 24, 2017	CONFIRMED
11. End of Open File Period		August 31, 2017	CONFIRMED
12. State sends contract to Contractor for signature		September 1, 2017	CONFIRMED
12. Contractor Signature Deadline		September 8, 2017	CONFIRMED
13. Contract Start Date		October 1, 2017	CONFIRMED

2. State responses to questions and comments in the table below amend and clarify this RFP.

Any restatement of RFP text in the Question/Comment column shall NOT be construed as a change in the actual wording of the RFP document.

QUESTION / COMMENT	STATE RESPONSE
<p>1 On Page 39 of the RFP document, in the table titled COST PROPOSAL SECTION D – RISK LEVEL FOR TENNCARE PROGRAM ONLY, the instructions require the contractor to accept from 2% to 6% of the risk. In this ask, what is the contractor risking-- the admin fee or overall drug costs?</p>	<p>Administration fee only.</p>
<p>2 On page 47, A.2., the RFP states specifically the Contractor must be a PAHP (Prepaid Ambulatory Health Plan). For a PBM to qualify as a PAHP, will a contractor be required to also provide services outside of the scope of a traditional PBM?</p>	<p>A prepaid ambulatory health plan (PAHP) is a form of a managed care arrangement that is defined in federal regulation at 42 CFR §438.2. A PAHP is defined as an entity that provides services to enrollees under some arrangement with the state other than a comprehensive risk contract, and that does not provide inpatient services. The selected Contractor must be able to provide the services specified in the <i>pro forma</i> contract. These services consist of pharmacy services provided to TennCare and CoverKids enrollees in a manner that is compliant with applicable laws and regulations. The Contractor will not be required to provide services not listed in the contract.</p>
<p>3 What is the estimated cost for this effort?</p>	<p>Please refer to Section 1.1.2. of the RFP.</p>
<p>4 What funding source has been allocated for this effort?</p>	<p>Federal and State dollars.</p>
<p>5 How does this relate to the Medicaid Management Information System (MMIS) project, if at all?</p>	<p>This does not relate to the MMIS project.</p>
<p>6 What type of pharmacy data will this system be tracking?</p>	<p>N/A</p>
<p>7 How is the Department currently meeting this need? Which vendor provides the incumbent Pharmacy Benefits Management Solution?</p>	<p>The need is currently being met through contracts with Magellan HealthCare and Express Scripts (CoverKids).</p>
<p>8 Would it be possible to name the three greatest challenges the Department is having with the current solution?</p>	<p>HCFA is not unsatisfied with our current vendor and solution. The current contractor is on its fifth and final year. By State law, we are required to re-procure the contract.</p>
<p>9 Which other systems will have to integrate or interface with the Pharmacy Benefits Management Solution, and will the State provide incumbent vendors for each system?</p>	<p>Referenced interfaces are defined within the RFP. The State will provide incumbent vendors as applicable. For example the incumbent MMIS vendor is DXC Technology.</p>

QUESTION / COMMENT	STATE RESPONSE
10 Which operating platform does the Department currently use? / Is desired for the Pharmacy Benefits Management Solution?	The current platform is windows based and all applications with the new vendor will be submitted on a windows based platform.
11 Can the Department elaborate on any additional drivers behind this acquisition that may not be addressed in the RFP?	Please refer to State's response to question #18.
12 What is the number of front/back-end users anticipated for the Pharmacy Benefits Management Solution?	HCFA's pharmacy department will require 8 users. Other department within HCFA and other State divisions may/will also require access, along with users working with TennCare's MCO's.
13 Who is the technical contact and/or project manager for the Pharmacy Benefits Management Solution?	HCFA Staff
14 Does the Department anticipate any professional or consulting services may be needed to accomplish this effort? (i.e. project planning/oversight, PM, QA, IV&V, staff augmentation, implementation services etc.)?	HCFA anticipates the use of an Implementation Contractor to assist the vendor to transition to this new contract.
15 If a respondent doesn't meet the criteria for references, will TennCare still accept their proposal?	Since the requirement for appropriate references is not a requirement in Mandatory Requirements in RFP Attachment 6.2, Section A, your proposal will be accepted and lack of required references will not result in disqualification. However, per RFP Attachment 6.2, Section B.17, General Qualifications and Experience, the failure to respond with required number of references would impact the respondent's score by evaluators.
16 p. 15, Section 4.8 Disclosure of Response Contents The RFP does not appear to reference any requirements about redacting portions of a proposal response or how to treat confidential/proprietary information. Does the State have any specific requirements around these issues?	Nothing submitted in response to this procurement will be redacted. Please refer to RFP Section 4.8, Disclosure of Response Contents.
17 p. 31, Attachment 6.2, C.12. Will the existing contractor turn over any portions of the current TennCare website or will the winning respondent be required to establish a new website?	The current PBM owns the website that they provide for HCFA. We will require our current PBM to turn over all documents currently residing on the website that they provide for us. It would be up to the current PBM if they decide to offer the website to the Contractor.
18 p. 48, Attachment 6.6 Is it the State's intention for the contractor to respond directly to any of the items included in Attachment 6.6, <i>Pro Forma</i> Contract?	No. The respondent is required to respond to those sections in Technical and Cost response models in RFP Attachment 6.2, section A, B, and C and Attachment 6.3, Cost Proposal.
19 p. 49, Attachment 6.6, A.2 Is it acceptable for the contractor to be approved	There is no formal approval process for prepaid ambulatory health plans (PAHPs). A PAHP is a form of managed care arrangement that is defined in federal

QUESTION / COMMENT	STATE RESPONSE
<p>as a Prepaid Ambulatory Health Plan (PAHP) upon contract award?</p>	<p>regulation at §42 CFR 438.2. A PAHP is defined as an entity that provides services to enrollees under some arrangement with the state other than a comprehensive risk contract, and that does not provide inpatient services. A PAHP is expected to meet the applicable federal requirements as enumerated in the Medicaid managed care regulations (42 CFR Part 438). TennCare will regard an entity that is able to fulfill the requirements listed in the <i>pro forma</i> contract as meeting these requirements.</p>
<p>20 p. 60, Attachment 6.6, A.7. a.1. Is it the State's expectation that the contractor will submit draft staffing plans with our proposal response or is that an expectation upon contract award?</p>	<p>Any deliverable in the <i>pro forma</i> shall be submitted after contract award. Please refer to State's response to question #18.</p>
<p>21 p. 59, Attachment 6.6, A.7.a.3. Please verify whether the contractor can submit the training plan after contract award and is not expected to submit the plan with the RFP response.</p>	<p>Confirmed. Per A.7.a.4. "<i>a Staff Training Plan (Training Plan) shall be submitted to HCFA for approval within ten (10) business days of the effective date of this Contract.</i>"</p>
<p>22 p. 81, Attachment 6.6, A.31 Are there any restrictions or limitations regarding where the primary data center and disaster recovery data center must be located?</p>	<p>Yes, all components handling the data must reside in the US and follow industry standard best practices, including at least 50 miles apart.</p>
<p>23 RFP – Amendment #1 How many State users will require access to the end user applications for pharmacy claims adjudication, prior authorization, and rebate administration respectively? Does the State have a preferred solution for end-user connectivity to these environments/ applications?</p>	<p>Adjudication System: HCFA's pharmacy department will require 8 users. Other departments within HCFA (TennCare Solutions Unit, KePRO, Program Integrity, Internal Audit, etc.) and other State divisions will also require access (State Comptroller Auditors, Office of Inspector General, MFCU, etc.), along with users working with TennCare's MCO's.</p> <p>Prior Authorization System: HCFA's pharmacy department will require 8 users. Other department within HCFA (TennCare Solutions Unit, KePRO, Program Integrity, Internal Audit, etc.) and other State divisions may also require access (State Comptroller Auditors, Office of Inspector General, MFCU, etc.), along with users working with TennCare's MCO's.</p> <p>Rebate Administration: HCFA's pharmacy department has one primary person who will use this application, along with possible access needed for HCFA Finance and possibly one other HCFA pharmacy associate.</p> <p>End-user access to the contractor's system can be via any secure connection that complies with all federal and state privacy and security regulations. Any custom software required must be provided at the contractor's expense. All data transfers between TennCare and the contract must occur over HCFA/TennCare's SFTP</p>

QUESTION / COMMENT	STATE RESPONSE
	server.
<p>24 RFP – Amendment #1</p> <p>Will the State require access to test environments/applications? Does the State have a preferred solution for end-user connectivity to these environments/ applications?</p>	<p>Access to the PBM contractor’s test and production environments are required for validation and oversight work. End-user access to the contractor’s system can be via any secure connection that complies with all federal and state privacy and security regulations. Any custom software required must be provided at the contractor’s expense. All data transfers between TennCare and the contract must occur over HCFA/TennCare’s SFTP server.</p>
<p>25 p. 262, Attachment C, Item 19</p> <p>RFP Language: <i>“The damage that may be assessed shall be one thousand dollars (\$500.00) per calendar day, per occurrence.”</i></p> <p>Can the state please clarify if this should be \$1,000 or \$500?</p>	<p>Please refer to Item #3 below for amended language.</p>
<p>26 p. 24, Attachment 6.2, B.13</p> <p>Is the State willing to accept representative resumes for any of the key staff positions or is the contractor expected to name the actual people that will be doing this work upon contract award?</p>	<p>The State is willing to accept representative resumes for key staff positions, but while scoring the RFP submissions, higher scores may be awarded to those who name actual people that will be doing this work upon contract award.</p>
<p>27 p. 118, Attachment 6.6, A.42.e</p> <p>Please provide the quarterly invoice volume for rebates.</p>	<p>764 invoices were generated for 1Q2017.</p>
<p>28 p. 98, Attachment 6.6, A.41.a</p> <p>Please provide the volume of claims processed annually for FFS and MCO.</p>	<p>Since pharmacy claims are carved out from the MCO model, only FFS pharmacy claims are reported: FFY 2017 (7/1/16 – 6/30/17)= 14,116,732</p>
<p>29 p.151, Attachment 6.6, Section A.49.b.4</p> <p>RFP Language: <i>“Contractor shall not impose limits on the number of licenses made available to State staff, designees, State and federal auditors, MCOs and other State entities”</i></p> <p>Can the State identify approximately how many licenses are currently provided in order to meet this requirement?</p>	<p>Please see the answer to #23 above for application access to Adjudication, PA and Rebate Administration.</p> <p>Licenses for the Decision Support tools that the Contractor will provide for HCFA will be the same as the Adjudication application.</p>
<p>30 p. 162, Attachment 6.6, A.53.c</p> <p>The requirement indicates that all contractor’s key staff must attend the project kick-off meeting. However, per the key staff requirements, the Account Director is the only key position that must be hired beginning on the contract effective date. Per the RFP instructions on page 61, paragraph 5 of item 2, <i>“All permanent Key Staff positions shall</i></p>	<p>The only key position that must be present for the project kick-off and throughout the entire implementation period is the Account Director.</p> <p>It is acceptable that the Contractor’s implementation team be present during kick-off meetings and until the rest of the Key Staff is hired within 60 days of go-live.</p>

QUESTION / COMMENT	STATE RESPONSE
<p><i>be hired and trained no less than sixty (60) days prior to TennCare and CoverRx Go-Live.”</i></p> <p>Can the State please clarify its expectations of which staff must be hired beginning on the contract effective date and which staff must be present for the project kick off?</p>	
<p>31 pp 64-65, Attachment 6.6, A.8.a</p> <p>Can the State please provide an estimated volume of the following member materials that will need to be printed and mailed: member handbooks, provider directories, member newsletters, identification cards, fact sheets, notices, brochures, form letters, mass mailings, and system-generated letters?</p>	<p>TennCare: The PBM is only responsible for the mailing of Pharmacy Identification Cards and Enrollee Notices. Approximately 4,500-5,000 ID cards are sent per month based on enrollee request.</p> <p>CoverRx-CY2016: ID Cards: 19,731</p> <p>Welcome letters, notices, correspondences, checks: 73,390</p> <p>Please refer to Item # 7 of this amendment for updated RFP Attachment 6.7, Bidder's Library.</p>
<p>32 p. 32, Attachment 6.2, C.13</p> <p>Could the State provide details on how it is currently using the services of MediSpan Drug Database (MDDDB) and First Databank (FDB)?</p>	<p>TennCare's current pharmacy vendor uses the FDB database. The State has used both FDB and MediSpan in the past, and our preference is MediSpan. If FDB is used, the State would want to have MediSpan's GPI (Generic Product ID) field included in the drug file and in the claims file. It would also be necessary to include the AWP values from the MediSpan database.</p>
<p>33 pp 36-38, Attachment 6.3</p> <p>Could the state please provide RFP Attachment 6.3, the cost proposal forms, in an Excel format if available?</p>	<p>The Cost Proposal is not available in an excel format. We can provide a word document.</p>
<p>34 p. 62, Attachment 6.6, A.7.b.2.</p> <p>Is it the State's expectation that the contractor name only the lead Fraud and Abuse Investigator or should all F&A supporting staff be named as well?</p>	<p>The lead investigator who is directly involved with TennCare member and/or provider investigations regarding suspected fraud or abuse shall be specifically named along with any and all supporting staff.</p>
<p>35 RFP – Amendment #1</p> <p>Please confirm whether the State has implemented National Average Drug Acquisition Cost (NADAC)?</p>	<p>TennCare implemented a state-specific AAAC program on April 1, 2017, and uses the NADAC price only if it is lower than the Tennessee AAAC.</p> <p>CoverRx and CoverKids do not use Acquisition cost reimbursement, and will continue to use AWP- and MAC-based reimbursement formulae.</p>
<p>36 p. 112, Attachment 6.6, A.41.g</p> <p>What are the current professional dispensing fees?</p>	<p>Ambulatory pharmacies</p> <p>\$10.09 if annual pharmacy volume is <65,000 Rx</p> <p>\$ 8.33 if annual pharmacy volume is >=65,000 Rx</p> <p>Long Term Care pharmacies = \$12.15</p> <p>340B pharmacies = \$15.40</p> <p>Blood Factor products = \$153.54 regardless of pharmacy type</p>

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<p>37 p. 112, Attachment 6.6, A.41.g.2.</p> <p>Can the State please clarify how the Average Acquisition Cost is calculated and who does that calculation? Please confirm that it is not the responsibility of the contractor to conduct these surveys.</p>	<p>AAAC is calculated by Myers & Stauffer LLC. It is not the responsibility of the PBM to conduct these surveys; however the <i>pro forma</i> contract states that it is mandatory for pharmacy to participate. The contractor may be involved with assisting the State and MSLC in contacting and bringing non-responding providers to contract compliance.</p>
<p>38 pp 165 & 204, Attachment 6.6, A.53.j., A.71.k</p> <p>Is the contractor expected to procure rebates on the CoverRx and CoverKids claims and pass them through to the State, or will the State collect rebates for these programs on their own?</p>	<p>The contractor is expected to procure rebates for all HCFA pharmacy programs and pass them through to the State.</p>
<p>39 p. 173, Attachment 6.6., A.54.g.2</p> <p>Can the State please verify whether the contractor will be responsible for setting the MAC prices for TennCare, CoverRx and/or CoverKids programs; or is the contractor expected to use NADAC, AAC or any other actual acquisition cost drug file?</p>	<p>The Contractor will be responsible to set the MAC prices for the CoverRx and CoverKids programs. At this time, TennCare does not utilize MAC.</p> <p>The contractor will not be responsible to use actual acquisition cost pricing for CoverKids or for CoverRx.</p>
<p>40 p. 121, Attachment 6.6, A.43</p> <p>How often are new enrollee cards printed and provided to enrollees? Is this a regular occurrence or only when they are newly eligible or report a lost card?</p>	<p>TennCare: New Enrollee cards are printed and mailed weekly. This is a regular occurrence for new members, name changes, DOB corrections, coverage changes and member requests</p> <p>CoverRx: ID cards are printed upon enrollment, re-enrollment, and request due to loss</p> <p>Please refer to Item # 7 of this amendment for updated RFP Attachment 6.7, Bidder's Library.</p>
<p>41 p. 131, Attachment 6.6, A.44.a.1(b)</p> <p>How many DUR Board members are there and what is the reimbursement amount per meeting?</p>	<p>There are 11 DUR Board members: 5 pharmacists, 5 physicians and 1 nurse practitioner. Board members are reimbursed for mileage only and/or hotel if used.</p>
<p>42 pp 117 & 129, Attachment 6.6, A.42.d., A.44.a.</p> <p>Can the State please clarify whether PAC and DUR meetings are held concurrently or are there eight (8) separate meetings annually? Has the State considered combining the PAC for TennCare and the Clinical Advisory Committee for the CoverRx Program, or will the CoverRx committee meetings be held separately from the PAC and DUR meetings?</p>	<p>There are 8 separate meetings held annually-- 4 meetings each for PAC and DUR.</p> <p>At this time, the State has not considered combining the committees for TennCare and CoverRx.</p>
<p>43 p. 134, Attachment 6.6, A.45</p> <p>Please provide historical or anticipated PA volumes for the TennCare and the CoverRx programs.</p>	<p>During FY2017 (July 1, 2016 – June 30, 2017), the PBM processed 277,243 PA's for TennCare</p> <p>CoverRx does not have a PA program</p>
<p>44 p. 135, Attachment 6.6, A.45.a.9</p> <p>How long do recorded calls need to be kept? Is this requirement different from other data retention</p>	<p>Requirement is the same as other data retention.</p>

QUESTION / COMMENT	STATE RESPONSE
policies?	
45 p. 145, Attachment 6.6, A.45.f. How many enrollee-initiated PAs are there each month?	During FY2017 (July 1, 2016 – June 30, 2017), the PBM processed 18,492 enrollee-initiated PA's for TennCare.
46 p. 29, Attachment 6.2, C.5 Please provide paid claims volume for TennCare, CoverRx and CoverKids (approximate) separated out by plan.	Please refer to State's response to question #28 for TennCare Claims volume. 812,463 FY17 CoverRx 306,595 claims during Calendar year 2016 for CoverKids
47 p. 91, Attachment 6.6, A.40.a <i>The RFP states: "The TennCare Project Plan shall also include a description of the participants on the Contractor's, Implementation Contractor's and the State's transition teams and their roles and schedules of meetings."</i> Is the State requiring that the contractor's Roles and Responsibilities Matrix for the project and meeting schedule be included within the MS project file? What does "transition" mean in this context? Is it the implementation phase or the transition from DDI to operations?	Knowing that all key personnel for the account are not required to be hired and in place until 60 days from the go-live date on June 1, 2018, it means that we understand that there may be a different team from the Contractor throughout the period from the contract start date until March 31, 2017.
48 p. 50, Attachment 6.6, A.2.c Does the State still envision about 72,000 enrollees in the CoverKids program once it goes live on January 1, 2020?	Yes, the State still envision about 75,000 enrollees in the CoverKids program on go live date of January 1, 2020.
49 p. 91, Attachment 6.6, A.40.b Can the State please clarify the specific scope of work requirements for what is needed for CMS certification?	Please refer to RFP Attachment 6.7, Item #7 of this amendment.
50 p. 118, Attachment 6.6, A.42.e Who are all the previous contractor(s) for the rebate administration program?	Magellan Catamaran (Optum) First Health (Magellan) ACS (Xerox)
51 p. 118, Attachment 6.6, A.42.e What is the specific information and format that the State staff require for invoices?	Refer to RFP Attachment 6.6, Section C.5.
52 p. 118, Attachment 6.6, A.42.e As it relates to rebate, how many HCFA PBM programs currently exist?	Supplemental rebates currently for TennCare. Federal Rebates currently for TennCare. Diabetic supply rebates for TennCare (not CMS' Covered Outpatient Drugs)

QUESTION / COMMENT	STATE RESPONSE
	CoverKids Rebates CoverRx Rebates
53 p. 118, Attachment 6.6, A.42.e Please define the type (electronic/paper), volume, and timeframes of historical data that would be transferred to the contractor.	7 years can be provided in TennCare standard claim extract formats.
54 RFP – Amendment #1 Does HCFA currently have only one PBM/rebate contractor?	Currently the PBM/rebate contractor for TennCare and CoverRx is Magellan Medicaid Administration. CoverKids' claims and rebates are administered through BlueCare of Tennessee.
55 p. 119, Attachment 6.6, A.42.e RFP language: "...and that no other monies other than rebates shall be collected based on the State's program." Could the contractor charge Data Niche for file generation and transfer?	No. TennCare does not currently use the services of Data Niche.
56 p. 50, Attachment 6.6, A.2.b. What pricing methodology will be used for CoverRx?	Please refer to RFP Attachment 6.3, Cost Proposal Section B.
57 p. 173, Attachment 6.6, A.54.g, item 2 Can the State please verify if the contractor will be responsible for setting the MAC prices for TennCare, CoverRx and/or CoverKids programs or is the contractor expected to use NADAC, AAC or any other actual acquisition cost drug file?	Please refer to State's response to question #39.
58 p.258, Attachment C p. 276, Attachment G In terms of the penalties assessed around the SLAs, can the State please confirm the contractor is not held responsible for not meeting deadlines when it is at the fault of another party?	Confirmed.
59 p. 131, Attachment 6.6, A.44.a.1.(a)(1)x The RFP requirement states: " <i>The DUR Clinical Pharmacist shall prepare... x. Additional reports, as requested by the State or the DUR Board.</i> " Can the State please provide examples of "additional reports" that may be required?	These requests have been common, and may come about based on the discussion during the DUR Board meeting. For example, during a discussion of blood glucose strips, it was asked how many of the users of over 300 strips per month were Type I diabetics. This information was used to eventually arrive at the MAX dose of diabetic strips.
60 p. 131, Attachment 6.6, A.44.a.1.(b) RFP language: " <i>Recruit, maintain, and reimburse a panel of clinical pharmacists...</i> " Will the State have any involvement in the recruitment process? In addition, what is the reimbursement amount and does it include	The review of 800 profiles per month is required of the Contractor. It is up to the Contractor as to how this is accomplished, although the review is not part of the job descriptions of other pharmacists that are required by this RFP and Scope of Work.

QUESTION / COMMENT	STATE RESPONSE
<p>mileage?</p>	
<p>61 p. 133, Attachment 6.6, A.44.b.1.(i)</p> <p>The RFP states: <i>“The data elements tracked will vary according to the focus of study and/or type of intervention employed and may include, but shall not be limited to:... (i) Hospitalizations and/or doctor visits pre and post intervention;”</i></p> <p>Based on our interpretation, in order to comply with this requirement, the contractor will require access to other claim types (aside from pharmacy). Will the State be able to provide these claim types?</p>	<p>Yes. The contractor will be provided with 15 months of medical claims history including ICD-10 codes and procedure codes.</p>
<p>62 p. 289, Bidders Library p. 91, Attachment 6.6, Section A.40.b.</p> <p>The section of the RFP that deals with CMS Certification mentions only a R3 final certification review with CMS. However, the required artifacts list contained in the Bidders’ Library contains required artifacts for both an R2 and R3 review. Under MECT 2.1, CMS requires both R2 and R3 reviews to comply with the Medicaid Enterprise Lifecycle.</p> <p>Can the State clarify whether it will conduct both R2 and R3 reviews or only an R3 review with CMS? Has the intended CMS Certification approach received approval from CMS?</p>	<p>The State will conduct all CMS-required reviews based upon the most current version of the CMS MECT Checklist and Required Artifacts (current version is MECT 2.1.1). All three milestone reviews are required by CMS, and the State expects the contractor to support any and all coordinated reviews with CMS.</p> <p>R1 – Project Initiation Milestone Review (<u>provided contractor is on board at the time of the review</u>)</p> <p>R2 – Operational Milestone Review</p> <p>R3 – MMIS Certification Final Review</p>
<p>63 p. 92, Attachment 6.6, Section A.40.b.</p> <p>Under MECT 2.1, independent validation and verification (IV&V) plays a critical role in the CMS Certification process.</p> <p>Has the State contracted with an IV&V contractor to support the project and/or CMS Certification? If not, does the State have a timeline for when IV&V contractor will join the project? If so, will the State provide the name of the selected firm?</p>	<p>Yes. The State has competitively procured Cognosante Consulting LLC as the IV&V contractor.</p>
<p>64 p. 92, Attachment 6.6, Section A.40.b.</p> <p>Under MECT 2.1, the project management team is a critical role in the CMS Certification process.</p> <ul style="list-style-type: none"> • Has the State contracted with a project management contractor to support the project and/or CMS Certification? If not, does the state intend to do so? • If a contractor has been selected, will the State provide the name of the selected firm? • If a project management contractor will not be contracted, does the State have a dedicated project management staff who will be the point of 	<p>The State will have a dedicated project management staff throughout the certification process. The contractor will need to provide a point of contact who will work with the State’s dedicated point of contact throughout the project’s lifecycle.</p>

QUESTION / COMMENT	STATE RESPONSE
<p>contact throughout the CMS Certification process?</p>	
<p>65 p. 92, Attachment 6.6, Section A.40.b.</p> <p>MECT 2.1 sets numerous expectations related to the State's MITA SS-A and requires artifacts that result from the SS-A.</p> <ul style="list-style-type: none"> • Has the State completed its SS-A and related artifacts so that this documentation can be used during the CMS Certification process? • If not, does the State intend to complete its SS-A and associated documents before the December 1, 2018 cut off for CMS Certification documentation readiness? • If the State has completed this documentation, will the State make its MITA SS-A and associated supporting artifacts available to the contractor community for review during the RFP response period? 	<p>Yes. The State completed a full MITA 3.0 State Self-Assessment in 2015; The required artifacts were completed and submitted to CMS in 2015. This and other relevant documentation can be made available to the selected contractor during the onboarding process</p>
<p>66 p. 92, Attachment 6.6, Section A.40.b. p. 284, Attachment I (Escrow Agreement), 1.1 and 1.2</p> <p>The RFP establishes a hard date of December 1, 2018 as the deadline for delivery of all CMS Certification artifacts. If artifacts are not delivered there will be a permanent withholding of the selected contractor's monthly administrative fee until the solution is certified.</p> <p>Would the State consider amending these references in the RFP to tie the deadline for delivery of required CMS Certification artifacts to 6 months after go-live instead of setting a hard date of December 1, 2018?</p>	<p>No, the State will not consider moving the deadline for delivery of required CMS certification artifacts. The Contractor is required to go live June 1, 2018, and December 1, 2018 is exactly six months.</p>
<p>67 p. 92, Attachment 6.6, Section A.40.b. p. 284, Attachment I (Escrow Agreement), 1.1 and 1.2</p> <p>Will the State consider delays in the certification timeline that are outside the control of the selected contractor when determining whether to institute the administrative fee withholdings? For example, delays in evidence review by the IV&V contractor, delays related to the CMS team's schedule, etc.</p>	<p>Yes.</p>
<p>68 p. 92, Attachment 6.6, Section A.40.b. p. 284, Attachment I (Escrow Agreement), 1.1 and 1.2</p> <p>CMS Certification is a resource intensive process, especially on the State side.</p>	<p>Yes. The State has experience with the CMS Certification process, and has the appropriate dedicated resources to support the certification process.</p>

QUESTION / COMMENT	STATE RESPONSE
<p>Will the State dedicate staff to the CMS certification effort to ensure that the project meets the timelines outlined in the RFP?</p>	
<p>69 p. 92, Attachment 6.6, Section A.40.b. p. 284, Attachment I (Escrow Agreement), 1.1 and 1.2</p> <p>With regard to the 12.5% permanent withhold in the event that the selected contractor does not <i>“provide the necessary artifacts and documentation, or fails to begin or complete the corrective action(s) by the sixtieth (60th) day from the date the initial corrective action was requested by CMS”</i>:</p> <p>Can the State confirm what would happen if the contractor met the initial evidence delivery deadline (e.g. the December 1, 2018 date) to qualify for the temporary withholding but triggered the withholding above? Upon receipt of Certification from CMS, would the contractor still receive back the funds from the temporary withholding between December 1, 2018 to the 61st day from the date the initial corrective action request was received (e.g. when withholdings become permanent)?</p>	<p>The contractor must complete all corrective actions within 60 days of the CMS’ issuance of said corrective actions. No withheld funds will be released until after successful certification.</p>
<p>70 p. 92, Attachment 6.6, Section A.40.b.</p> <p>The Bidder’s Library in Amendment #1 of the RFP was updated to provide MECT 2.1.1, which is the latest version released on November 30, 2016. If CMS releases another version of the MECT toolkit prior to the start of the TN certification effort, will the State still certify under MECT 2.1.1 (as stipulated in the RFP) or will they expect to certify based on the most recent MECT release at the time the contract begins? Can the State also confirm that once DDI and certification efforts begin that they will not deviate from the selected MECT version?</p>	<p>When the Project Process Agreement (PPA) in MECT is developed with CMS, the version of the toolkit will be established at that time. The State, CMS and contractor parties involved will agree on the most applicable version of the toolkit for certification pursuit at that time.</p>
<p>71 p. 92, Attachment 6.6, Section A.40.b.</p> <p>Has the State identified which checklists are in scope for the PBM certification? Has the State begun a certification effort based on the new MECT process with other modules?</p>	<p>The State has experience with CMS’ Certification process. The checklists determined to be in scope for PBM will be confirmed as part of the MECT Project Process Agreement (PPA) process outlined in State’s response to question # 70.</p>
<p>72 p. 74, Attachment 6.6, A.23.a.1.</p> <p>Can the State please clarify what the expectation is regarding reporting of “tips” and what would be the expected solution as far as how tips are to be reported?</p>	<p>All tips (any program integrity case opened within the previous two (2) weeks) shall be reported to TennCare Office of Program Integrity and TBI MFCU simultaneously on a Bi-Monthly basis, which is the 1st and 15th of each month. OPI has a template for the contractor to fill out regarding internal tips along with a secure server (SFTP) for delivery.</p>

QUESTION / COMMENT	STATE RESPONSE
<p>73 p. 74, Attachment 6.6, A.23.a.2.</p> <p>Will the State require desk or on-site or both types of audits?</p>	<p>Both. State requires desk audits and 10 on-site audits per calendar quarter (40 per year).</p>
<p>74 p. 88, Attachment 6.6, A.39.e</p> <p>Would HCFA be willing to provide a few examples of recently acceptable clinical and non-clinical Performance Improvement Projects (PIPs)?</p>	<p>A.39.e is deleted. Please refer to item #5 of this amendment.</p>
<p>75 p. 115, Attachment 6.6, A42.b.1</p> <p>Reports from the Medicaid Evidence Based Decisions Project (MED) are required source materials. Is it the expectation that these reports would be available to the contractor via Tennessee's participation in that project or is the contractor expected to secure access to these reports?</p>	<p>Reports will be made available to the contractor via HCFA's participation. Yes, secure access is expected and use is restricted solely for HCFA programs.</p>
<p>76 p. 117, Attachment 6.6, A.42.d</p> <p>Is it acceptable to distribute meeting material exclusively by electronic means?</p>	<p>No.</p>
<p>77 p. 134, Attachment 6.6, A.45.a.3.</p> <p>The 42 CFR 438.210(b)3: Is it correct to assume that appropriately licensed pharmacists and physicians would meet the requirement of "appropriate expertise" to be able to render approvals and denials and that there is no expectation of specific provider type or specialist or sub-specialist physician input?</p>	<p>Confirmed.</p>
<p>78 p. 134, Attachment 6.6, A.45.a.2.</p> <p>Is the physician support expected to be available 24/7?</p>	<p>No.</p>
<p>79 p. 135, Attachment 6.6, A.45.a.10.</p> <p>Is the physician availability for reconsideration and clinical support referred to in this requirement expected to be 24/7?</p>	<p>No.</p>
<p>80 p. 137, Attachment 6.6, A.45.c</p> <p>Is it correct to assume that peer to peer suggests physician to physician contact in this instance and does not imply that the physician needs to be of any particular specialty or subspecialty?</p>	<p>Confirmed.</p>
<p>81 p. 138, Attachment 6.6, A. 45.a.3</p> <p>Since, based on the RFP text and the cited 42 CFR, HCFA will determine whether our proposed decision maker has "<i>appropriate clinical expertise in treating the enrollee's condition or disease</i>";</p>	<p>No. Board certified physicians with broad training and experience particularly in drug utilization and review are acceptable.</p>

QUESTION / COMMENT	STATE RESPONSE
<p>can HCFA confirm if there will be an expectation of specific provider types or specialists or sub-specialists being provided for grievances and appeals, for example of like specialty to the requesting physician? Or will board certified physicians with broad training and experience particularly in drug utilization and review be acceptable?</p>	
<p>82 p. 142, Attachment 6.6, A.45.d.14</p> <p>Please describe the current # of FTE of physicians working with the prior authorization unit and grievance /appeal procedures unit as well as the specialties of the involved physicians.</p>	<p>Please refer to State's response to question #81.</p> <p>Physicians are sub-contracted and have a broad training and experience</p>
<p>83 p. 138, Attachment 6.6, A.45.d</p> <p>1) How many reconsiderations that required physician input or peer to peer contact occurred over a recent 1-year period?</p> <p>2) How many grievances/appeals occurred over the last year?</p>	<p>During FY2017 (7/1/2016 – 6/30/2017), Magellan processed 3372 appeals.</p> <p>There were also 44 peer to peer requests that required physician input in the same time frame.</p>
<p>84 p. 269, Attachment D, Report #34</p> <p>Can the State please explain its expectation for calculating SRs on a monthly basis when the Federal Medicaid URA is not available until 1-4 months after a claim is processed?</p>	<p>This report is not about calculating SR's on a monthly basis. It is a tool for the PBM to report to HCFA on a monthly basis, any negotiations that have taken place, and the results, and any rates and possible savings that have been presented.</p>
<p>85 p. 268, Attachment D, Report #23</p> <p>Other than market share/shift data, what data/information is to be included in the Clinical Initiative Report?</p>	<p>Summary of market shift and success of shift data based on previous forecasts.</p>
<p>86 Is TennCare prohibited (by legislation or rule) from including any drug classes in the PDL program?</p>	<p>No.</p>
<p>87 RFP – Amendment #1</p> <p>Has CoverRx been designated by CMS as exempt from Best Price?</p>	<p>No.</p>
<p>88 RFP – Amendment #1</p> <p>How many pharmacies are currently in the TennCare network?</p> <p>Can the State please provide a detailed listing of these pharmacies, including out-of-state pharmacies that may be enrolled within a 50-mile radius of TennCare state lines?</p>	<p>Please refer to Item #7 of this amendment for RFP Attachment 6.7 amended to add pharmacy network link.</p>
<p>89 p. 95, Attachment 6.6, A.40.f.3.</p> <p>What are the volumes on the first days of the</p>	<p>For the first Monday of the last 4 months: 4/3 = 65,312</p>

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<p>month that should be used as a reference for testing load and stress?</p>	<p>5/1 = 79,243 6/5 = 53,076 7/3 = 53,294</p>
<p>90 p. 95, Attachment 6.6, A.40.e.2. Is the Unit Test Plan referenced in this item related specifically to user acceptance testing (UAT) type of tests?</p>	<p>Yes.</p>
<p>91 p. 98, Attachment 6.6, A.41.a. Regarding the requirement in the last paragraph to "<i>process claims on batch electronic media</i>": Would the State please clarify what is specifically meant in this requirement? i.e., CD/DVD of NCPDP D.0, SFTP of NCPDP Batch files, etc.?</p>	<p>Batch claims are only accepted from the State of Tennessee Public Health clinics. Claims should be accepted by the Contractor via either SFTP or CD/DVD of NCPDP batch files.</p>
<p>92 p. 53, Attachment 6.6, A.6 Regarding the section on Nondiscrimination Compliance Requirements: Can the state please verify that these guidelines are relevant to a contract with this scope of work? Can the state provide an example of the type of information they are looking to receive with this requirement?</p>	<p>Yes, these requirements apply to entities that accept federal funding. Copies of nondiscrimination/civil rights policies/procedures and trainings.</p>
<p>93 p. 107, Attachment 6.6, A.41.d.16. Is the current contractor identifying products that should be a medical benefit, or is the State?</p>	<p>The current Contractor is identifying all new products that should be a medical benefit, with the State has the final decision.</p>
<p>94 p. 191, Attachment 6.6, A.70.a.2. RFP language: "<i>The Contractor shall maintain a test environment that exactly mirrors the production environment.</i>" Can the State please clarify whether the mirrored environment must include the same data from the production environment?</p>	<p>Yes, same data.</p>
<p>95 p. 147, Attachment 6.6, A.46.c. The RFP states: <i>The Contractor shall install, operate, monitor and support an automated call distribution system that has capability to provide messaging regarding time to live agent pick up, tele-FAQs and fax-on-demand. The contractor's system shall record all calls in a digital format.</i> <i>The contractor shall allow State staff to monitor calls in real-time and hear specific calls made to the Help Desk if the State provides the date, time or callers number.</i></p>	<p>Question 1- Confirmed, except in the case of an investigation by Tennessee Office of Inspector General, MFCU, Tennessee Bureau of Investigation, Attorney General, etc. Question 2- HCFA collects HIPAA forms from enrollees when they wish to have family members, or other party's involved in their prescription benefit for questions or assistance. If an enrollee is on the phone and gives verbal permission for another interested party to receive information or ask questions, it should be granted by the Contractor, regardless if a HIPAA form is on file or not (the verbal permission suffices).</p>

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<ul style="list-style-type: none"> ▪ Please confirm that only State staff will need access to the call recordings. • What are the State's actions on the enrollee's behalf in terms of gathering a PHI disclosure, which provides consent to release call recordings that contain PHI/PII? • Is it permissible to provide recordings to the state in the form of WAV files through secure transmission as opposed to direct access into the vendor's internal tools? 	<p>We do not know of an instance where HCFA has ever shared a recorded phone conversation, based on a WAV file with another party where PHI is involved.</p> <p>Question 3- No. The contract requires both direct access and a retrievable, electronic copy of all call center calls.</p>
<p>96 p. 147, Attachment 6.6, A.46 p. 161, Attachment 6.6, A.53.a.7. p. 195, Attachment 6.6, A.70.c.8.</p> <p>Can the State identify how many calls are expected to come into to the call center for each program (i.e., TennCare, CoverRx, and CoverKids)?</p>	<p>TennCare: During FY2017 (July 1, 2016 – June 30, 2017), the PBM received 405,596 calls for TennCare</p> <p>CoverRx: During FY2017 (July 1, 2016 – June 30, 2017), the PBM received 20,032 calls for CoverRx</p> <p>CoverKids: 905 calls were received by the HCFA plan administrator, however BlueCross BlueShield of TN is not able to separate the number of calls made on CoverKids business from all of the Blues' business.</p>
<p>97 p. 215, Attachment 6.6, A.77.c.</p> <p>Does the State have up-to-date enrollee demographic data to utilize for CoverKids survey mailings?</p>	<p>Yes, the state has up to date enrollee demographic data to utilize for CoverKids survey mailings. It's the enrollee's responsibility to update their demographics within 14 days of any changes within the household.</p>
<p>98 Will the Contractor's Chief Compliance Officer fulfill this duty, or does the state expect an exclusive person for this? We do not have such a person other than the Chief E&C Officer. Can the Contractor choose its own committee from its existing employees?</p>	<p>Contractor's Chief Compliance Officer can fulfill duty.</p> <p>Yes, contractor can choose committee in compliance with CFR § 438-608</p>
<p>99 p. 227, Attachment 6.6, D.5</p> <p>Regarding Termination for Convenience: In the event there is such a termination, will contractor be compensated for any transition activities that may occur?</p>	<p>No.</p> <p><i>The Contractor shall be entitled to compensation for all conforming goods delivered and accepted by the State or for satisfactory, authorized services completed as of the termination date. In no event shall the State be liable to the Contractor for compensation for any goods neither requested nor accepted by the State or for any services neither requested by the State nor satisfactorily performed by the Contractor.</i></p>
<p>100 p. 227, Attachment 6.6, D.6</p> <p>Regarding Termination for Cause: Will the State consider increasing the termination for cause to 30 days, to be consistent with term for convenience?</p>	<p>Termination for Cause is brought about as a result of an immediate action, therefore, D.6 remains as immediate termination.</p>
<p>101 p. 228, Attachment 6.6, D.7</p> <p>Regarding Assignment and Subcontracting: Will the contractor be able to assign to a successor-in-interest or as a result of a merger or change in</p>	<p>Yes.</p>

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control?	
<p>102 p. 230, Attachment 6.6, D.20.d</p> <p>Given the broad scope of the indemnification, will the State consider replacing its broad indemnification with the following?</p> <p>“Indemnification. In the event of any unauthorized use or disclosure of Protected Health Information constituting a “Breach” as defined under 45 C.F.R. § 164.402 which is caused by the negligent act(s) or omission(s) of Business Associate, Business Associate agrees to indemnify STATE, to the extent Business Associate is responsible, from and against (i) any administrative fines or penalties assessed against STATE by the Secretary or other regulatory authority having jurisdiction; (ii) any award which may be made pursuant to a state Attorney General action and levied against STATE; and (iii) in the event of any such Breach requires the issuance of notice(s) to affected individuals pursuant to the relevant provisions of ARRA, all direct reasonable costs associated with production and delivery of such required notice(s). Business Associate’s indemnification obligations under this section are subject to STATE (a) making written demand for indemnification from Business Associate pursuant to the foregoing; (b) to the extent STATE has notice of same, promptly notifying Business Associate of any investigation or the filing of any action by the Secretary, any State Attorney General, or other regulatory authority having jurisdiction; (c) granting to Business Associate the right to determine the means and methods by which any required notices are delivered to affected individuals (Business Associate hereby acknowledging that STATE shall retain the right to determine the content of same), and (d) granting to Business Associate the sole right to control any associated defense or negotiation for settlement or compromise. Business Associate agrees to work cooperatively with STATE to ensure that liability is properly determined and assigned by the Secretary or other regulatory authority having jurisdiction with regard to any such Breach.”</p>	<p>Request Denied. We cannot accept this change. It limits the indemnification to breaches, which are not the only possible violations of HIPAA, further it does not include their subcontractors, and does not include all remediation actions potentially taken such as providing identity theft protection.</p>
<p>103 p. 29, Attachment 6.2, C.7</p> <p>RFP states: <i>“Describe how Respondent’s system will partial fill transactions including those from 340B pharmacies using a virtual 340B model per the specifications of the most current NCPDP version being utilized”</i></p> <p>Question: Can the State please provide clarification on a “partial fill transaction” and how it relates to 340B?</p>	<p>Please refer to Item # 6 of this amendment for language modification.</p>

QUESTION / COMMENT	STATE RESPONSE
<p>104 p. 126, Attachment 6.6, A.43.j</p> <p>ID Cards – Does the State have a preference on the material that the ID cards are printed on and how many total colors will likely be needed to print on the cards?</p>	<p>Please refer to Item # 7 of this amendment for updated RFP Attachment 6.7, Bidder's Library.</p>
<p>105 p. 147, Attachment 6.6, A.47.a</p> <ul style="list-style-type: none"> • Pharmacy Network – Does the CoverRx pharmacy network have the same reimbursement rate as the TennCare network? • Do providers have to pass the HCFA test in order to enroll in the CoverRx network? • Of the current networks today, how many are accepting EFT payments? 	<p>Please see the answer to question #35 for the answer to the reimbursement rate question.</p> <p>All 3 programs (TennCare, CoverRx and CoverKids) will have the same pharmacy network and the same rules for inclusion.</p> <p>An average of approximately 250 providers per week are paid via EFT.</p>
<p>106 p. 155, Attachment 6.6, A.50.e.</p> <p>Will eligibility for each of the 3 programs (TennCare, CoverRx, and CoverKids) be sent to the vendor separately?</p>	<p>Yes, the state will distribute separate enrollment files for each program.</p> <p>CoverRx – the current vendor will provide member database; ongoing enrollment process is responsibility of the vendor.</p>
<p>107 RFP Section 3.3.7.A</p> <p>Please clarify intent of this provision: <i>A Respondent must not submit a response as a prime contractor while also permitting one or more other Respondents to offer the Respondent as a subcontractor in their own responses. Such may result in the disqualification of all Respondents knowingly involved. This restriction does not, however, prohibit different Respondents from offering the same subcontractor as a part of their responses (provided that the subcontractor does not also submit a response as a prime contractor).</i></p>	<p>It means that the vendor can only submit a response as either the prime contractor, or as a subcontractor on another prime contractor, not both.</p>
<p>108 p. 112, Pro Forma Contract Section A.41.g.2</p> <p>Regarding the statement “...pricing methodologies will be set by TennCare rules and policies.”:</p> <p>Does the program require that the PBM reimburse pharmacies at the rates provided in the TennCare rules and policies (transparent model) or, alternatively, are the rates in such policies setting forth the rate that TennCare will reimburse the PBM (allowing the PBM to negotiate alternative rates with pharmacies – “non-transparent” model)?</p>	<p>There is no difference between the amount paid to the pharmacy and the amount paid to the PBM.</p> <p>The PBM may not recalculate the payment amount to pharmacy providers, and may not keep any portion of the payment from HCFA to the PBM.</p>
<p>109 p. 112, Pro Forma Contract Section A.41.g.2</p> <p>Regarding the statement “The Contractor’s system shall allow for such any price adjustments</p>	<p>Prior to implementing the Actual Acquisition Cost reimbursement model, TennCare has made MAC adjustment requests in the past. We have not made</p>

QUESTION / COMMENT	STATE RESPONSE
<p><i>submitted by the HCFA Pharmacy Director...to be effective within two (2) business days.”:</i></p> <ol style="list-style-type: none"> 1. What types of changes might be required? Can examples of the type of changes required be provided? 2. What is the approximate volume of such changes based upon past history? 	<p>change requests since April 1, 2017 and beginning AAAC. This type of a request could be made for the other programs that still will utilize MAC pricing, although we anticipate that it would not be a common occurrence.</p> <p>CoverRx – MAC Rate Review Requests</p> <p>CoverRx – less than 5 requests per month since April 1, 2017.</p>
<p>110 p. 113, <i>Pro Forma Contract Section A.41.g.7 (a)/(b)</i></p> <p>How often will the PBM be required to distribute/collect surveys?</p>	<p>Please refer to State’s response to question #37.</p>
<p>111 p. 167, <i>Pro Forma Contract Section A.53.a.5</i></p> <p>Regarding the statement: <i>“The Contractor shall use the TennCare Ambulatory Pharmacy Network described in Section A.47 above.”:</i></p> <p>Please confirm that the network participants are required to be the same as in the TennCare network and, as a result, only pharmacies who agree to both reimbursement rates (ie AAC/NADAC for TennCare; AWP/MAC for CoverRx) will be included in the network.</p>	<p>Confirmed.</p>
<p>112 p. 180, <i>Pro Forma Contract Section A.54.g.2 & 7</i></p> <ol style="list-style-type: none"> 1. Does the program require that the PBM reimburse pharmacies at the rates provided (transparent model) or, alternatively, are the rates in such policies setting forth the rate that TennCare will reimburse the PBM (allowing the PBM to negotiate alternative rates with pharmacies – “non-transparent” model)? 2. Will claim reimbursement rates for CoverKids mirror those for CoverRx? 	<p>Please refer to State’s response to question #108.</p> <p>The CoverKids program will utilize the commercial claim reimbursement rates.</p> <p>CoverRx and CoverKids reimbursement rates are not the same.</p>
<p>113 p. 161, <i>Pro Forma Contract Section A.50.f</i></p> <p>Prescription Limit Letters – Please provide additional details on this requirement</p>	<p>Please refer to RFP Attachment 6.7, Item #7 of this amendment for examples of required enrollee notices.</p>
<p>114 p. 134, <i>Pro Forma Contract Section A.45.a.1</i></p> <p>Requirement indicates that the help desk must be staffed by a licensed pharmacist to address systems calls. Can the help desk be staffed by licensed PA technician and/or non-licensed health care professional/layperson (e.g., CSR or CSL)? Ultimately, does it have to be a licensed clinical</p>	<p>Yes, the help desk may be staffed by licensed PA technician and/or non-licensed health care professional. However, a licensed clinical pharmacist must be on hand for clinical questions, PA denials, pharmacist-only PA reviews.</p>

QUESTION / COMMENT	STATE RESPONSE
pharmacist.	
115 p. 101, <i>Pro Forma</i> Contract Section A.41.c.3 CMS Rebate Eligible Drug File - What is the process for obtaining the most current CMS rebate eligible file for identify and deny claims (unless specifically instructed differently by the State) that contain National Drug Code (NDC) numbers for which drug rebates?	There is an indicator on the FDB file that indicates whether the manufacturer has a contract for rebates with CMS. The CMS list of Covered Outpatient Drugs is available on their website.
116 p. 209, <i>Pro Forma</i> Contract Section A.71.a Formulary changes will be reviewed by the Contractors pharmacy and therapeutics committee and coordinated with the Contractor's rebate offers, and financial modeling support. How often does P&T committee meet? How soon after formulary changes are provided do we have to implement?	Our expectation is to use the Contractor's P&T Committee and rebate contracts for CoverKids.
117 Will bidders receive claims utilization data for analysis?	TennCare utilization showing top drug classes and top drugs by volume and amount paid to pharmacies is available in all quarterly DUR Board meeting presentations, found at https://tenncare.magellanhealth.com and then "Committees" and "DUR Committee"
118 What is the current enrollment by plan by product?	TennCare: Total on 7/1/2017 is 1,414,386 in multiple groups based on eligibility and copay type CoverRx: One Plan only: June 2017- 33,143 members CoverKids: 72,600 in 4 different plan groups.
119 RFP Amendment 1 Re-release, 3.1.1.2, Technical Response Is it permissible to use a smaller font than the 12 point font for tables and graphics within the proposal response?	Yes.
120 RFP Amendment 1 Re-release, Attachment 6.2, A.5. Please confirm that a full Dun and Bradstreet report containing credit information will satisfy the credit bureau report requested in A.5.	Confirmed.
121 RFP Amendment 1 Re-release, Attachment 6.2, B.17 In RFP Section B.17, page 23, Bidders are required to provide customer references from individuals who are not current or former State employees for projects similar to the goods or	A completed project would be a contract that has completed at least the original term and has been extended to optional years, or a contract that successfully completed (not terminated) entire term of a contract.

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<p>services sought under this RFP and which represent: These references are to include two accounts Respondent currently services that are similar in size to the State and three completed projects. Please clarify the definition of completed projects.</p>	
<p>122 RFP Amendment 1 Re-release, Attachment 6.2, C.9</p> <p>Please confirm/clarify whether HCFA wants respondents to submit their national formulary to meet the requirement for the CoverKids PDL/formulary as outlined in C.9.</p>	<p>Yes. Respondents should submit their national formulary to meet the requirement for CoverKids PDL/Formulary as outlined in C.9.</p>
<p>123 RFP Amendment 1 Re-release, Attachment 6.6, A.27.a.1</p> <p>Does the date the overpayment is identified count as the date the overpayment is approved for recovery by HCFA?</p>	<p>No. The date that the overpayment is identified may be some period of time after the error was made.</p> <p>All overpayments are recouped back to the original date that the error was made, not the day when the error was discovered.</p>
<p>124 RFP Amendment 1 Re-release, Attachment 6.6, A.39.e</p> <p>Please confirm that the selected vendor may complete the two (2) clinical and three (3) non-clinical Performance Improvement Projects (PIPs) over the full term of the contract. Should the PIPs pricing be included in the firm fixed fees or priced out separately as an optional item?</p>	<p>Please refer to State's response to question #74 and Item #5 of this amendment.</p>
<p>125 RFP Amendment 1 Re-release, Attachment 6.6, A.41.d.14.d.2</p> <p>This section states that the only reject code that can count as a TPL claim is NCPDP code 41 being the only remaining reason for the claims denial. Can this be extended to include NCPDP code 13, so that if there is a need to specify the portion of the TPL segment that needs to be corrected, the claim would not be excluded from cost savings reporting?</p>	<p>Yes. NCPDP code 13 can be also included.</p>
<p>126 RFP Amendment 1 Re-release, Attachment 6.6, A.41.d.14.d.2</p> <p>In terms of the first fill date, if there are multiple drugs being filled on the first fill date, and the original claim is rejected for a 41, and then the insurance bills the provided insurance for the remaining prescriptions on that day, would those claims count as cost avoidance, given that they would not be rejected with a 41?</p>	<p>It would all depend on the flow in the pharmacy, which isn't controlled by the contractor or by HCFA.</p> <p>In the pharmacy, if the person entering information and transmitting claims sends them all before seeing the denials, they would all result in "41" denials. If the person looks at the results from the first claim before sending the rest, there may be only one "41" denial.</p>
<p>127 RFP Amendment 1 Re-release, Attachment 6.6, A.42.e</p> <p>This section states <i>"the quarterly rebate invoices shall be generated for all pharmaceutical</i></p>	<p>The Quarterly Rebate Invoices will be generated for all pharmaceutical manufacturers and TennCare approval by thirty (30) days after the receipt of the quarterly CMS file for Supplemental Rebates.</p>

QUESTION / COMMENT	STATE RESPONSE
<p><i>manufacturers and state approval by thirty (30) days after receipt of the quarterly CMS file for supplemental rebates and sixty (60) days for federal rebates.</i>" CMS requires federal rebate invoices be sent by the 60th day after the close of the quarter, which differs from the requirement. Is the contractor to follow CMS requirements and submit invoices 60 days after quarter close (normally around 15-20 days after receipt of CMS file)?</p>	<p>The Quarterly Rebate Invoices shall be generated for all pharmaceutical manufactures and TennCare approval by sixty (60) days after the receipt of the quarterly CMS file for Federal Rebates</p>
<p>128 RFP Amendment 1 Re-release, Attachment 6.6, A.42.e</p> <p>Regarding past due notifications, the requirement states <i>"Notifications shall be issued within 5 days of delinquent date for supplemental rebates"</i>. Is the State's definition of delinquent date the date of the past due notification (i.e. 45, 75 or 90 days) making the due date 50, 80, or 95 days? This only references supplemental rebate but this requirement looks to be for all rebate programs (federal, supplemental, diabetic supply, CoverRx, and CoverKids). Please confirm.</p>	<p>Delinquent past due notifications shall be collected by State for all Rebate Programs (i.e. 45, 75 and 90 days)</p> <p>The CoverKids program does not have supplemental rebates.</p>
<p>129 RFP Amendment 1 Re-release, Attachment 6.6, A.42.e</p> <p>Please confirm the selected vendor will be responsible for all rebate history back to 1991 Q1.</p>	<p>Confirmed.</p>
<p>130 RFP Amendment 1 Re-release, Attachment 6.6, A.43.i.2</p> <p>Regarding the potential establishment of a risk-bearing entity, would the State prefer that Respondents provide fixed monthly pricing for these services separate from the monthly Administrative Fee required by the RFP?</p>	<p>No. Please provide the monthly administrative fee as requested.</p>
<p>131 RFP Amendment 1 Re-release, Attachment 6.6, A.45.a.4</p> <p>When a reconsideration level request is received from a provider, does HCFA require that a Notice of Adverse Benefit Determination (NABD) be mailed to the member, or will a fax notification of decision be deemed adequate notification?</p>	<p>A Notice of Adverse Benefit Determination must be mailed to the member.</p>
<p>132 RFP Amendment 1 Re-release, Attachment 6.6, A.45.a.6</p> <p>Can the existing TN VPN connection which is dedicated to TN be re-used for the new contract?</p>	<p>No. A new connection will be required since it will have a different terminating IP address.</p>
<p>133 RFP Amendment 1 Re-release, Attachment 6.6, A.45.b</p> <p>Please provide an estimate of the number of PA requests where querying Controlled Substance</p>	<p>During FY2017 (July 1, 2016 – June 30, 2017), the PBM processed 34,022 PA's involving Controlled Substances.</p>

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Monitoring Database would be applicable/required.	
<p>134 RFP Amendment 1 Re-release, Attachment 6.6, A.45.d.5.b</p> <p>Is the intent for a copy of the Controlled Substance Monitoring Database profile to be provided only to the member who requests such data? Or is the intent for this information to be provided to TennCare? If the intent is to provide this information to TennCare, how does that fit into the regulations surrounding the CSMDDB?</p>	<p>The intent is to use the information found in the CSMDDB like all other health records used to make a determination if the requested drug is appropriate or not, and should be approved or denied.</p> <p>The following language in TCA 53-10-306 was added in 2016, after TennCare pharmacy personnel worked closely with the Executive Director of the Controlled Substance Monitoring Database:</p> <p>(a)....and to the following persons.....:</p> <p>(4) A licensed pharmacist conducting drug utilization or medication history reviews who is actively involved in the care of the patient or making decisions regarding care of the patient or patient enrollment.</p>
<p>135 RFP Amendment 1 Re-release, Attachment 6.6, A.45.d.8.b, A.45.d.8.c, and A50.d</p> <p>NABD timing section indicates a Notice of Adverse Benefit Determination (NABD) must be issued within 24 hours of receiving a PA request. A.50.d indicates notices to be mailed daily except for Sunday. Does section A.45.d.(8) define 'issue' of an NABD as the decision date of the prior authorization?</p>	<p>Yes. The NABD must be mailed on the day that the prior authorization request is denied.</p>
<p>136 RFP Amendment 1 Re-release, Attachment 6.6, A.45.d.17.d (second d)</p> <p>What constitutes a failure of an appealed case?</p>	<p>A failure of an appealed case is when an enrollee has appealed an adverse benefit determination and TennCare discovers that the contractor has failed to issue a timely NABD or a correct and complete NAMB.</p> <p>A failure is also when the contractor fails to completely respond or not respond timely to TennCare during the Reconsideration component of an appeal and when it fails to timely provide the drug(s) that TennCare may have directed it to provide.</p>
<p>137 RFP Amendment 1 Re-release, Attachment 6.6, A.45.e</p> <p>The State's re-released RFP contains an A.45.d requirement followed by an A.45.f requirement. Please confirm that there is no requirement for A.45.e in the Pro Forma Contract.</p>	<p>Confirmed. Please refer to Item # 4 of this amendment for amended language.</p>
<p>138 RFP Amendment 1 Re-release, Attachment 6.6, A.47.b</p> <p>Given that the reimbursement rate is determined by HCFA and MTM is furnished by Tennessee-licensed pharmacists, is the contractor's role limited to developing and setting up a network with appropriate policies and procedures to implement MTM (with the reimbursement as a pass-through fee, once it is determined)?</p>	<p>MTM administration, reimbursement, and network management has been delegated to TennCare's managed care partners and the use of the pharmacy vendor is unlikely. However, the option for use at a future date is still a possibility. Please refer to Item #8 of this amendment for amended A.47.b.</p>
<p>139 RFP Amendment 1 Re-release, Attachment 6.6,</p>	<p>Refer to State's response to question #138.</p>

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<p>A.47.b</p> <p>Given the potential variability in the volume of members deemed eligible for the MTM program, should MTM pricing be included in the firm fixed fees or priced out separately as an optional item?</p>	
<p>140 RFP Amendment 1 Re-release, Attachment 6.6, A.47.b</p> <p>Is there a specific volume of members that should be targeted for MTM? If so, what is the volume?</p>	<p>Refer to State's response to question #138.</p>
<p>141 RFP Amendment 1 Re-release, Attachment 6.6, A.47.b</p> <p>Are there specific therapeutic areas of interest for MTM? If so, what are they?</p>	<p>Refer to State's response to question #138.</p>
<p>142 RFP Amendment 1 Re-release, Attachment 6.6, A.47.b</p> <p>Does the State anticipate requesting the selected vendor to implement the TennCare MTM Pilot Program at program go-live, 6/1/18? If the State anticipates that the MTM program will be implemented at some point after go-live, would the State prefer that Respondents provide fixed monthly pricing for these services separate from the monthly Administrative Fee required by the RFP?</p>	<p>Refer to State's response to question #138.</p>
<p>143 RFP Amendment 1 Re-release, Attachment 6.6, A.48.f.1</p> <p>Will the requested field audits be included in the required 10 quarterly field audits?</p>	<p>Yes. If a time-sensitive field audit is requested, and the Contractor has already performed the required 10 quarterly field audits, the Contractor would only have to perform 9 field audits in the next quarter.</p>
<p>144 RFP Amendment 1 Re-release, Attachment 6.6, A.70</p> <p>Please provide the CoverKids help desk/call center volumes, including number of calls and call handle times.</p>	<p>The PBM does not currently separate the CoverKids line of business from the other BlueCross BlueShield of Tennessee lines of business. This number would mostly be based on mail orders and prior authorization requests.</p>
<p>145 RFP Amendment 1 Re-release, Attachment 6.6, A.70.h</p> <p>Please provide an estimated volume of manual claims for the CoverKids program.</p>	<p>There were less than 25 CoverKids manual pharmacy claims processed on an annual basis.</p>
<p>146 RFP Amendment 1 Re-release, Attachment 6.6, A.71.k</p> <p>In the Rebate Administration section for CoverKids, there is a reference to accepting historic data from the current CoverKids vendor for rebate services. How much history exists? What rebate rates are used currently to invoice for CoverKids?</p>	<p>With the current PBM, we have prescription drug claims data back to 1/1/13. Currently, rebates are based on the commercial preferred formulary</p>

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<p>147 RFP Amendment 1 Re-release, Attachment 6.6, A.75.a</p> <p>Are the RetroDUR requirements for CoverKids all report-driven? The RFP contains requirements to identify trends in providers' prescribing habits, members who may be abusing resources/poly-pharmacy, and quality of care and potential fraud and abuse. Would the State clarify what its expectations are for contractor activity regarding RetroDUR interventions subsequent to identification of issues? Please provide details as to the types of interventions and number of interventions that the State requires to be performed.</p>	<p>HCFA plans to include CoverKids' claims with TennCare claims and include both programs in the existing TennCare RetroDUR program.</p>
<p>148 RFP Amendment 1 Re-release, Attachment 6.6, A.75.d</p> <p>Please provide an estimated volume of appeals/grievances for the CoverKids program.</p>	<p>BlueCross handles an average of 7 appeals per month for CoverKids.</p> <p>There were no grievances filed in 2016.</p>
<p>149 RFP Amendment 1 Re-release, Attachment 6.6, C.3.2.5.d</p> <p>The Payment Methodology states that costs for certain mailings for the TennCare program shall be handled as pass-through costs to the State. Please confirm that applicable mailing costs for the CoverRx and CoverKids programs should be handled as pass-through costs to the State.</p>	<p>Confirmed.</p>
<p>150 RFP Amendment 1 Re-release, Attachment A, Definitions and Acronyms, Number 46</p> <p>In the first fill date definition, it is defined as the day on which the new TPL information provided by the Contractor's POS system to the pharmacy attempting to fill an enrollee prescription results in an NCPDP code 41. If there is a new TPL segment that when provided on the first day, is not in a place in the member's benefit stage where the other payer will pay for a portion of the claim but at a later date the member hits the threshold where the other payer will pay out? Can this be extended to the first day on which new TPL information provided by the Contractor's POS system pays for all of or a portion of a submitted claim?</p>	<p>Language request denied.</p>
<p>151 RFP Amendment 1 Re-release, Attachment A, Definitions and Acronyms, Number 46</p> <p>When referring to the first fill date, would that be referring to the date of service, or the adjudication date of the claim, and if it refers to the date of service, and the final adjudication takes place after the date of service, would it still fall under the</p>	<p>The first time that a pharmacy submits a claim that is denied with a "41" reject code, whether it be the date of service or the adjudication date.</p> <p>If the adjudication date is after the service date, and a claim is denied for "41" if there are others that were denied for "41" between the two dates, then the claim submitted on the adjudicated date is not considered the</p>

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first fill date criteria?	"First Fill Date".
<p>152 Bidders Library, TennCare Reports</p> <p>The Monthly Call Center Service Level (SLA) report (document titled Help Desk and PA SLA) for TennCare shows 34,497 calls received during January, 2017 on the first page. On page 5 of the same report, the Grand Total of call types is shown as 71,924. Would HCFA please explain the difference in these statistics?</p>	<p>There were 71,924 Call Type issues for TennCare, inside of those issues, were 34,497 calls and 25,536 faxes making that a total of 60,033 calls and faxes. However, there were 71,924 issues because some calls involved more than one issue.</p>
<p>153 Section 1.1. CoverRx Program (CoverRx): The State's pharmacy assistance program...</p> <p>Does CMS recognize CoverRx as a State Pharmaceutical Assistance Program (SPAP)?</p> <p>In order to estimate the level of effort for all requirements, the vendor needs to be able predict the expected volumes of services to be provided. Therefore, would the State please provide expected enrollment levels for TennCare, CoverRx, and CoverKids? Additionally, could the State please provide current utilization statistics for each program?</p> <p>Could the State please provide current and expected volumes of the clinical, technical, and member call centers as well as current claim volumes for each of the three populations?</p>	<p>The CoverKids expected enrollment levels for January 1, 2020 should be around 75,000.</p> <p>CoverKids pharmacy calls are received through the Plan Administrator, see question #96. The technical call volume would be to Express Scripts (BlueCare Pharmacy Contractor) and additional data not readily available.</p> <p>Please refer to State's response to question #46 for CoverKids claims volume.</p> <p>CoverRx - CMS does not recognize CoverRx as a State pharmacy assistance program. Enrollment approximately 32,000 (not to exceed 50,000). Currently approximately 48% utilizing benefits. Refer to State's response to questions #46 and #96.</p> <p>Please see the answer to Question #28 for TennCare claims volume.</p>
<p>154 RFP Attachment 6.2, Section C.7: <i>Describe your capabilities to allow 340B covered entities to flag claims that have been submitted with 340B pricing, and those that have not, and your experience in working with Labelers to submit non-340B claims from covered entities for federal rebates.</i></p> <p>Currently, are claims that have been submitted with 340B pricing excluded from rebate invoicing at the claim level or at the provider level?</p>	<p>Claims from 340B providers are currently excluded from rebate invoicing at the level of the provider.</p> <p>On 4/1/2017, with the implementation of the new Acquisition Cost reimbursement methodology, TennCare also began to require 340B Covered Entities to transmit 340B claims with the NCPDP indicator fields flagged. Our plans are to exclude claims from 340B at the claims level, but we have not implemented this yet.</p> <p>Please refer to Item #6 of this amendment.</p>
<p>155 RFP Attachment 6.2, Section C.9: <i>Describe how the Respondent plans to implement, maintain, and modify (at TennCare's request), include details related to timing and quality assurance, including details related too timing and quality assurance:</i></p> <p>(1) Preferred Drug List (PDL), quantity limits, and clinical criteria</p> <p>(2) Prescription limits</p> <p>(3) Prior authorizations</p> <p>(4) Morphine Daily Equivalence calculations</p>	<p>Please refer to Item # 7 of this amendment for information.</p>

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<p><i>for individual enrollees</i></p> <p>(5) Overrides</p> <p>Can TennCare provide a list of its current UM programs?</p>	
<p>156 RFP Attachment 6.2, Section C.10: <i>Provide details on your system's capabilities to manage opioid overuse, and overuse of opioids in combination with other CNS depressants and stimulants.</i></p> <p>Could TennCare provide information regarding their current opioid risk management program in place?</p>	<p>Please refer to Magellan's TennCare's website, which includes all clinical criteria and PA forms. The respondent can also find information in the Agenda, meeting minutes and presentations from past PAC and DUR Board meetings.</p> <p>Refer to State's response to question #155 and Item #7 of this amendment..</p>
<p>157 RFP Attachment 6.2, Section C.9:</p> <p><i>Provide a disruption analysis elated to a switch from the current TennCare PDL to any alternate PDL that you propose TennCare consider. Please indicate whether the disruption on the drug is due to a supplemental rebate contract or not.</i></p> <p>Could HCFA provide a copy of TennCare's current PDL complete with NDC numbers to assist the Respondent in completing this analysis?</p>	<p>Please refer to Item #7 of this amendment.</p>
<p>158 Cost Proposal: Is the Evaluation Score for this section equal to the Risk Level checked by the Respondent? If not, please explain how it is calculated.</p>	<p>Correct.</p>
<p>159 A.6.h.5. <i>Subcontractors identified in Contractor's response to the RFP associated with this Contract that were previously approved by the State are deemed to be approved subcontractors. Contractor may only substitute an approved subcontractor or add anew subcontractor at the discretion of the State, and with the State's prior written approval after review of the proposed subcontract. All subcontract agreements entered into by the Contractor for the provision of HCFA PBM Program services shall require the subcontractor to comply with all applicable provisions of this Contract. The State reserves the right to refuse approval, in its sole discretion, of any proposed subcontract or subcontractor.</i></p> <p>Would the State consider limiting the scope of this section to include only those subcontractors being hired for the sole-purpose of participating in this contract? In other words, subcontractors that provide shared services across our book of</p>	<p>Request denied.</p>

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<p>business would not need to be included.</p>	
<p>160 <i>A.10.a. The Contractor shall submit one (1) complete copy of each template Provider Service Agreement/Addendum, and any revisions thereof, to HCFA once they have been approved by the Tennessee Department of Commerce and Insurance (TDCI) and prior to entering into such agreements with Providers. The Contractor shall also provide HCFA with copies of the face and signature pages of all fully executed Provider Service Agreements/Addenda no later than thirty (30) days prior to Go Live of the TennCare and CoverRx PBM Programs. Thereafter, Contractor shall provide HCFA with any new Provider Service Agreements/Addenda it enters into, as well as any documentation evidencing termination of any Provider Service Agreements/Addenda, within five (5) business days of full execution of such documents. All documentation required to be provided pursuant to this Section A.10.a shall be transmitted using the electronic format specified in writing by the State.</i></p> <p>Would the State consider allowing the vendor to have one Provider Service Agreement that is encompassing of all three programs, rather than one Agreement per program?</p>	<p>HCFA currently has both TennCare and CoverRx in the same provider contract, and plan to add CoverKids to this contract via Addenda and Attachments prior to going live in 2020.</p>
<p>161 <i>A.32.b.31 The Contractor shall dedicate two (2) Subject Matter Experts (SMEs) to be onsite to participate in the disaster recovery drills.</i></p> <p>Can the State please identify the frequency and expected level of effort for these drills?</p>	<p>The State anticipates that the drills will not occur any more frequently than once a year and the State will provide adequate advance notice of the drill to the Contractor. The Contractor's expected level of effort for each disaster recovery drill is set forth in Contract Section A.32.</p>
<p>162 <i>A.38. Performance Guarantee</i></p> <p><i>The State may, in its sole discretion and upon thirty (30) days prior written notice, select any other services or deliverables required in the Contract to use for determining the amount of Administrative Fee to be paid by the State each month for each HCFA PBM Program. In addition to selecting different performance metrics, the State may also use this thirty (30) day notice to change the weight of the selected performance metrics to be higher or lower than the weights currently shown in Attachment G.</i></p> <p>If the State were to exercise its rights under this section, would the contractor have the ability to modify its pricing to accommodate those changes?</p>	<p>No. HCFA expects the contractor to guarantee their performance throughout the entire Scope of Work.</p>
<p>163 <i>A.40.a. TennCare Services Implementation Plan Overview. Implementation of the TennCare PBM Program portion of this Contract shall be</i></p>	

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<p><i>conducted as series of defined phases described below, with the date for Go Live, on which the Contractor is to assume full responsibility for operation of TennCare PBM Program, scheduled for June 1, 2018. The Contractor shall be required to complete all the tasks, obligations and responsibilities listed under each phase by the dates identified in the TennCare Project Plan which shall be developed by the Contractor and an implementation contractor procured by the State (Implementation Contractor) and submitted to the State for review and approval in accordance with the TennCare Services Plan Implementation Schedule. The TennCare Project Plan shall be prepared using Microsoft Project or such other program as the State may direct, and shall include a detailed timeline description of all work to be performed both by the Contractor, Implementation Contractor and the State. The TennCare Project Plan shall also include a description of the participants on the Contractor's, Implementation Contractor's and the State's transition teams and their roles and schedules of meetings.</i></p> <p>By "Implementation Contractor" does the State mean an Independent Verification and Validation (IV&V) contractor? What is the expected ongoing interaction between the Implementation Contractor and the PBM? What role or authority does the Implementation Contractor play during the implementation period?</p>	<p>The Implementation Contractor will work closely with both HCFA and the Contractor during the transition period of October 1, 2017 – May 31, 2018 to ensure all tasks for readiness prior to Go Live on June 1, 2018 have been accomplished all appropriate testing is completed and successful. The HCFA pharmacy team retains all authority for the content of the contract and implementation of the contract.</p>
<p>164 <i>A.40.j. TennCare PBM Services Implementation Plan and Readiness Review Schedule. Within twenty (20) days of the Effective Date of this Contract, the Contractor shall submit a TennCare PBM Services Implementation Plan and Readiness Review Plan (TennCare Services Implementation/Readiness Plan) containing all necessary deliverables and activities with projected dates for delivery and/or completion of these items. Upon approval of the TennCare Project Plan by the State, HCFA will direct the Contractor to begin work on the TennCare Services Implementation/Readiness Plan through a Control Memorandum and Control Directive in which all deliverable and activity due dates match the dates in the approved TennCare Project Plan.</i></p> <p>Please confirm the expected format of the TennCare PBM Services Implementation Plan and Readiness Review Plan. Is it acceptable to include this level of detail as part of the Project Plan or does HCFA expect a separate document?</p>	<p>The State expects a separate document.</p>
<p>165 <i>A.41.b Cash Flow, Section 3 If the Contractor</i></p>	<p>The Contractor pays the checks from its own bank</p>

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<p><i>submits a claims payment request and the State overpays the claim, the State reserves the right to withhold the overpaid monies.</i></p> <p>Does the Contractor pay the checks from its own bank account and then request payment from the State? If not, is there a State funded bank account that is used for such payments? Would the State funded bank account be maintained by the Contractor?</p>	<p>account. However, the State intends to fund the payments prior to the payment release schedule. For example, the contractor shall deliver identified files to the State on the preceding Friday of each week. The State will in turn fund the Contractor's bank account by the Friday of the next week allowing the payments to be released.</p>
<p>166 <i>A.41.b Cash Flow, section 5 The term "pay" means that the Contractor shall either send the provider cash or cash equivalent in full satisfaction of the clean claim...</i></p> <p>Does the Contractor pay the automatic deposits to the providers from its own bank account or is there a State funded bank account that is used for such payments?</p>	<p>The Contractor pays the checks from its own bank account. However, the State intends to fund the payments prior to the payment release schedule. For example, the contractor shall deliver identified files to the State on the preceding Friday of each week. The State will in turn fund the Contractor's bank account by the Friday of the next week allowing the payments to be released.</p>
<p>167 <i>A.41.e.5. TennCare Pro-DUR Enrollee Profile Records - The Contractor's system shall provide and maintain enrollee profiles for Pro-DUR processing of submitted claims. Recipient profiles shall be based on inferred diagnoses from pharmacy claims, actual diagnoses from medical claims provided by the State to Contractor, and other available data.</i></p> <p>Please confirm the number of months of medical data that will be provided for conversion into the successful bidders system.</p>	<p>15 months of medical data will be provided to the successful bidder.</p>
<p>168 <i>A.42.b. The Contractor shall develop and present to the TennCare Pharmacy Advisory Committee the clinical and pharmacoeconomic review criteria the Contractor used to make recommendations regarding preferred and non-preferred drugs and the specific written guidelines/criteria to be used in the administration of the prior authorization of nonpreferred drugs.</i></p> <p>Are the actual results from the pharmacoeconomic modeling presented to the TennCare Pharmacy Advisory Committee or just the pharmacoeconomic review criteria?</p> <p>If the actual results are presented, is information regarding rebates (Federal and/or supplemental) withheld or presented?</p>	<p>See T.C.A 71-5-197, 71-5-2404. Results are presented rebate values are withheld or modified to show approximate value [\$, \$\$, \$\$\$, \$\$\$\$].</p>
<p>169 <i>TennCare Pharmacy Advisory Committee: The Contractor shall attend, support and facilitate meetings of the TennCare Pharmacy Advisory Committee (PAC) as necessary to maintain the</i></p>	<p>See T.C.A 71-5-197, 71-5-2404. It is a combined effort for all stakeholders. The vendor makes recommendations to the PAC. The PAC has the option to accept, reject or modify recommendations from the vendor. TennCare has the final authority to adopt,</p>

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<p><i>TennCare PDL. Such support shall include the responsibility to develop drug class reviews, prior authorization criteria, quantity limits and step therapy recommendations. The Contractor shall create and maintain records including contact information and duration of each TennCare PAC Committee member's appointment. The Contractor shall coordinate with the State to determine quarterly dates for the PAC meetings. The Contractor shall also be responsible for arrangements and costs for meeting facilities, distribution of meeting materials and preparation of meeting minutes. At the State's request, the Contractor shall create and maintain a contingency plan in accordance to sunset rules of the State. No less than twenty-one (21) business days prior to the scheduled PAC meeting, the Contractor shall have the meeting materials approved by the State and distributed to committee members. Meeting minutes are to be taken by Contractor and the draft copy shall be available for review by the appropriate State staff no more than four (4) weeks after the scheduled PAC meeting. After approval, the draft minutes shall be disseminated to PAC members for approval at the next regularly scheduled PAC meeting.</i></p> <p><i>After approval of the minutes they shall be posted on the TennCare and Contractor's dedicated websites. The TennCare Pharmacy Advisory Committee make up and duties may be found at Tennessee Code Annotated (TCA) § 71-5-2401, et seq.</i></p> <p>Is TennCare managing the PDL itself? Or is TennCare expecting the vendor to manage the PDL through its P&T committee?</p>	<p>reject, or modify PDL recommendations and criteria.</p>
<p>170 <i>A.42.e. The Contractor shall process, invoice and collect federal (OBRA, CMS) and supplemental rebates through the Contractor's rebate administration systems, and shall assume all responsibility for uncollected receivables for each HCFA PBM Program at Go Live for each program.</i></p> <p>In regard to federal rebates, are OBRA and CMS synonymous? If not, please explain the difference(s) between the two</p>	<p>In regard to federal rebates, OBRA and CMS are synonymous.</p>
<p>171 <i>A.42.e. The Contractor shall provide the designated State staff data files that contain the specific information and in the specified format as required by the State.</i></p>	<p>If drug rebate then the federal layouts at www.cms.gov should be used for all data reporting.</p>

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<p>Please provide the layouts for the data that the Contractor will be required to provide to designated State staff.</p>	
<p>172 <i>A.42.e. The Contractor shall import historical quarterly rebate data into their rebate management system, provided by the State's current rebate vendor.</i></p> <p>Is all the historical data that the Contractor will receive in an electronic format? If not, please identify by rebate quarter, program (e.g., Federal, Supplemental, MCO) and data type (e.g., claims, invoices, payments, disputes) the historical data that will be provided in an electronic format and the historical data that will not be provided in an electronic format.</p>	<p>All data from the incumbent will be in electronic format. Data prior to 2001q4 is managed by HCFA.</p> <p>HCFA has approximately 30 cases of microfiche data from prior to 2001q4 that we would want to be housed by the Contractor.</p>
<p>173 <i>A.42.e. The Contractor shall import historical quarterly rebate data into their rebate management system, provided by the State's current rebate vendor.</i></p> <p>For historical data, will invoice data be provided by rebate quarter / program / NDC and include original invoice records and prior quarter adjustments? If not, please explain or provide the layout of the invoice data that the Contractor will receive.</p>	<p>All available data from the incumbent will be provided as stated in the question.</p>
<p>174 <i>A.42.e. The Contractor shall import historical quarterly rebate data into their rebate management system, provided by the State's current rebate vendor.</i></p> <p>For historical data, will payment data include check number, payment postmark date, rebate quarter / program / NDC, and other ROSI/PQAS data elements? If not, please explain or provide the layout of the payment data that the Contractor will receive.</p>	<p>All available data from the incumbent will be provided as stated in the question.</p>
<p>175 <i>A.42.e. The Contractor shall import historical quarterly rebate data into their rebate management system, provided by the State's</i></p>	<p>All available data from the incumbent will be provided as stated in the question.</p>

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<p><i>current rebate vendor.</i></p> <p>For historical data, will dispute status information (e.g., resolved, unresolved) be provided? If not, please explain how the status of a dispute will be conveyed to the Contractor. If so, will dispute status information be provided by rebate quarter / program / NDC? If not, please explain or provide the layout of the disputes status information that the Contractor will receive.</p>	
<p>176 <i>A.42.e. The Contractor shall import historical quarterly rebate data into their rebate management system, provided by the State's current rebate vendor.</i></p> <p>Will all historical data look the same or is it expected that the Contractor may see different variations/formats of data (due to historical rebate vendor changes)? For example, the Contractor might see data represented one way from 1991-1998 and then represented another way 1999 and forward.</p>	<p>All data from the incumbent will be in one format. Data prior to 2014 is managed by TennCare and will be different if turned over to contractor.</p>
<p>177 <i>A.42.e. The quarterly rebate invoices shall be generated for all pharmaceutical manufacturers and State approval by thirty (30) days after the receipt of the Quarterly CMS file for supplemental rebates and by sixty (60) days for federal rebates.</i></p> <p>Does this requirement mean invoices are to be delivered 30 days after receipt of the CMS file and 60 days after the end of the quarter? If so, does this requirement apply to both supplemental rebates and federal rebates? If not, please explain.</p>	<p>Please refer to State's response to question #127.</p>
<p>178 <i>A.42.e. The Contractor shall import historical quarterly rebate data into their rebate management system, provided by the State's current rebate vendor.</i></p> <p>Will the Contractor be required to take ownership of any paper rebate documentation from the current rebate vendor? If so, approximately how many boxes of rebate documentation will the Contractor be required to take and where (city and state) is it currently located?</p> <p>Will the Contractor be required to assume any costs of transferring paper documents from the current rebate vendor or will the current rebate vendor be responsible for any costs?</p>	<p>In addition to the 30 microfiche cases housed at HCFA, there are at least 50 boxes in the PBM's Richmond, VA Iron Mountain storage.</p>
<p>179 <i>A.42.e. The Contractor shall ensure that claims received and paid from pharmacies contracted as 340B providers, are not submitted for federal rebates if such claims are flagged as 340B claims.</i></p>	<p>The flagging of 340B claims is referring to pharmacy claims, using the two appropriate NCPDP fields to indicate that the claim was filled using drugs that were acquired with the Covered Entity's 340B discounted price. It does not refer to medical claims.</p>

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<p>Are medical claims identified as 340B at the claim level? If so, what fields are used by the provider to flag them as 340B? If not, how is 340B utilization from medical providers identified for exclusion from rebates?</p>	<p>Claims processed by medical providers are excluded from federal rebate submission at the provider level.</p>
<p>180 <i>A.42.e. The Contractor shall accept medical claims data from the State including but not limited to, current procedural terminology codes, in a format mutually agreed upon by both parties, and shall submit paid claims for physician-administered drugs for federal and supplemental (if applicable) rebates.</i></p> <p>Are medical providers required to include NDCs on claims when billing procedural terminology codes that are associated with drugs?</p>	<p>Yes.</p>
<p>181 <i>A.42.e. The Contractor agrees that all rebates collected on behalf of the State shall be collected for the sole benefit of the State's share of costs, and that no other monies other than rebates shall be collected based on the State's program.</i></p> <p>Will the vendor be required to maintain a lockbox for the State? If so, will deposits for TennCare Rebate Program, CoverRx and CoverKids be deposited into the same account, or would there be different accounts for each program?</p> <p>Would the various programs covered by TennCare Rebate Administration (FFS, MCO, Supplemental, and Diabetic Supplies) require separate lockbox accounts?</p> <p>If the State maintains the lockbox, will the vendor have access to facilitate payment entry?</p>	<p>The State maintains operation of the lockbox account. The lock box account has web access so the contractor is able to view the data. A lockbox is maintained for TennCare. Both CoverKids and CoverRx rebates should be remitted by check to the following address with the appropriate program name noted:</p> <p>State of Tennessee Insert program name (CoverKids <u>or</u> CoverRx) 310 Great Circle Rd, 4E Nashville, TN 37243</p>
<p>182 <i>A.42.e Dispute resolution pertaining to units billed for supplemental rebates shall be done by the Contractor based on unit resolution performed on CMS Rebates. The Contractor shall perform all dispute resolution activities with pharmaceutical manufacturers pertaining to supplemental rebate calculations and collections. The Contractor shall present for State approval remedies for all disputes within ninety (90) days of dispute. The State shall have final approval of all settlements negotiated.</i></p> <p>Is the 90 day requirement limited to supplemental rebates only? Does this requirement include only new disputes, or does it include inherited disputes as well? For inherited disputes, is there a specific timeframe allowed for inherited disputes from the current vendor?</p>	<p>Dispute Resolution Proposal for Federal & Supplemental Rebates shall be settled within ninety (90) days of dispute.</p> <p>State will work with Contractor during implementation to determine feasible timeframe for resolving historical disputes.</p>
<p>183 <i>A.42.e The quarterly rebate invoices shall be</i></p>	<p>Invoices generated quarterly:</p>

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<p><i>generated for all pharmaceutical manufacturers and State approval by thirty (30) days after the receipt of the quarterly CMS file for supplemental rebates and by sixty (60) days for federal rebates.</i></p> <p>Approximately how many invoices are generated quarterly for each program? Does the current vendor use another method of delivery other than the U.S. mail (i.e. manufacturer portal)? If so, approximately how many invoices are distributed electronically vs. paper mailing? Are any specific programs, e.g. CHIP, ADAP, invoiced separately?</p> <p>Are any specific programs other than Title 21 CHIP, excluded from invoicing?</p>	<p>FFS – 541 Invoices for 1Q2017 MCO – 146 Invoices for 1Q2017 Supplemental – 75 Invoices for 1Q2017 Diabetic Supply – 2 Invoices for 1Q2017</p> <p>Possible methods of Delivery: online, secure invoice portal</p> <p>Approximately 80%+ are sent electronically</p> <p>Current Medicaid Rebate vendor does not support ADAP and there is no CHIP identified for separate invoicing. Rebate streams are as follows: FFS, MCO, Supplemental, and Diabetic Supply</p>
<p>184 <i>A.42.e The Contractor shall ensure that claims received and paid from pharmacies contracted as 340B providers, are not submitted for federal rebates if such claims are flagged as 340B claims.</i></p> <p>What methodology is currently used by the current vendor for identifying 340B providers for rebate administration purposes? Does the current vendor use any other source to identify 340B entities? How does the State currently identify out-of-state providers identified as 340B?</p>	<p>Any pharmacy with an NPI listed on HRSA’s website as a Covered Entity is identified as a 340B provider.</p> <p>Out-of-state 340B providers would have to be within 50 miles of the border of the State of Tennessee, and we are not currently aware of any of these pharmacies in our network.</p>
<p>185 <i>A.42.e The quarterly rebate invoices shall be generated for all pharmaceutical manufacturers and State approval by thirty (30) days after the receipt of the quarterly CMS file for supplemental rebates and by sixty (60) days for federal rebates.</i></p> <p>Is the MCO utilization that is invoiced for rebates limited to medical claims (physician-administered drugs)? If not, please explain. If so, is the MCO utilization invoiced separately from the fee-for-service (FFS) utilization? If the MCO utilization is invoiced separately, is all MCO utilization aggregated for invoicing or is each MCO’s utilization invoiced separately? If invoiced separately, how many MCO’s utilization is invoiced for rebates?</p>	<p>Limited to medical claims.</p> <p>MCO utilization should be invoiced separately from pharmacy claims. Each MCO does not need to be invoiced separately.</p>
<p>186 <i>A.42.e The quarterly rebate invoices shall be generated for all pharmaceutical manufacturers and State approval by thirty (30) days after the receipt of the quarterly CMS file for supplemental rebates and by sixty (60) days for federal rebates.</i></p> <p>Is the MCO utilization eligible for supplemental rebates? If so, is the MCO utilization invoiced</p>	<p>Please refer to State’s response to question #185.</p> <p>MCO claims would only be eligible for supplemental rebates if contracts are in place.</p>

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<p>separately from the fee-for-service (FFS) utilization? If the MCO utilization is invoiced separately, is all MCO utilization aggregated for invoicing or is each MCO's utilization invoiced separately?</p>	
<p>187 <i>A.45.d.11. The Contractor shall timely comply with any TennCare Directive. Contractor must authorize provision of the benefits under appeal (or reimbursement for the benefits under appeal) within 72 hours of receiving a TennCare Directive instructing Contractor to do so. For example, if TennCare determines during the Contractor appeal process or during the State Fair Hearing process that the benefits under dispute are medically necessary, TennCare will issue a Directive instructing Contractor to authorize provision of the benefits under appeal within 72 hours (or sooner if the enrollee's health condition requires). [42 CFR 438.424(a)]</i></p> <p>Would the State please provide a definition of "Directive" under the contract definitions section?</p>	<p>TennCare Directive.</p> <p>(a) The Contractor shall timely comply with any TennCare Directive. Contractor must authorize provision of, or reimbursement for, the benefits which were being contested at the SFH (SFH) within seventy-two (72) hours of receiving a TennCare Directive instructing Contractor to do so. For example, if TennCare determines during the SFH process that the benefits under dispute are medically necessary, TennCare will issue a Directive instructing Contractor to authorize provision of the benefits under dispute. The Directive will instruct Contractor to approve provision of the benefit within seventy-two (72) hours of the Directive's issuance, or sooner if the enrollee's health condition requires. [42 CFR 438.424(a)]</p>
<p>188 <i>A.53.a.1.e Rebate contracting and administration: ...The Contractor shall negotiate contracts for CoverRx rebates and submit all manufacturer proposals and contracts to the State for review and approval...</i></p> <p>Is the State currently receiving rebates for CoverRx utilization? If so, are rebate contracts between the State and manufacturers or between the State's current rebate vendor and manufacturers? If the State is currently receiving rebates, are rebates limited to brand products or is the State receiving rebates for generic products? If the answer is no, is the State expecting the PBM to utilize its existing rebate agreements for this population or are we to develop rebate agreements similar to the TennCare supplemental program?</p>	<p>Yes. Rebate contracts are between the PBM vendor and manufacturer. Currently receiving rebates only on four (4) CoverRx Brand products and expect the PBM to utilize existing rebate agreements.</p>
<p>189 <i>A.53.a.1.e Rebate contracting and administration: ...The Contractor shall negotiate contracts for CoverRx rebates and submit all manufacturer proposals and contracts to the State for review and approval...</i></p> <p>Is the State receiving rebates for vaccines? Is the State receiving rebates for products not listed on the CoverRx Covered Drug List? If so, please identify the products.</p>	<p>Question 1: CoverRx is not receiving rebates for vaccines.</p> <p>Question 2: No.</p>
<p>190 <i>A.53.j CoverRx PBM Services Implementation Plan and Readiness Review Schedule. Within twenty (20) days of the Effective Date of this Contract, the Contractor shall submit a CoverRx PBM Services Implementation Plan and</i></p>	<p>Both programs, TennCare and CoverRx can be implemented with the same Project Plan.</p>

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<p><i>Readiness Review Plan (CoverRx Services Implementation/Readiness Plan) containing all necessary deliverables and activities with projected dates for delivery and/or completion of these items. Upon approval of the CoverRx Project Plan by the State, HCFA will direct the Contractor to begin work on the CoverRx Services Implementation/Readiness Plan through a Control Memorandum and Control Directive in which all deliverable and activity due dates match the dates in the approved CoverRx Project Plan.</i></p> <p>Please confirm the expected format of the CoverRx PBM Services Implementation Plan and Readiness Review Plan. Is it acceptable to include this level of detail as part of the Project Plan or does HCFA expect a separate document?</p>	
<p>191 <i>A.54.b. 2.b If the Contractor submits a claims payment request and the State overpays....</i></p> <p>Does the Contractor pay the checks from its own bank account and then request payment from the State? If not, is there a State funded bank account that is used for such payments? Would the State funded bank account be maintained by the Contractor?</p>	<p>The Contractor pays the checks from its own bank account. However, the State intends to fund the payments prior to the payment release schedule. For example, the contractor shall deliver identified files to the State on Tuesday of each week. The State will in turn fund the Contractor's bank account by Friday, allowing the payments to be released.</p>
<p>192 <i>A.54.b.2.d The term "pay" means that the Contractor shall either send the provider cash or cash equivalent in full satisfaction of the clean claim...</i></p> <p>Does the Contractor pay the automatic deposits to the providers from its own bank account or is there a State funded bank account that is used for such payments?</p>	<p>The Contractor pays the checks from its own bank account. However, the State intends to fund the payments prior to the payment release schedule. For example, the contractor shall deliver identified files to the State on Tuesday of each week. The State will in turn fund the Contractor's bank account by Friday, allowing the payments to be released.</p>
<p>193 <i>A.56g 3 In no event may the Contractor provide, grant, allow, or otherwise give, access to CoverRx member information to anyone without the express written permission of the State. In the event that information is used and/or disclosed in any manner, the Contractor shall assume all liabilities under both State and federal law. (125)</i></p> <p>Does the State consider subcontractors allowed to perform services under the Agreement as excluded from being able to have access per this provision? Would the State consider including language such as "except as set forth elsewhere in this agreement" or "Or as set forth in the BAA"?</p>	<p>Language changes denied.</p>
<p>194 <i>A.54.g.1 All payments for pharmacy claims shall be made through the Contractor's system and electronically invoiced to the State weekly.</i></p> <p>Are payments made using Contractor's funds with reimbursement by State? If so, is reimbursement based on amount actually paid (i.e., electronic</p>	<p>The Contractor pays the checks from its own bank account. However, the State intends to fund the payments prior to the payment release schedule. For example, the contractor shall deliver identified files to the State on Tuesday of each week. The State will in turn fund the Contractor's bank account by Friday, allowing the payments to be released. Yes,</p>

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transfer and cleared checks only)? How soon are funds reimbursed after invoice?	reimbursement is based on the amount actually paid.
<p>195 <i>A.55.h.1 The Contractor shall develop and present to the CoverRx Clinical Advisory Committee the clinical and pharmacoeconomic review criteria the Contractor used to make recommendations regarding CDL drugs.</i></p> <p>Are the actual results from the pharmacoeconomic modeling presented to the CoverRx Clinical Advisory Committee or just the pharmacoeconomic review criteria? If the actuals results are presented, is information regarding rebates withheld or presented?</p>	Just the pharmacoeconomic review criteria.
<p>196 Section A.55.a indicates that the CDL will be provided to the Contractor, but section A.55.f indicates that the Contractor will be supplying the CDL. Can the State please provide clarity on this process?</p>	Current CDL will be provided to Contractor and is available on the website. Preparation of revisions/updates to CDL for posting to the website mailings, etc. will be made by Contractor.
<p>197 <i>A.55.j.1 The Contractor shall import historical quarterly rebate data into their rebate management system, provided by CoverRx's current rebate vendor.</i></p> <ol style="list-style-type: none"> 1. Please identify CoverRx's current rebate vendor. 2. Is all the historical data that the Contractor will receive in an electronic format? If not, please identify by rebate quarter and data type (e.g., claims, invoices, payments, disputes) the historical data that will be provided in an electronic format and the historical data that will not be provided in an electronic format. 3. For historical data, will invoice data be provided by rebate quarter / NDC and include original invoice records and prior quarter adjustments? If not, please explain or provide the layout of the invoice data that the Contractor will receive. 4. For historical data, will payment data include check number, payment postmark date, rebate quarter / NDC? If not, please explain or provide the layout of the payment data that the Contractor will receive. 5. For historical data, will dispute status information (e.g., resolved, unresolved) be provided? If not, please explain how the status of a dispute will be conveyed to the Contractor. If so, will dispute status information be provided by rebate quarter / NDC? If not, please explain or provide the layout of the disputes status information that the Contractor will receive. 6. Will the Contractor be required to take ownership of any paper rebate documentation 	<p>The Current rebate vendor for CoverRx is Magellan Medicaid Administration.</p> <p>All current data is electronic, and will be provided by the current PBM to the new Contractor.</p> <p>All invoice data will be provided by the current PBM to the new Contractor.</p> <p>Payment data will include the information requested in the question.</p> <p>Dispute information will be provided by the current PBM to the new Contractor.</p> <p>There is very little paper documentation specific to CoverRx. The documentation is currently stored in Richmond, VA Iron Mountain.</p>

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<p>from the current rebate vendor? If so, approximately how many boxes of rebate documentation will the Contractor be required to take and where (city and state) is it currently located? Will the Contractor be required to assume any costs of transferring paper documents from the current rebate vendor or will the current rebate vendor be responsible for any costs?</p>	
<p>198 <i>A.55.j.4 One hundred percent (100%) of all monies collected on behalf of the State shall be remitted to the State. The Contractor agrees that all rebates collected on behalf of the State shall be collected for the sole benefit of the State's share of costs, and that no other monies other than rebates shall be collected based on the State's program.</i></p> <p>Is it expected that the Contractor will establish and maintain a bank account on behalf of the State that will be solely designated for the collection of CoverRx rebates for the State? If so, what is the schedule and preferred method for Contractor's submission of rebates to the State?</p>	<p>All drug rebate monies for TennCare are remitted to a lockbox that is set up by the State and ties to a State depository account. The Contractor will have access via the internet to the items deposited to the lockbox.</p> <p>Drug rebate monies for CoverRx will be remitted directly to the state by check to the following address:</p> <p>State of Tennessee CoverRx 310 Great Circle Rd. 4E Nashville, TN 37243</p>
<p>199 <i>A.70.b Cash Flow, Section 4(c) If the Contractor submits a claims payment request and the State overpays the claim, the State reserves the right to withhold the overpaid monies.</i></p> <p>Does the Contractor pay the checks from its own bank account and then request payment from the State? If not, is there a State funded bank account that is used for such payments? Would the State funded bank account be maintained by the Contractor?</p>	<p>The Contractor pays the checks from its own bank account. However, the State intends to fund the payments prior to the payment release schedule. For example, the contractor shall deliver identified files to the State on the preceding Friday of each week. The State will in turn fund the Contractor's bank account by the Friday of the next week allowing the payments to be released.</p>
<p>200 <i>A.70.b Cash Flow, section 4(g) The term "pay" means that the Contractor shall either send the provider cash or cash equivalent in full satisfaction of the clean claim...</i></p> <p>Does the Contractor pay the automatic deposits to the providers from its own bank account or is there a State funded bank account that is used for such payments?</p>	<p>The Contractor pays the checks from its own bank account. However, the State intends to fund the payments prior to the payment release schedule. For example, the contractor shall deliver identified files to the State on the preceding Friday of each week. The State will in turn fund the Contractor's bank account by the Friday of the next week allowing the payments to be released.</p>
<p>201 <i>A.70.d.14. CoverKids Recipient Validation</i></p> <p><i>(d) If the Contractor has been billed for any claims for a recipient who was deceased at the time the service was allegedly provided or who is no longer eligible for CoverKids, then the Contractor shall be required to recoup monies paid to any provider that had knowledge of, or should have had knowledge of the recipient's death and to repay any monies collected by the Contractor for the claims that were paid post date</i></p>	<p>Federal regulations (42 C.F.R. § 433.312) define "overpayment" for both Medicaid and CHIP programs as "any funds that a person received or retains under subchapter XVIII or XIX of this chapter to which the person, after applicable reconciliation, is not entitled". This regulation prohibits improper overpayments of State and federal funds on behalf of recipients who are not eligible for CoverKids services. While the eligibility information contained in 834 Transaction files sent to the Contractor is deemed accurate at the time of transmission by the State, the</p>

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<p><i>of death or post eligibility for enrollment. On a monthly basis, the Contractor shall report the amount recouped by the Contractor and the amount to be repaid to HCFA. In addition, the Contractor shall reimburse HCFA monthly for monies owed to HCFA as a result of billing for recipients not eligible to receive services.</i></p> <p>Since the Contractor will be relying on the State's eligibility system as the system of record to determine eligibility in the CoverKids program, how can the Contractor be expected to reimburse the State for billing for ineligible recipient services presuming that those errors came from the eligibility system</p>	<p>eligibility status of CoverKids enrollees is subject to change which is one reason 834 Transaction files are updated on a daily basis. The State cannot update its eligibility files to reflect that an enrollee has died until it receives official notice of the death from the Social Security Administration. Therefore, even though the State's eligibility information may show an enrollee was eligible for CoverKids services at the time a prescription was filled, if it is later determined that the enrollee was deceased at that point in time, State and federal regulations require recoupment of the improper overpayment. The recoupment process is a necessary component of the services to be provided by the HCFA PBM.</p>
<p>202 <i>A.70.f All payments for pharmacy claims shall be made through the Contractor's system and electronically invoiced to CoverKids weekly.</i></p> <p>Are payments made using Contractor's funds with reimbursement by State? If so, is reimbursement based on amount actually paid (i.e., electronic transfer and cleared checks only)? How soon are funds reimbursed after invoice?</p>	<p>The Contractor pays the checks from its own bank account. However, the State intends to fund the payments prior to the payment release schedule. For example, the contractor shall deliver identified files to the State on the preceding Friday of each week. The State will in turn fund the Contractor's bank account by the Friday of the next week allowing the payments to be released. Yes, reimbursement is based on the amount actually paid.</p>
<p>203 Section A.71.a indicates that it will be at the State's option whether the Contractor manages the CoverKids formulary consistent with the PBM's national formulary. Section A.71.d indicates that the Contractor shall assume responsibility for maintaining and administering the existing CoverKids' formulary. Could the State please provide clarity on whether the Contractor will be using the formulary associated with its national commercial programs or if we will be using a formulary to be determined by the State?</p>	<p>Contractor will be using the formulary associated with its national commercial programs; however HCFA retains the option to manage the formulary.</p>
<p>204 <i>A.71.k.1 The Contractor shall import historical quarterly rebate data into their rebate management system, provided by CoverKids' current rebate vendor.</i></p> <ol style="list-style-type: none"> 1. Please identify CoverKids' current rebate vendor. 2. Is all the historical data that the Contractor will receive in an electronic format? If not, please identify by rebate quarter and data type (e.g., claims, invoices, payments, disputes) the historical data that will be provided in an electronic format and the historical data that will not be provided in an electronic format. 3. For historical data, will invoice data be provided by rebate quarter / NDC and include original invoice records and prior quarter adjustments? If not, please explain or provide 	<p>CoverKids is currently administered by BlueCross BlueShield of Tennessee, who uses Express Scripts as their PBM.</p> <p>Rebates are earned as part of Express Scripts national formulary. Details of rebates, claims, invoices, payments and disputes are not available at this time.</p>

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<p>the layout of the invoice data that the Contractor will receive.</p> <p>4. For historical data, will payment data include check number, payment postmark date, rebate quarter / NDC? If not, please explain or provide the layout of the payment data that the Contractor will receive.</p> <p>5. For historical data, will dispute status information (e.g., resolved, unresolved) be provided? If not, please explain how the status of a dispute will be conveyed to the Contractor. If so, will dispute status information be provided by rebate quarter / NDC? If not, please explain or provide the layout of the disputes status information that the Contractor will receive.</p> <p>6. Will the Contractor be required to take ownership of any paper rebate documentation from the current rebate vendor? If so, approximately how many boxes of rebate documentation will the Contractor be required to take and where (city and state) is it currently located? Will the Contractor be required to assume any costs of transferring paper documents from the current rebate vendor or will the current rebate vendor be responsible for any costs?</p>	
<p>205 <i>A.71.k CoverKids Rebate Administration</i></p> <p>Is the State currently receiving rebates for CoverKids utilization? If so, are rebate contracts between the State and manufacturers or between the State's current rebate vendor and manufacturers?</p>	<p>The State is currently receiving rebates for CoverKids, and contracts are between the manufacturer and the current rebate vendor.</p>
<p>206 <i>A.71.k.4 One hundred percent (100%) of all monies collected on behalf of the State shall be remitted to the State. The Contractor agrees that all rebates collected on behalf of the State shall be collected for the sole benefit of the State's share of costs, and that no other monies other than rebates shall be collected based on the State's program.</i></p> <p>Is it expected that the Contractor will establish and maintain a bank account on behalf of the State that will be solely designated for collection of CoverKids rebates for the State?</p> <p>If so, what is the schedule and preferred method for Contractor's submission of rebates to the state?</p>	<p>Drug rebate monies for CoverKids will be remitted directly to the state by check to the following address:</p> <p>State of Tennessee</p> <p>CoverKids</p> <p>310 Great Circle Rd. 4E</p> <p>Nashville, TN 37243</p>

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207 Please confirm that the geolocation requirements in Section A.76.h. apply only to eligible individuals residing in the State of Tennessee.	Confirmed.
208 <i>Section D.20.(d)</i> Would the State consider limiting indemnification of this provision to arising out of a material breach of the BAA? Would the State consider limiting the costs to notice and credit monitoring and other agreed upon costs?	Language Request Denied.
209 <i>Section E.13. Personally Identifiable Information</i> Would the State consider “prompt” notification and 2 business days to report any unauthorized disclosure in connect with this provision? Would the state consider adding “if feasible” regarding return of PII to the state, and allowing Contractor to keep one copy for records retention policies and regulations?	Language Request Denied.
210 <i>Section E.16. Notification of Breach and Notification of Suspected Breach</i> Would the state consider “prompt” notification and 2 business days to report any unauthorized disclosure in connect with this provision?	Language Request Denied.
211 <i>Section E.4. Ownership of Software and Work Products.</i> Would the State consider modifying the definition of Contractor Owned Software contained in section E.4 to allow for Contractor owned software that is not commercially available, but which is the intellectual property of the Contractor and was not paid for using State money or resources?	Language Request Denied.
212 <i>Attachment C – Liquidated Damages</i> Will the State entertain a maximum cap on the total amount of Liquidated Damages paid by Contractor per year and / or per line item? Several items have the potential for large exposure (e.g. \$1,000 per member per occurrence).	Language Request Denied.
213 <i>Attachment H - TennCare PBM Program Risk Sharing Module Illustration</i> Where in the technical response would TennCare like the Respondent to respond to requirements detailed in Attachment H?	This section is not included in the technical response. It is part of the pro forma and will be in the executed contract. Please refer to RFP Attachment 6.1, Mandatory Requirement.
214 <i>Attachment G - HCFA PBM Program Performance Metrics; Table 1. TennCare Program PG #1 and Table 3. Cover Kids Program PG</i>	Question 1: No. Question 2: Language request denied.

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<p>#1;PA Processing: Complete PAs</p> <p><i>Ninety-nine point five percent (99.5%) of all complete PA requests received [phone, fax or email] shall be approved or denied with applicable reasons, within twenty four (24) hours of receipt.</i></p> <p>Question 1: Would the State consider replacing email with electronic prior authorization (which is now the industry standard for electronic point to point prior authorization requests from providers to the pharmacy benefit manager).</p> <p>Question 2: Would the State consider adding the language in red?</p> <p><i>Ninety-nine point five percent (99.5%) of all complete PA requests received [phone, fax or email] shall be approved or denied with applicable reasons, within twenty four (24) hours of receipt of the prescriber's supporting statement.</i></p>	
<p>215 <i>Attachment G - HCFA PBM Program Performance Metrics; Table 1. TennCare Program PG #2 and Table 3. Cover Kids Program PG #2; PA Processing: Pended PAs</i></p> <p><i>Missing information for Pended PAs shall be obtained by the Contractor and ninety-nine point five percent (99.5%) of all Pended PA Requests shall be approved or denied with applicable reasons, within seventy-two (72) hours of the time they were originally pended</i></p> <p>By adding the red statement above, would customer consider eliminating this requirement as it would no longer be needed with the adjustment to the previous requirement?</p>	<p>Language Request denied.</p>
<p>216 <i>Attachment G - HCFA PBM Program Performance Metrics; Table 1. TennCare Program PG #3 and Table 3. Cover Kids Program PG #3; PA Processing: PAs Needing Attestation</i></p> <p><i>Missing attestations shall be obtained by the Contractor and ninety-nine point five percent (99.5%) of all PA requests requiring attestations shall be approved or denied with applicable reasons, within ninety-six (96) hours of the time at which it was determined an attestation was needed.</i></p> <p>Will the State recognize that while the PBM can request attestations, we cannot guarantee a response? Can the requirement be reworded to guarantee the PBM's efforts to obtain the attestation rather than guaranteeing that we successfully receive the attestations?</p> <p>For example, "The PBM will attempt no less than</p>	<p>Please refer Item # 9 and Item #10 of this amendment for modified language Attachment G..</p>

QUESTION / COMMENT	STATE RESPONSE
<p>three times via two separate methods to obtain a required attestation before rendering a final decision”.</p>	
<p>217 <i>Attachment G HCFA PBM Program Performance Metrics; Table 2. CoverRx Program; PG #5; Reporting: Required Reports</i></p> <p><i>No more than two (2) of the required reports referenced in Attachment D are incomplete and/or untimely in a single month</i></p> <p>Please confirm the correct reference is Attachment E for CoverRx reporting requirements.</p>	<p>Confirmed.</p>
<p>218 <i>Attachment G HCFA PBM Program Performance Metrics; Table 3. Cover Kids Program; PG #6; Reporting: Required Reports</i></p> <p><i>No more than two (2) of the required reports referenced in Attachment D are incomplete and/or untimely in a single month</i></p> <p>Please confirm the correct reference is Attachment F for Cover Kids reporting requirements</p>	<p>Confirmed.</p>
<p>219 <i>Attachment 6.8. Section 2.5 Business Associate Contracts. Business Associate shall require any agent, including a Subcontractor, to whom it provides PHI received from, maintained, created or received by Business Associate on behalf of Covered Entity, or that carries out any duties for the Business Associate involving the use, custody, disclosure, creation of, or access to PHI or other confidential HCFA information, to agree, by written agreement with Business Associate, to the same restrictions and conditions that apply through this Agreement to Business Associate with respect to such information except for the provision at section 4.6, which shall only apply to the Business Associate notwithstanding the requirements in this section 2.5.</i></p> <p>Would the State consider restrictions “at least as stringent” instead of the same for this provision?</p>	<p>Yes.</p> <p>Please refer to Item #11 of this amendment for revised RFP Attachment 6.8.</p>
<p>220 <i>Attachment 6.8. Section 2.7 Reporting of Violations in Use and Disclosure of PHI. Business Associate shall require its employees, agents, and Subcontractors to promptly report to Business Associate immediately upon becoming aware of any use or disclosure of PHI in violation of this Agreement and to report to Covered Entity any use or disclosure of the PHI not provided for by this Agreement. The Business Associate shall report such violation to Covered Entity immediately upon</i></p>	<p>We would consider the use of “promptly” but not the change to two business days. Around holidays this could mean a long delay between discovery and report.</p> <p>Please refer to Item #11 of this amendment for revised RFP Attachment 6.8.</p>

QUESTION / COMMENT	STATE RESPONSE
<p><i>becoming aware of, and in no case later than 48 hours after discovery.</i></p> <p>Would the State consider changing “immediately” to promptly and the 48 hours to 2 business days?</p>	
<p>221 <i>Attachment 6.8. Section 2.8.1 Business Associate shall provide to Covered Entity notice of a Breach of Unsecured PHI immediately upon becoming aware of the Breach, and in no case later than 48 hours after discovery.</i></p> <p>Would the State consider changing “immediately” to promptly and the 48 hours to 2 business days?</p>	<p>We would consider the use of “promptly” but not the change to two business days. Around holidays this could mean a long delay between discovery and report.</p> <p>Please refer to Item #11 of this amendment for revised RFP Attachment 6.8.</p>
<p>222 <i>Attachment 6.8. Section 2.15. Privacy Compliance Review upon Request. Business Associate agrees to make its internal practices, books and records, including policies, procedures, and PHI, relating to the use and disclosure of PHI received from, created by or received by Business Associate on behalf of Covered Entity available to the Covered Entity or to the Secretary of the United States Department of Health in Human Services or the Secretary’s designee, in a time and manner designated by the requester, for purposes of determining Covered Entity’s or Business Associate’s compliance with the Privacy Rule.</i></p> <p>Would the State consider limiting this provision to review by the Secretary? Or allow us to provide a copy of anything provided to the Secretary? Compliance with this provision for the State can be addressed through annual audits.</p>	<p>No. The State is under a number of Federal and State regulatory requirements, not just the Secretary, and as such it reserves this right in order to meet its own responsibilities.</p> <p>Please refer to Item #11 for revised RFP Attachment 6.8.</p>
<p>223 <i>Attachment 6.8. Section 3.3. Security Provisions in Business Associate Contracts. Business Associate shall ensure that any agent to whom it provides Electronic PHI received from, maintained, or created for Covered Entity or that carries out any duties for the Business Associate involving the use, custody, disclosure, creation of, or access to PHI supplied by Covered Entity, shall execute a bilateral contract (or the appropriate equivalent if the agent is a government entity) with Business Associate, incorporating the same restrictions and conditions in this Agreement with Business Associate regarding PHI except for the provision in Section 4.6.</i></p> <p>Would the State consider revising this paragraph to state that our BAAs with subcontractors or agents include at least as restrictive provisions?</p>	<p>That is the intent of this paragraph. No change will be accepted.</p>
<p>224 <i>Attachment 6.8. Section 3.5. Reporting of Security Incidents.</i></p>	<p>Yes. Please refer to Item #11 of this amendment for revised RFP Attachment 6.8.</p>

QUESTION / COMMENT	STATE RESPONSE
<p>Would the State consider “upon request” instead of “within 60 days of the anniversary of this agreement?”</p>	
<p>225 <i>Attachment 6.8. Section 3.7. Security Compliance Review upon Request.</i></p> <p>Would the State consider adding “reasonably requested” or limiting to once per year, unless there have been concerns?</p>	<p>We cannot limit the Secretary’s access to these records. State requests are generally cooperative and on reasonable terms and timelines if there are no ongoing concerns.</p>
<p>226 <i>Attachment 6.8. Section 4.2 Other Uses of PHI.</i></p> <p>Would the State consider allowing Contractor to De-identify PHI and provide Data Aggregation services related to the Health Care operations of the Covered Entity?</p>	<p>If the Covered Entity meaning is the State, then identified or de-identified PHI use for services provided to the State is permitted per the contract terms.</p>
<p>227 <i>Attachment 6.8. Section 4.6. Prohibition of Offshore Disclosure.</i></p> <p>Does the State consider allowing support services, such as IT support, to be “any medium”? Our data is located in the United States but our systems may be supported offshore from time to time.</p>	<p>Any potential access to PHI, even for tech support services, from off-shore needs State review and approval.</p>
<p>228 <i>Attachment 6.8. Section 6.2.1. Upon Covered Entity’s knowledge of a Breach by Business Associate, Covered Entity shall either: (a) Provide notice of breach and an opportunity for Business Associate to reasonably and promptly cure the breach or end the violation, and terminate this BAA if Business Associate does not cure the breach or end the violation within the reasonable time specified by Covered Entity; or (b) Immediately terminate this BAA if Business Associate has breached a material term of this BAA and cure is not possible.</i></p> <p>Would the state consider a breach cure period of 30 days?</p> <p>Would the State consider this provision to be “as mutually agreed upon”?</p>	<p>The reasonable time to cure would vary depending on the significance and complexity of the breach and potential risk to members’ information. It is not a “mutually agreed upon” provision .</p>
<p>229 <i>Attachment 6.8. Section 7.10 Governing Law.</i></p> <p>Would the State consider removing the County Jurisdiction?</p>	<p>Request denied.</p>

3. Delete *pro forma* Attachment C.19 in its entirety and insert the following in its place (any sentence or paragraph containing revised or new text is highlighted):

19	Failure by the Contractor to comply with any HCFA PBM Program general or Key Staff	The damage that may be assessed shall be one thousand dollars (\$1,000.00) per
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<p>requirements, including failure by the Contractor to have replacement in place within sixty (60) days of vacancies, unless HCFA grants an exception to the requirement and failure by the Contractor to provide copies of current Tennessee licenses for key staff.</p> <p>(Section A.7)</p>	<p>calendar day, per occurrence. If the Contractor fails to comply with the Key Staff requirements for more than thirty (30) days, the damage that may be assessed shall be two thousand (\$2,000) per calendar day, per occurrence.</p> <p>For Key Staff vacancies, the damage that may be assessed shall be \$2,500 per month in addition to the salary of the position being withheld from the monthly payment. Calculation of the damages may begin on the sixty-first day following the vacancy of the position and may continue until monthly until the position is filed.</p> <p>For licenses, the damage that may be assessed shall be \$2,500 per week per employee, and may continue until receipt of the licensure verification by TennCare.</p>
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4. Delete headings for *pro forma* Section A.45 f and A.45.g and renumber

as below:

(any sentence or paragraph containing revised or new text is highlighted)

A.45.e. TennCare Enrollee-Initiated Prior Authorization (PA) Request

A.45.f. PA Program Administration for the TennCare PDL

5. **Contract Section A. 39.e. is deleted in its entirety and each section after re-numbered.**

6. **RFP Attachment 6.2, Section C.7 is deleted in its entirety and replaced with the following:**
 (any sentence or paragraph containing revised or new text is highlighted)

<p>C.7.</p>	<p>Describe your experience and expertise in working with 340B covered entity providers and 340B claims with other Medicaid agencies.</p> <p>Describe your capabilities to allow 340B covered entities to flag claims that have been submitted with 340B pricing, and those that have not , and your experience in working with Labelers to submit non-340B claims from covered entities for federal rebates</p> <p>Include any experience you have had with other states in handling claims from 340B contract pharmacies, and how you have worked with covered entities to ensure no discount duplication occurs.</p> <p>If a 340B covered entity using a virtual 340B model submits a partial quantity for a prescription that was purchased with 340B discount pricing and the replacement product is not available with 340B discount pricing, or vice versa, how will Respondent's system handle this scenario?</p>		<p>3</p>	
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7. **Delete RFP Attachment 6.7 in its entirety and replace with the following:**
(any sentence or paragraph containing revised or new text is highlighted)

RFP ATTACHMENT 6.7

BIDDER'S LIBRARY

- (1) **MEDICAID ENTERPRISE CERTIFICATION TOOLKIT (MECT) 2.1**
Modular Required Artifacts List

<http://tn.gov/assets/entities/tenncare/attachments/RFP31865-00465.pdf>

- (2) **SAMPLE REPORT TEMPLATES**

TennCare Reports

http://tn.gov/assets/entities/tenncare/attachments/RFP_31865-00465_Bidders_Library_Reports_TennCare.zip

CoverRx Reports

http://tn.gov/assets/entities/tenncare/attachments/RFP_31865-00465_Bidders_Library_Reports_CoverRx.zip

CoverKids Reports

http://tn.gov/assets/entities/tenncare/attachments/RFP_31865-00465_Bidders_Library_Reports_CoverKids.zip

- (3) **Claim Extract Layouts**

http://tn.gov/assets/entities/tenncare/attachments/RFP_31865-00465_Bidders_Library_CTX_Extract_Layouts_20151001.xls

- (4) **834 Supplemental Documents**

http://tn.gov/assets/entities/tenncare/attachments/RFP_31865-00465_Bidders_Library_834_2300_Loop_Definitions.pdf

- (5) **TennCare Member Identification Card-General Requirements**

<http://tn.gov/assets/entities/tenncare/attachments/RFP31865-00465BiddersLibraryHCFAMEMBERIDCARDREQUIREMENT.docx>

- (6) **Notices**

<http://tn.gov/assets/entities/tenncare/attachments/RFP31865-00465BiddersLibraryNotices.zip>

- (7) **Pharmacy Network**

http://tn.gov/assets/entities/tenncare/attachments/RFP31865-00465Bidders_LibraryTENNCAREPHARMACYNETWORK.xlsx

(8) Requested Documentation Needed for Response to Question #155

PDL:

https://tenncare.magellanhealth.com/static/docs/Preferred_Drug_List_and_Drug_Criteria/TennCare_PDL.pdf
https://tenncare.magellanhealth.com/static/docs/Program_Information/TennCare_Formulary.zip

Prior authorization Criteria & quantity limits:

https://tenncare.magellanhealth.com/static/docs/Preferred_Drug_List_and_Drug_Criteria/Criteria_PDL.pdf

Additional criteria for agents not listed on the PDL that links from the main page:

<https://tenncare.magellanhealth.com>

Auto-exempt list & attestation list are:

https://tenncare.magellanhealth.com/static/docs/Program_Information/TennCare_AutoExempt_List.pdf
https://tenncare.magellanhealth.com/static/docs/Program_Information/TennCare_Attestation_List.pdf

Morphine daily equivalents calculations: see CMS reference chart here, please note only products in the short-acting narcotic and long-acting narcotic PDL classes will be subject to the edit:

<https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Opioid-Morphine-EQ-Conversion-Factors-March-2015.pdf>

Overrides, ICD overrides:

https://tenncare.magellanhealth.com/static/docs/Program_Information/Dx_PA_Bypass.pdf

8. RFP Attachment 6.6, Section A.47.b is deleted in its entirety and replaced with the following: (any sentence or paragraph containing revised or new text is highlighted)

A.47.b. TennCare MTM Pilot Program. The Contractor shall, upon request from the State **via contract amendment**, establish, maintain and administer a TennCare MTM Pilot Program in accordance with T.C.A. § 71-5-149, the TennCare Rules, and all applicable State and federal statutes and regulations. The **amendment** implementing the TennCare MTM Pilot Program shall set forth the specifics of the program, including but not limited to, identifying eligible providers and TennCare enrollees, required documentation, reporting and measurement requirements, data exchange information, and Contractor reimbursement tiers and parameters.

[Paragraph Deleted]

9. RFP Attachment 6.6, Attachment G, Table 1: TennCare Program, Item #3 is deleted and replaced with the following: (any sentence or paragraph containing revised or new text is highlighted)

Contractor shall attempt to obtain requested attestations one hundred percent (100%) of the time. Ninety-nine point five percent (99.5%) of attestations with complete information shall be approved or denied with applicable reasons, within ninety-six (96) hours of the time at which it was determined an attestation was needed.

- 10. RFP Attachment 6.6, Attachment G, Table 3: CoverKids Program, Item #3 is deleted in its entirety and shall remain blank.
- 11. RFP Attachment 6.8 is deleted in its entirety and replaced with the following: (any sentence or paragraph containing revised or new text is highlighted)



State of Tennessee
Department of Finance and Administration
Division of Health Care Finance and Administration

HIPAA Business Associate Agreement

THIS HIPAA BUSINESS ASSOCIATE AGREEMENT (“Agreement”) is between **The State of Tennessee, Department of Finance and Administration, Health Care Finance and Administration** (“HCFA” or “Covered Entity”), 310 Great Circle Road, Nashville, TN 37243 and _____ (“Business Associate”), located at _____, including all office locations and other business locations at which Business Associate data may be used or maintained. Covered Entity and Business Associate may be referred to herein individually as “Party” or collectively as “Parties.”

BACKGROUND

The Parties acknowledge that they are subject to the Privacy and Security Rules (45 C.F.R. Parts 160 and 164) promulgated by the United States Department of Health and Human Services pursuant to the Health Insurance Portability and Accountability Act of 1996 (HIPAA), Public Law 104-191, and as amended by the final rule modifying the HIPAA Privacy, Security, Enforcement, and Breach Notification Rules under the Health Information Technology for Economic and Clinical Health Act (HITECH). If Business Associate provides services to Covered Entity pursuant to one or more contractual relationships, said Agreements are detailed below and hereinafter referred to as “Service Agreements.”

LIST OF AGREEMENTS AFFECTED BY THIS HIPAA BUSINESS ASSOCIATE AGREEMENT:

In the course of performing services under a Service Agreement, Business Associate may come into contact with, use, or disclose Protected Health Information (“PHI”). Said Service Agreements are hereby incorporated by reference and shall be taken and considered as a part of this document the same as if fully set out herein.

In accordance with the federal privacy and security rules and regulations set forth at 45 C.F.R. Part 160 and Part 164, Subparts A, C, D and E, which require Covered Entity to have a written memorandum with each of its Business Associates, the Parties wish to establish satisfactory assurances that Business Associate will appropriately safeguard PHI that Business Associate may receive (if any) from or on behalf of Covered Entity, and, therefore, execute this Agreement.

1. DEFINITIONS

All capitalized terms used, but not otherwise defined, in this Agreement shall have the same meaning as those terms defined in 45 C.F.R. Parts 160 through 164 or other applicable law or regulation. A reference in this Agreement to a section in the Privacy or Security Rule means the section as in effect or as amended.

1.1 “Commercial Use” means obtaining PHI with the intent to sell, transfer or use it for commercial, or personal gain, or malicious harm; sale to third party for consumption, resale, or processing for resale; application or conversion of data to make a profit or obtain a benefit contrary to the spirit of this Agreement, including but not limited to presentation of data or examples of data in a conference or meeting setting where the ultimate goal is to obtain or gain new business.

1.2 “Confidential Information” shall mean any non-public, confidential or proprietary information, whether written, graphic, oral, electronic, visual or fixed in any tangible medium or expression, which is supplied by HCFA to the Business Associate under this Agreement. Any information, whether written, graphic, oral, electronic, visual or fixed in any tangible medium or expression, relating to individuals enrolled in the HCFA program (“HCFA enrollees”), or relating to individuals who may be potentially enrolled in the HCFA program, which is provided to or obtained through the Business Associate’s performance under this Agreement, shall also be treated as “Confidential Information” to the extent that confidential status is afforded such information under state and federal laws or regulations. All confidential information shall not be subject to disclosure under the Tennessee Public Records Act.

1.3 “Electronic Signature” means an electronic sound, symbol, or process attached to or logically associated with a record and executed or adopted by a person with the intent to sign the record.

1.4 “Marketing” shall have the meaning under 45 C.F.R. § 164.501 and the act or process of promoting, selling, leasing or licensing any HCFA information or data for profit without the express written permission of HCFA.

2. OBLIGATIONS AND ACTIVITIES OF BUSINESS ASSOCIATE (Privacy Rule)

2.1 Compliance with the Privacy Rule. Business Associate shall fully comply with the requirements under the Privacy Rule applicable to "business associates," as that term is defined in the Privacy Rule and not use or further disclose PHI other than as permitted or required by this Agreement, the Service Agreements, or as required by law. In case of any conflict between this Agreement and the Service Agreements, this Agreement shall govern.

2.2 HITECH Act Compliance. The Health Information Technology for Economic and Clinical Health Act (HITECH) was adopted as part of the American Recovery and Reinvestment Act of 2009. HITECH and its implementing regulations impose new requirements on Business Associates with respect to privacy, security, and Breach notification. Business Associate hereby acknowledges and agrees that to the extent it is functioning as a Business Associate of Covered Entity, Business Associate shall comply with any applicable provisions of HITECH. Business Associate and the Covered Entity further agree that the provisions of HIPAA and HITECH that apply to business associates and that are required to be incorporated by reference in a business associate agreement have been incorporated into this Agreement between Business Associate and Covered Entity. Should any provision not be set forth specifically, it is as if set forth in this Agreement in its entirety and is effective as of the Applicable Effective Date, and as amended.

2.3 Business Management. Business Associate may use and disclose PHI for the proper management and administration of the Business Associate or to carry out the legal responsibilities of Business Associate. Business Associate may provide data aggregation services relating to the Health Care Operations of HCFA, or as required by law. Business Associate is expressly prohibited from using or disclosing PHI other than as permitted by this Agreement, any associated Service Agreements, or as otherwise permitted or required by law, and is prohibited from uses or disclosures of PHI that would not be permitted if done by the Covered Entity.

2.4 Privacy Safeguards and Policies. Business Associate shall use appropriate safeguards to prevent use or disclosure of PHI other than as provided for by the Service Agreement(s), this Agreement or as required by law. This includes the implementation of Administrative, Physical, and Technical Safeguards to reasonably and appropriately protect the Covered Entity's PHI against any reasonably anticipated threats or hazards, utilizing the technology commercially available to the Business Associate (See also Section 3.2). The Business Associate shall maintain appropriate documentation of its compliance with the Privacy Rule, including, but not limited to, its policies, procedures, records of training and sanctions of members of its Workforce.

2.5 Business Associate Contracts. Business Associate shall require any agent, including a Subcontractor, to whom it provides PHI received from, maintained, created or received by Business Associate on behalf of Covered Entity, or that carries out any duties for the Business Associate involving the use, custody, disclosure, creation of, or access to PHI or other confidential HCFA information, to agree, by written agreement with Business Associate, to **at least as stringent** restrictions and conditions that apply through this Agreement to Business Associate with respect to such information except for the provision at section 4.6, which shall only apply to the Business Associate notwithstanding the requirements in this section 2.5.

2.6 Mitigation of Harmful Effect of Violations. Business Associate agrees to mitigate, to the extent practicable, any harmful effect that is known to Business Associate of a use or disclosure of PHI by Business Associate in violation of the requirements of this Agreement.

2.7 Reporting of Violations in Use and Disclosure of PHI. Business Associate shall require its employees, agents, and Subcontractors to promptly report to Business Associate immediately upon becoming aware of any use or disclosure of PHI in violation of this Agreement and to report to Covered Entity any use or disclosure of the PHI not provided for by this Agreement. The Business Associate shall report such violation to Covered Entity **promptly** upon becoming aware of, and in no case later than 48 hours after discovery.

2.8 Breach of Unsecured Protected Health Information. As required by the Breach Notification Rule, Business Associate shall, and shall require its Subcontractor(s) to, maintain systems to monitor and detect a Breach of Unsecured PHI, whether in paper or electronic form.

2.8.1 Business Associate shall provide to Covered Entity notice of a Breach of Unsecured PHI **promptly** upon becoming aware of the Breach, and in no case later than 48 hours after discovery.

2.8.2 Business Associate shall cooperate with Covered Entity in timely providing the appropriate and necessary information to Covered Entity.

2.8.3 Covered Entity shall make the final determination whether the Breach requires notification to affected individuals and whether the notification shall be made by Covered Entity or Business Associate.

2.9 Access of Individual to PHI and other Requests to Business Associate. If Business Associate receives PHI from Covered Entity in a Designated Record Set, Business Associate agrees to provide access to PHI in a Designated Record Set to Covered Entity in order to meet its requirements under 45 C.F.R. § 164.524. If Business Associate receives a request from an Individual for a copy of the Individual's PHI, and the PHI is in the sole possession of the Business Associate, Business Associate will provide the requested copies to the Individual in a timely manner. If Business Associate receives a request for PHI not in its possession and in the possession of the Covered Entity, or receives a request to exercise other Individual rights as set forth in the Privacy Rule, Business Associate shall promptly forward the request to Covered Entity. Business Associate shall then assist Covered

Entity as necessary in responding to the request in a timely manner. If a Business Associate provides copies of PHI to the Individual, it may charge a reasonable fee for the copies as the regulations shall permit.

2.10 Requests to Covered Entity for Access to PHI. The Covered Entity shall forward to the Business Associate in a timely manner any Individual's request for access to or a copy (in any form they choose, provided the PHI is readily producible in that format) of their PHI that shall require Business Associate's participation, after which the Business Associate shall provide access to or deliver such information as follows:

- (a) The Parties understand that if either Party receives a request for access to or copies of PHI from an Individual which the Party may complete with only its own onsite information, the time for such response shall be thirty (30) days, with notification to the Covered Entity upon completion.
- (b) If the Covered Entity receives a request and requires information from the Business Associate in addition to the Covered Entity's onsite information to fulfill the request, the Business Associate shall have fifteen (15) days from date of Covered Entity's notice to provide access or deliver such information to the Covered Entity so that the Covered Entity may timely respond to the Individual within the sixty (30) day requirement of 45 C.F.R. § 164.524.
- (c) If the Party designated above as responding to the Individual's request is unable to complete the response to the request in the time provided, that Party shall provide the Individual, or Individual's designee, with a written statement of the reasons for the delay and the date by which the Party will complete its action on the request. The Party may extend the response time once for no more than thirty (30) additional days.
- (d) Business Associate is permitted to send an Individual or Individual's designee unencrypted emails including Electronic PHI if the Individual requests it, provided the Business Associate has advised the Individual of the risk and the Individual still prefers to receive the message by unencrypted email.

2.11 Individuals' Request to Amend PHI. If Business Associate receives PHI from Covered Entity in a Designated Record Set, Business Associate agrees to make any amendments to PHI in a Designated Record Set that Covered Entity directs or agrees to pursuant to 45 C.F.R. § 164.526, regarding an Individual's request to amend PHI. The Business Associate shall make the amendment promptly in the time and manner designated by Covered Entity, but shall have thirty (30) days' notice from Covered Entity to complete the amendment to the Individual's PHI and to notify the Covered Entity upon completion.

2.12 Recording of Designated Disclosures of PHI. Business Associate shall document any and all disclosures of PHI by Business Associate or its agents, including information related to such disclosures as would be required for Covered Entity to respond to a request by an Individual for an accounting of disclosures of PHI in accordance with 45 C.F.R. § 164.528.

2.13 Accounting for Disclosures of PHI. The Business Associate agrees to provide to Covered Entity or to an Individual, or Individual's designee, in time and manner designated by Covered Entity, information collected in accordance with this Agreement, to permit Covered Entity to respond to a request by an Individual for an accounting of disclosures of PHI in accordance with 45 C.F.R. § 164.528. The Covered Entity shall forward the Individual's request requiring the participation of the Business Associate to the Business Associate in a timely manner, after which the Business Associate shall provide such information as follows:

- (a) If Covered Entity directs Business Associate to provide an accounting of disclosures of the Individual's PHI directly to the Individual, the Business Associate shall have sixty (60) days from the date of the Individual's request to provide access to or deliver such information to the Individual or Individual's designee. The Covered Entity shall provide notice to the Business Associate in time to allow the Business Associate a minimum of thirty (30) days to timely complete the Individual's request.
- (b) If the Covered Entity elects to provide the accounting to the Individual, the Business Associate shall have thirty (30) days from date of Covered Entity's notice of request to provide information for the Accounting to the Covered Entity so that the Covered Entity may timely respond to the Individual

within the sixty (60) day period.

- (c) If either of the Parties is unable to complete the response to the request in the times provided above, that Party shall notify the Individual with a written statement of the reasons for the delay and the date by which the Party will complete its action on the request. The Parties may extend the response time once for no more than thirty (30) additional days.
- (d) The accounting of disclosures shall include at least the following information:
 - (1) date of the disclosure;
 - (2) name of the third party to whom the PHI was disclosed,
 - (3) if known, the address of the third party;
 - (4) brief description of the disclosed information; and
 - (5) brief explanation of the purpose and basis for such disclosure.
- (e) The Parties shall provide one (1) accounting in any twelve (12) months to the Individual without charge. The Parties may charge a reasonable, cost-based fee, for each subsequent request for an accounting by the same Individual if he/she is provided notice and the opportunity to modify his/her request. Such charges shall not exceed any applicable State statutes or rules.

2.14 Minimum Necessary. Business Associate shall use reasonable efforts to limit any use, disclosure, or request for use or disclosure of PHI to the minimum amount necessary to accomplish the intended purpose of the use, disclosure, or request in accordance with the requirements of the Privacy Rule.

2.14.1 Business Associate represents to Covered Entity that all its uses and disclosures of, or requests for, PHI shall be the minimum necessary in accordance with the Privacy Rule requirements.

2.14.2 Covered Entity may, pursuant to the Privacy Rule, reasonably rely on any requested disclosure as the minimum necessary for the stated purpose when the information is requested by Business Associate.

2.14.3 Business Associate shall adequately and properly maintain all PHI received from, or created or received on behalf of, Covered Entity.

2.15 Privacy Compliance Review upon Request. Business Associate agrees to make its internal practices, books and records, including policies, procedures, and PHI, relating to the use and disclosure of PHI received from, created by or received by Business Associate on behalf of Covered Entity available to the Covered Entity or to the Secretary of the United States Department of Health in Human Services or the Secretary's designee, in a time and manner designated by the requester, for purposes of determining Covered Entity's or Business Associate's compliance with the Privacy Rule.

2.16 Cooperation in Privacy Compliance. Business Associate agrees to fully cooperate in good faith and to assist Covered Entity in complying with the requirements of the Privacy Rule.

3. OBLIGATIONS AND ACTIVITIES OF BUSINESS ASSOCIATE (Security Rule)

3.1 Compliance with Security Rule. Business Associate shall fully comply with the requirements under the Security Rule applicable to "Business Associates," as that term is defined in the Security Rule. In case of any conflict between this Agreement and Service Agreements, this Agreement shall govern.

3.2 Security Safeguards and Policies. Business Associate shall implement Administrative, Physical, and Technical Safeguards that reasonably and appropriately protect the confidentiality, integrity, and availability of the Electronic PHI that it creates, receives, maintains, or transmits on behalf of the Covered Entity as required by the Security Rule. This includes specifically, but is not limited to, the utilization of technology commercially available at the time to the Business Associate to protect the Covered Entity's PHI against any reasonably anticipated threats or hazards. The Business Associate understands that it has an affirmative duty to perform a regular review or assessment of security risks, conduct active risk management and supply best efforts to assure that only authorized persons and devices access its computing systems and information storage, and that only authorized transactions are allowed. The Business Associate will maintain appropriate documentation of its

compliance with the Security Rule.

3.3 Security Provisions in Business Associate Contracts. Business Associate shall ensure that any agent to whom it provides Electronic PHI received from, maintained, or created for Covered Entity or that carries out any duties for the Business Associate involving the use, custody, disclosure, creation of, or access to PHI supplied by Covered Entity, shall execute a bilateral contract (or the appropriate equivalent if the agent is a government entity) with Business Associate, incorporating the same restrictions and conditions in this Agreement with Business Associate regarding PHI except for the provision in Section 4.6.

3.4 Reporting of Security Incidents. The Business Associate shall track all Security Incidents as defined and as required by HIPAA and shall periodically report such Security Incidents in summary fashion as may be requested by the Covered Entity. The Covered Entity shall not consider as Security Incidents, for the purpose of reporting, external activities (port enumeration, etc.) typically associated with the “footprinting” of a computing environment as long as such activities have only identified but not compromised the logical network perimeter, including but not limited to externally facing firewalls and web servers. The Business Associate shall reasonably use its own vulnerability assessment of damage potential and monitoring to define levels of Security Incidents and responses for Business Associate’s operations. However, the Business Associate shall expediently notify the Covered Entity’s Privacy Officer of any related Security Incident, immediately upon becoming aware of any unauthorized acquisition including but not limited to use, disclosure, modification, or destruction of PHI by an employee or otherwise authorized user of its system of which it becomes aware.

3.4.1 Business Associate identifies the following key contact persons for all matters relating to this Agreement:

Business Associate shall notify Covered Entity of any change in these key contacts during the term of this Agreement in writing within ten (10) business days.

3.5 Contact for Security Incident Notice. Notification for the purposes of Sections 2.8 and 3.4 shall be in writing made by email/fax, certified mail or overnight parcel immediately upon becoming aware of the event, with supplemental notification by facsimile and/or telephone as soon as practicable, to:

HCFA Privacy Officer
310 Great Circle Rd.
Nashville Tennessee 37243
Phone: (615) 507-6855
Facsimile: (615) 734-5289
Email: Privacy.TennCare@tn.gov

3.6 Security Compliance Review upon Request. Business Associate shall make its internal practices, books, and records, including policies and procedures relating to the security of Electronic PHI received from, created by or received by Business Associate on behalf of Covered Entity, available to the Covered Entity or to the Secretary of the United States Department of Health in Human Services or the Secretary’s designee, in a time and manner designated by the requester, for purposes of determining Covered Entity’s, Business Associate’s compliance with the Security Rule.

3.7 Cooperation in Security Compliance. Business Associate shall fully cooperate in good faith to assist Covered Entity in complying with the requirements of the Security Rule.

3.8 Refraining from intimidation or retaliation. A Covered Entity or Business Associate may not threaten, intimidate, coerce, harass, discriminate against, or take any other retaliatory action against any Individual or other person for-- (a) Filing of a complaint under 45 C.F.R. § 160.306; (b) testifying, assisting, or participating in an investigation, compliance review, proceeding, or hearing; or (c) opposing any act or practice made unlawful, provided the Individual or person has a good faith belief that the practice opposed is unlawful, and the manner of opposition is reasonable and does not involve a disclosure of PHI in violation of HIPAA.

4. USES AND DISCLOSURES BY BUSINESS ASSOCIATE

4.1 Use and Disclosure of PHI for Operations on Behalf of Covered Entity. Except as otherwise limited in this Agreement, Business Associate may use or disclose PHI to perform Treatment, Payment or Health Care Operations for, or on behalf of, Covered Entity as specified in Service Agreements, provided that such use or disclosure would not violate the Privacy and Security Rule, if done by Covered Entity.

4.2 Other Uses of PHI. Except as otherwise limited in this Agreement, Business Associate may use PHI within its Workforce as required for Business Associate's proper management and administration, not to include Marketing or Commercial Use, or to carry out the legal responsibilities of the Business Associate.

4.3 Third Party Disclosure Confidentiality. Except as otherwise limited in this Agreement, Business Associate may disclose PHI for the proper management and administration of the Business Associate or to carry out the legal responsibilities of the Business Associate, provided that disclosures are required by law, or, if permitted by law, this Agreement, and the Service Agreement, provided that, if Business Associate discloses any PHI to a third party for such a purpose, Business Associate shall enter into a written agreement with such third party requiring the third party to: (a) maintain the confidentiality, integrity, and availability of PHI and not to use or further disclose such information except as required by law or for the purpose for which it was disclosed, and (b) notify Business Associate of any instances in which it becomes aware in which the confidentiality, integrity, and/or availability of the PHI is Breached immediately upon becoming aware.

4.4 Other Uses Strictly Limited. Nothing in this Agreement shall permit the Business Associate to share PHI with Business Associate's affiliates or contractors except for the purposes of the Service Agreement(s) between the Covered Entity and Business Associate(s) identified in the "LIST OF AGREEMENTS AFFECTED BY THIS HIPAA BUSINESS ASSOCIATE AGREEMENT" on page one (1) of this Agreement.

4.5 Covered Entity Authorization for Additional Uses. Any use of PHI or other confidential HCFA information by Business Associate, its Subcontractors, its affiliate or Contractor, other than those purposes of this Agreement, shall require express written authorization by the Covered Entity, and a Business Associate agreement or amendment as necessary. Activities which are prohibited include, but not are not limited to, Marketing or the sharing for Commercial Use or any purpose construed by Covered Entity as Marketing or Commercial use of HCFA enrollee personal or financial information with affiliates, even if such sharing would be permitted by federal or state laws.

4.6 Prohibition of Offshore Disclosure. Nothing in this Agreement shall permit the Business Associate to share, use or disclose PHI in any form via any medium with any third party beyond the boundaries and jurisdiction of the United States without express written authorization from the Covered Entity.

4.7 Prohibition of Other Uses and Disclosures. Business Associate shall not use or disclose PHI that is Genetic Information for underwriting purposes. Moreover, the sale, marketing or the sharing for commercial use or any purpose construed by Covered Entity as the sale, marketing or commercial use of HCFA enrollee personal or financial information with affiliates, even if such sharing would be permitted by federal or state laws, is prohibited.

4.8 Data Use Agreement - Use and Disclosure of Limited Data Set. Business Associate may use and disclose a Limited Data Set that Business Associate creates for Research, public health activity, or Health Care Operations, provided that Business Associate complies with the obligations below. Business Associate may not make such

use and disclosure of the Limited Data Set after any cancellation, termination, expiration, or other conclusion of this Agreement.

4.9 Limitation on Permitted Uses and Disclosures. Business Associate will limit the uses and disclosures it makes of the Limited Data Set to the following: Research, public health activity, or Health Care Operations, to the extent such activities are related to covered functions, including business planning and development such as conducting cost-management and planning-related analysis related to managing and operating Business Associates functions, formulary development and administration, development and improvement of methods of payment or coverage policies, customer service, including the provision of data analysis for policy holders, plan sponsors, or other customers, to the extent such activities are related to covered functions, provided that PHI is not disclosed and disclosure is not prohibited pursuant to any other provisions in this Agreement related to Marketing or Commercial use.

4.10 Business Associate shall enter into written agreements that are substantially similar to this Business Associate Agreements with any Subcontractor or agent which Business Associate provides access to Protected Health Information.

4.11 Business Associates shall implement and maintain information security policies that comply with the HIPAA Security Rule.

5. OBLIGATIONS OF COVERED ENTITY

5.1 Notice of Privacy Practices. Covered Entity shall provide Business Associate with the notice of Privacy Practices produced by Covered Entity in accordance with 45 C.F.R. § 164.520, as well as any changes to such notice.

5.2 Notice of Changes in Individual's Access or PHI. Covered Entity shall provide Business Associate with any changes in, or revocation of, permission by an Individual to use or disclose PHI, if such changes affect Business Associate's permitted or required uses.

5.3 Notice of Restriction in Individual's Access or PHI. Covered Entity shall notify Business Associate of any restriction to the use or disclosure of PHI that Covered Entity has agreed to in accordance with 45 C.F.R. § 164.522, to the extent that such restriction may affect Business Associate's use of PHI.

5.4 Reciprocity for Requests Received by Business Associate. The Parties agree that this Section (Section 5) is reciprocal to the extent Business Associate is notified or receives an inquiry from any Individual within Covered Entity's covered population.

6. TERM AND TERMINATION

6.1 Term. This Agreement shall be effective as of the date on which it has been signed by both parties and shall terminate when all PHI which has been provided, regardless of form, by Covered Entity to Business Associate, or created or received by Business Associate on behalf of Covered Entity, is destroyed or returned to Covered Entity, or, if the Parties agree that it is unfeasible to return or destroy PHI, subsection 6.3.5 below shall apply.

6.2 Termination for Cause. This Agreement authorizes and Business Associate acknowledges and agrees Covered Entity shall have the right to terminate this Agreement and Service Agreement in the event Business Associate fails to comply with, or violates a material provision of this Agreement and any provision of the Privacy and Security Rules.

6.2.1 Upon Covered Entity's knowledge of a Breach by Business Associate, Covered Entity shall either:

- (a) Provide notice of breach and an opportunity for Business Associate to reasonably and promptly cure the breach or end the violation, and terminate this BAA if Business Associate does not cure the breach or end the violation within the reasonable time specified by Covered Entity; or

- (b) Immediately terminate this BAA if Business Associate has breached a material term of this BAA and cure is not possible.

6.3 Effect of Termination. Upon termination of this Agreement for any reason, except as provided in subsections 6.3.2 and 6.3.5 below, Business Associate shall at its own expense either return and/or destroy all PHI and other confidential information received from Covered Entity or created or received by Business Associate on behalf of Covered Entity. This provision applies to all confidential information regardless of form, including but not limited to electronic or paper format. This provision shall also apply to PHI and other confidential information in the possession of sub-contractors or agents of Business Associate.

6.3.1 The Business Associate shall consult with the Covered Entity as necessary to assure an appropriate means of return and/or destruction and shall notify the Covered Entity in writing when such destruction is complete. If information is to be returned, the Parties shall document when all information has been received by the Covered Entity.

6.3.2 This provision (Section 6.3 and its subsections) shall not prohibit the retention of a single separate, archived file of the PHI and other confidential HCFA information by the Business Associate if the method of such archiving reasonably protects the continued privacy and security of such information and the Business Associate obtains written approval at such time from the Covered Entity. Otherwise, neither the Business Associate nor its Subcontractors and agents shall retain copies of HCFA confidential information, including enrollee PHI, except as provided herein in subsection 6.3.5.

6.3.3 The Parties agree to anticipate the return and/or the destruction of PHI and other HCFA confidential information, and understand that removal of the confidential information from Business Associate's information system(s) and premises will be expected in almost all circumstances. The Business Associate shall notify the Covered Entity whether it intends to return and/or destroy the confidential with such additional detail as requested. In the event Business Associate determines that returning or destroying the PHI and other confidential information received by or created for the Covered Entity at the end or other termination of the Service Agreement is not feasible, Business Associate shall provide to Covered Entity notification of the conditions that make return or destruction unfeasible.

6.3.4 Except for Business Associate Agreements in effect prior to April 21, 2005 when the Security Rule became effective, for the renewal or amendment of those same Agreements, or for other unavoidable circumstances, the Parties contemplate that PHI and other confidential information of the Covered Entity shall not be merged or aggregated with data from sources unrelated to that Agreement, or Business Associate's other business data, including for purposes of data backup and disaster recovery, until the parties identify the means of return or destruction of the HCFA data or other confidential information of the Covered Entity at the conclusion of the Service Agreement, or otherwise make an express alternate agreement consistent with the provisions of Section 6.3 and its subsections.

6.3.5 Upon written mutual agreement of the Parties that return or destruction of PHI is unfeasible and upon express agreement as to the means of continued protection of the data, Business Associate shall extend the protections of this Agreement to such PHI and limit further uses and disclosures of such PHI to those purposes that make the return or destruction unfeasible, for so long as Business Associate maintains such PHI.

7. MISCELLANEOUS

7.1 **Regulatory Reference.** A reference in this Agreement to a section in the Privacy and/or Security Rule means the section as in effect or as amended.

7.2 **Amendment.** The Parties agree to take such action to amend this Agreement from time to time as is necessary for Covered Entity to comply with the requirements of the Privacy and Security Rules and the Health Insurance Portability and Accountability Act, Public Law 104-191. Business Associate and Covered Entity shall comply

with any amendment to the Privacy and Security Rules, the Health Insurance Portability and Accountability Act, Public Law 104-191, and related regulations upon the effective date of such amendment, regardless of whether this Agreement has been formally amended, including, but not limited to, changes required by the American Recovery and Reinvestment Act of 2009, Public Law 111-5.

7.3 Survival. The respective rights and obligations of Business Associate under Confidentiality and Section 6.3 of this Agreement shall survive the termination or expiration of this Agreement.

7.4 Interpretation. Any ambiguity in this Agreement shall be resolved in favor of a meaning that permits Covered Entity and the Business Associate to comply with the Privacy and Security Rules.

7.5 Headings. Paragraph Headings used in this Agreement are for the convenience of the Parties and shall have no legal meaning in the interpretation of the Agreement.

7.6 Notices and Communications. All instructions, notices, consents, demands, or other communications required or contemplated by this Agreement shall be in writing and shall be delivered by electronic mail, hand, by facsimile transmission, by overnight courier service, or by first class mail, postage prepaid, addressed to the respective party at the appropriate facsimile number or address as set forth below, or to such other party, facsimile number, or address as may be hereafter specified by written notice. (For purposes of this section, effective notice to "Respective Party" is not dependent on whether the person named below remains employed by such Party.) The Parties agree to use their best efforts to immediately notify the other Party of changes in address, telephone number, and fax numbers and to promptly supplement this Agreement as necessary with corrected information.

Notifications relative to Sections 2.8, and 3.4 of this Agreement must be reported to the Privacy Officer pursuant to Section 3.5.

COVERED ENTITY:

Wendy Long, MD, Director
Department of Finance and Adm.
Health Care Finance & Admin.
310 Great Circle Rd.
Nashville, TN 37243
Fax: (615) 253-5607

BUSINESS ASSOCIATE:

All instructions, notices, consents, demands, or other communications shall be considered effectively given as of the date of hand delivery; as of the date specified for overnight courier service delivery; as of three (3) business days after the date of mailing; or on the day the facsimile transmission is received mechanically by the facsimile machine at the receiving location and receipt is verbally confirmed by the sender.

7.7 Transmission of PHI or Other Confidential Information. Regardless of the transmittal methods permitted above, Covered Entity and Business Associate agree that all deliverables set forth in this Agreement that are required to be in the form of data transfers shall be transmitted between Covered Entity and Business Associate via the data transfer method specified in advance by Covered Entity. This may include, but shall not be limited to, transfer through Covered Entity's SFTP system. Failure by the Business Associate to transmit such deliverables in the manner specified by Covered Entity, may, at the option of the Covered Entity, result in liquidated damages as set forth in one (1) or more of the Service Agreements between Covered Entity and

Business Associate listed above. All such deliverables shall be considered effectively submitted upon receipt or recipient confirmation as may be required.

7.8 Strict Compliance. No failure by any Party to insist upon strict compliance with any term or provision of this Agreement, to exercise any option, to enforce any right, or to seek any remedy upon any default of any other Party shall affect, or constitute a waiver of, any Party's right to insist upon such strict compliance, exercise that option, enforce that right, or seek that remedy with respect to that default or any prior, contemporaneous, or subsequent default. No custom or practice of the Parties at variance with any provision of this Agreement shall affect, or constitute a waiver of, any Party's right to demand strict compliance with all provisions of this Agreement.

7.9 Severability. With respect to any provision of this Agreement finally determined by a court of competent jurisdiction to be unenforceable, such court shall have jurisdiction to reform such provision so that it is enforceable to the maximum extent permitted by applicable law, and the Parties shall abide by such court's determination. In the event that any provision of this Agreement cannot be reformed, such provision shall be deemed to be severed from this Agreement, but every other provision of this Agreement shall remain in full force and effect.

7.10 Governing Law. This Agreement shall be governed by and construed in accordance with the laws of the State of Tennessee except to the extent that Tennessee law has been pre-empted by HIPAA and HITECH and without giving effect to principles of conflicts of law. Jurisdiction shall be Davidson County, Nashville, Tennessee, for purposes of any litigation resulting from disagreements of the parties for purpose of this Agreement and the Service Agreement (s).

7.11 Compensation. There shall be no remuneration for performance under this Agreement except as specifically provided by, in, and through, existing administrative requirements of Tennessee State government and Services Agreement(s) referenced herein.

7.12 Validity of Execution. Unless otherwise agreed, the parties may conduct the execution of this Business Associate Agreement transaction by electronic means. The parties may agree that an electronic record of the Agreement containing an Electronic Signature is valid as an executed Agreement.

IN WITNESS WHEREOF, the Parties execute this Agreement to be valid and enforceable from the last date set out below:

HEALTH CARE FINANCE & ADMINISTRATION BUSINESS ASSOCIATE

By: _____
Wendy Long, MD, Director
Date: _____

By: _____

Date: _____

State of Tennessee, Dept. of Finance & Adm.
Health Care Finance and Administration
310 Great Circle Road Nashville, TN 37243
Fax: (615) 253-5607

12. RFP Amendment Effective Date. The revisions set forth herein shall be effective upon release. All other terms and conditions of this RFP not expressly amended herein shall remain in full force and effect.