



MARYLAND Department of Health

Larry Hogan, Governor · Boyd Rutherford, Lt. Governor · Dennis Schrader, Secretary

Pharmacy Point-of-Sale Electronic Claims Management Services (POSEMCS)

RFP # DHMH-OPASS #19-17712 / M00B7400545

Addendum # 4

Issued: February 7, 2018

All persons who are known by the Issuing Office to have received the above-mentioned RFP are hereby advised of the following revisions to the RFP.

Revision to TORFP is as follows:

Extend Due Date for Receipt of Pharmacy Point-of-Sale Electronic Claims Management Services (POSEMCS)

The Department has extended the Due Date for Receipt of Proposals to **Wednesday, March 7, 2018 no later than 2pm local time.**

Section 1.2 - Abbreviations and Definitions - Definition for DUM is not applicable or pertinent to this RFP.

Section 1.2 has the following lines added:

Term	Definition
Designated Record Set (DRS)	“Designated Record Set” (DRS) shall mean a group of data elements that are obtained, maintained, or produced by POSECMS vendor as part of program operations. Sources for DRS may include interfaces, claims adjudication systems, and other information produced during program operations. At a minimum the DRS shall include Participant information, drug information, claim information, PA information, Prescriber and Pharmacy Provider information.
Nominal Price	The price of any drug sold by a manufacturer for less than 10 percent of the drug’s AMP in the same quarter for which the AMP is computed.

Section 3.1 (e) now reads:

E-Prescribing Support

Section 3.2.4.5 now reads:

3.2.4.5 E-PRESCRIBING SUPPORT

E-Prescribing is a valued element in the delivery of accurate and error-free prescription delivery from Prescribers to pharmacy providers. The adoption and support of this service can have great impact on the improvement of not only the quality of member care but also the member healthcare experience. In addition to facilitating the distribution of new and refill prescription information between healthcare professionals, E-Prescribing supports the exchange of member eligibility data, Program benefit design, and member profile review and reconciliation activities. The State currently does not have an E-Prescribing functionality in place.

Section 3.3.1 (E) added the following language:

All services performed to meet the requirements of this RFP shall be performed in the United States.

Section 3.3.2.6.1 (g) (5) now reads:

E-Prescribing Support

Section 3.3.2.19.12 (a) now reads:

- a. Office space (enclosed with locking door) and supporting equipment for two (2) MPP staff throughout the term of the Contract. Supporting equipment shall include, at a minimum:
 - 1) Operational networked workstation with printer access
 - 2) Telephone
 - 3) Desk
 - 4) Chairs
 - 5) Document filing cabinet
 - 6) Two (2) parking spaces for designated Department staff

Section 3.3.3.1.8 (e) now reads:

E-Prescribing Support

Section 3.3.3.2.5 now reads:

Systems Maintenance and Support shall include monitoring and managing network security such as intrusion detection.

Section 3.3.3.2.15 now reads:

Ensure all interfaces, communications, and file exchanges are performed in a secure manner.

- a. As part of routine system maintenance all interfaces shall have a corresponding load/error report. This report shall identify the information coming in and the information that was loaded and identify any error associated with the interface.

Section 3.3.3.4.9 (c) (6) now reads:

Support online near real-time (within 60 minutes) summary information such as, but not limited to, number and type of Providers, beneficiaries and services.

Section 3.3.3.5.9 now reads:

Provide to the Contract Monitor an updated OPM, training materials, policies and procedures, operational reports, interface layouts, data, and all other artifacts received, produced, or otherwise obtained during the term of the Contract no later than thirty (30) days of request by the Contract Monitor (SLA 3.8.14).

Section 3.3.3.9.53 now reads:

Provide the ability to define coverage and apply business rules for claims edits at varying drug identifier levels including, but not limited to, National Drug Code (NDC), Generic Sequence Number (GSN), Therapeutic Class (TC), Generic Code Number (GCN).

Section 3.3.3.9.79 now reads:

The PA Functionality must include document imaging capabilities that includes the ability to maintain imaging files, provide users with access and retrieval functions, and create an imaging environment proposed to meet the functional requirements of this RFP.

Section 3.3.3.9.94 now reads:

Receive daily TPL information on existing MPP members. The Contractor shall use this information when appropriate to cost avoid Pharmacy claims through the ECMS.

Section 3.3.3.10.7 (b) now reads:

The guidelines for the proper use of medication shall be consistent with 42 CFR 456.703 (f) (1).

Section 3.3.3.10.27 now reads:

Be compliant with 42 CFR Subpart K as it relates to the Prospective Drug Use Review (Pro-DUR) Program and Electronic Claims Management System for Outpatient Drug Claims.

Section 3.3.3.12.1 is removed from this RFP.

Section 3.3.3.12.2 is removed from this RFP.

Section 3.3.3.12.4 now reads:

Propose an E-Prescribing solution that adheres to all State and federal regulations. The solution shall support functionality available in E-Prescribing relevant to serving the Maryland Medicaid population. The Contractor is not restricted by the traditional E-Prescribing delivery channels and may propose alternative methods of information delivery that support the value-added service that E-Prescribing can deliver to public sector healthcare.

Section 3.3.3.12.5 now reads:

Develop training materials and record training webinars to train providers on the E-Prescribing support. These materials shall be accessible via the Web Portal.

Section 3.3.3.12.6 now reads:

Be responsible for designing, implementing, operating and maintaining all aspects of the E-Prescribing support solution.

Section 3.3.3.12.7 now reads:

Work with the Department to identify the appropriate metrics and reports associated with the E-Prescribing support solution.

Section 3.3.3.12.8 now reads:

Bill the Department for costs associated with transactions of the E-Prescribing support solution.

Section 3.3.3.12.9 is removed from this RFP.

Section 3.3.3.12.11 is removed from this RFP.

Section 3.3.3.13.3 now reads:

Structure its procedures to accommodate the two separate and distinct rebate invoicing Programs for MADAP as described in the prior Section. Both rebate invoicing processes are based on utilization of units for a covered period. The Supplemental Rebate invoices for the covered period must include the data listed in Section 3.3.3.13.86. Over time, the number of medications associated with Supplemental Rebates may change. MADAP shall provide updates to the Contractor as changes occur.

Section 3.3.3.13.87 (b) (1) now reads:

ACA New Adults MCO – invoiced separately 2014 to current

Section 3.3.3.15.6 now reads:

Support the DUR Board, the Corrective Managed Care and P&T Committees as it relates to:

- a. Attending meetings (approximately 8 meetings per year);
- b. Presenting information related to POSECMS data; and
- c. Responding to inquiries, including action items, related to POSECMS operations.

Section 3.3.3.17.27 (b) now reads:

Average Speed of Answer: Ninety-five percent (95%) of all calls shall be answered within three (3) rings or thirty (30) seconds. The performance standard shall be measured monthly and shall be reviewed with the Department in detail as part of the monthly Audit. “Answer” shall mean for each caller who elects to speak to a live representative. (SLA 3.8.18)

Section 3.3.3.17.27 (c) now reads:

Timely and Accurate Response to Call Center Inquiries: One-hundred percent (100%) of Call Center inquiries (phone, fax, electronic) shall be accurately resolved and closed within one (1) working day. The performance standard shall be measured monthly and shall be reviewed with the Department as part of the monthly Audit. The Department shall provide the definition of “closed” for this performance measure during implementation. (SLA 3.8.19)

Section 3.3.4.7 (a) (4) now reads:

Certified Project Management Professional or have a comparable project management experience

Section 3.3.6.1 (A) now reads:

The Contractor shall provide to the State the ability to export data at will. If Contractor provides the State the ability to export data, access and instructions shall be provided. If Contractor intends to perform data extraction on the State’s behalf, Contractor shall perform an export of State data within 24 hours of a request. For the purposes of this RFP the Contractor shall assume one request per year.

Section 3.3.9.1 now reads:

For all custom software provided to the State pursuant to any Contract, the Contractor shall provide the source code directly to the State in a form acceptable to the State at no additional cost to the State following the terms as set forth in Section 3.3.9.

Section 3.3.10 now reads:

This section is not applicable to this RFP.

Section 3.5.1 now reads:

The Labor Categories are identified and described in Attachment U. To be responsive to this RFP, Offerors must be capable of providing and meeting the minimum qualifications for all the labor categories listed. Offeror shall submit a Price Sheet (Attachment F) that provides labor rates for all labor categories for all contract years (initial term and any option periods). Actual resumes shall be provided only for Key Personnel as described in Attachment U. Resumes for resources provided later shall be coordinated by the Contract Manager per the Technical Proposal.

Each Labor Category includes Titles, Position Description, Education and Experience (General and Specialized).

Education and experience described in Attachment U constitute the minimum qualifications for candidates proposed in response to a RFP. All experience required must have occurred within the most recent (10) years.

Section 3.8.1 now reads:

SLA ID #	Requirement	Credits
3.8.1	3.3.2.2 – Implement the POSECMS System within six (6) months of receiving the Notice to Proceed (NTP) or as otherwise directed by the Contract Manager.	The Contractor shall be liable for \$20,000 per day until the System is fully operational. This SLA may not be imposed before the six (6) months following the NTP.

Section 3.8.14 now reads:

SLA ID #	Requirement	Credits
3.8.14	3.3.5.9 – Provide updated OPM, training materials, policies and procedures, operational reports, interface layouts, data, and all other artifacts received, produced, or otherwise obtained during the term of the contract no later than thirty (30) days of request by the Contract Monitor.	<p>The Contractor shall be liable for 50% of all monthly invoices for the period of non-compliance</p> <p>For every week thereafter that the deliverable is late the Contractor shall be liable for an additional 10% of all monthly invoices</p>

Section 3.8.18 now reads:

SLA ID #	Requirement	Credits
3.8.18	<p>Call Center Standard 2: Average Speed of Answer: Ninety-five percent (95%) of all calls shall be answered within three (3) rings or thirty (30) seconds. The performance standard shall be measured monthly and shall be reviewed with the Department in detail as part of the monthly Audit.</p> <p>“Answer” shall mean for each caller who elects to speak to a live representative.</p>	<p>The Contractor shall be liable for 2.5% of the monthly Call Center invoice for failing to have 95% of calls answered within three (3) rings or thirty (30) seconds.</p>

Section 3.8.19 now reads:

SLA ID #	Requirement	Credits
3.8.19	Timely and Accurate Response to Call Center Inquiries: One-hundred percent (100%) of Call Center inquiries (phone, fax, electronic) shall be accurately resolved and closed within one (1) working day. The performance standard shall be measured monthly and shall be reviewed with the Department as part of the monthly Audit. The Department shall provide the definition of “closed” for this performance measure during implementation. (SLA 3.8.19)	The Contractor shall be liable for 0.5% of the monthly Call Center invoice for every instance where a inquiry is not resolved within one (1) working day unless authorized by the Contract Manager.

Section 3.10.9.3 (a) now reads:

As part of the Financial Proposal include a list of associated labor categories and rates for the personnel that would be responsible for implementing System enhancements. The following table shall be part of the Offeror’s financial proposal and list all applicable personnel and rates for system enhancement activities.

Section 4.2.2.7.1 now reads:

The Department seeks to maximize the retention of personnel working under this Contract whenever there is a transition of the Contract from one contractor to another so as to minimize disruption due to a change in contractor and maximize the maintenance of institutional knowledge accumulated by such personnel. To help achieve this objective of staff retention, each Offeror shall agree that if awarded the Contract, the Offeror’s employees and agents filling the positions set forth in the staffing requirements of Section 3.3.4 working on the State contract shall be free to work for the contractor awarded the State contract notwithstanding any non-compete clauses to which the employee(s) may be subject. The Offeror agrees not to enforce any non-compete restrictions against the State with regard to these employees and agents if a different vendor succeeds it in the performance of the Contract. To evidence compliance with this non-compete clause prohibition, each Offeror must include an affirmative statement in its technical proposal that the Offeror, if awarded a Contract, agrees that its employees and agents shall not be restricted from working with or for any successor contractor that is awarded the State contract.

Section 4.4.4 now reads:

Beginning with Tab B (see RFP Section 4.2.2.3), all pages of both Proposal volumes shall be consecutively-numbered from beginning (Page 1) to end (Page “x”). The Title Page, Table of Contents, and any Claim of Confidentiality (Tabs A and A-1; see RFP Sections 4.2.2.1 and 4.2.2.3), should be numbered using romanettes (ex. I, ii, iii, iv, v, etc.).

Section 5.2 now reads:

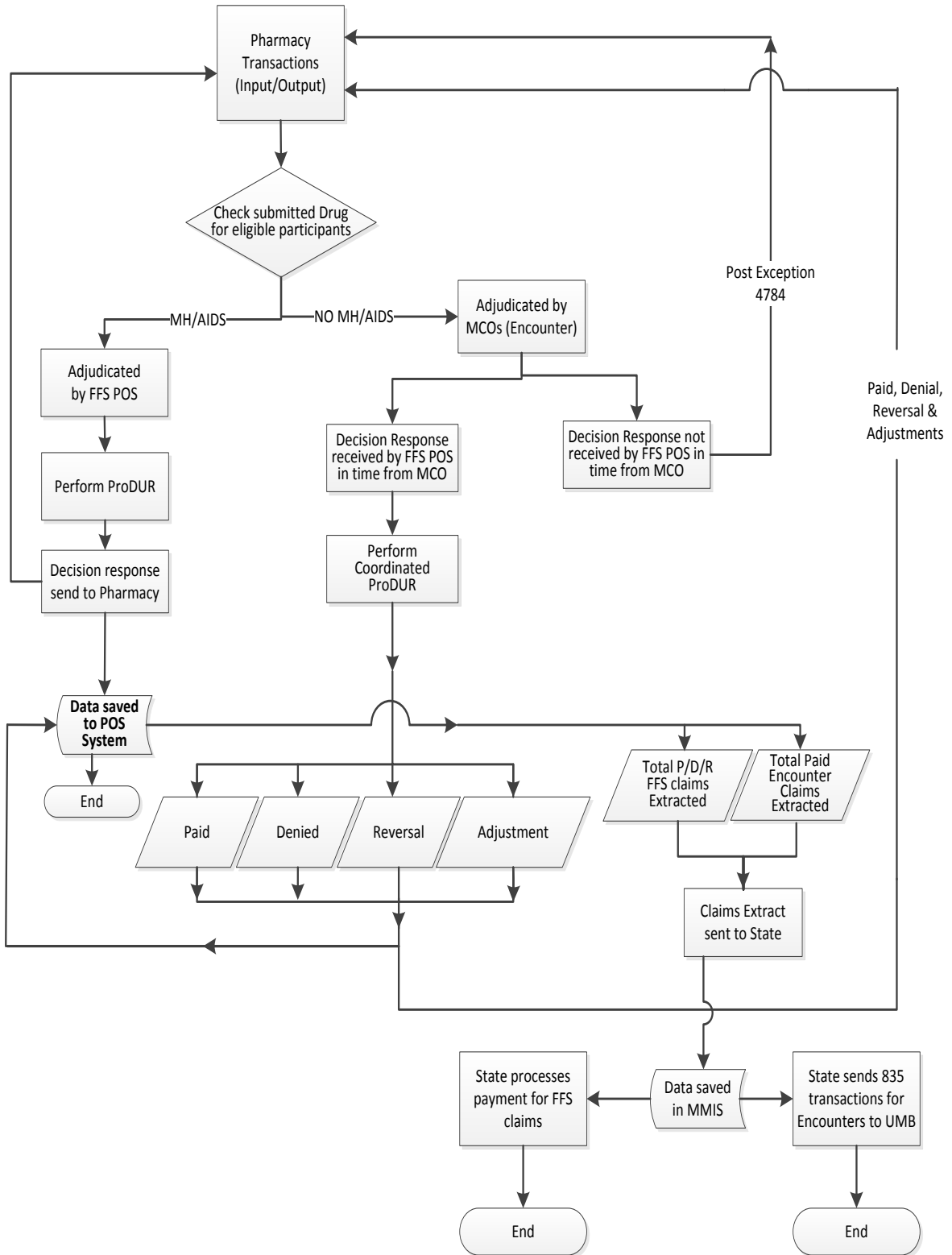
- 5.2.1 The criteria to be used to evaluate each Technical Proposal are listed below in descending order of importance. Unless stated otherwise, any sub-criteria within each criterion have equal weight.
- 5.2.2 Offeror’s Technical Response to RFP Requirements and Work Plan (See RFP § 4.2.2.6). The State prefers an Offeror’s response to work requirements in the RFP that illustrates a comprehensive understanding of work requirements and mastery of the subject matter, including an explanation of how the work will be done. Proposals which include limited responses to work requirements such as “concur” or “will comply” will receive a lower ranking than those Proposals that demonstrate an understanding of the work requirements and include plans to meet or exceed them.
- 5.2.3 Experience and Qualifications of Proposed Staff (See RFP § 4.2.2.8)
- 5.2.4 Offeror’s overall performance during the Oral Presentations and demos.
- 5.2.5 Offeror Qualifications and Capabilities, including proposed Subcontractors (See RFP § 4.2.2.9 – 4.2.2.14)
- 5.2.6 Economic Benefit to State of Maryland (See RFP § 4.2.2.16)

***** Note: The State will not be negotiating any of the language in Attachment A - Contract. The language is the State of Maryland's standard terms and conditions intended to put all perspective vendors on the same level playing field. *****

Revised Attachment F-1 – Price Sheet - Is Attached in Excel Format:

The Revised Excel Financial Proposal Form shall contain all price information in the format specified on these pages. Complete the Financial Proposal Form only as provided in the Financial Proposal Instructions. Do not amend, alter or leave blank any items on the Revised Excel Financial Proposal Form. If option years are included, Offerors must submit pricing for each option year. Failure to adhere to any of these instructions may result in the Proposal being determined not reasonably susceptible of being selected for award. For 6-month implementation and 5 years Base Contract Period utilize the attached excel Financial Proposal Form:

Attachment X has been replaced with the following:



Attachment Z has the following table added to show percentages of calls per time of day.

Year	Month	Total ACD Calls	Total Answered	Total Abandoned	% Abandoned	Total PDL	Total Medwatch	Total Medicare	Other	% PDL
2016	Jan	2,115	1,899	216	10.21	72	12	179	1,636	3.79
2016	Feb	2,351	2,153	198	8.42	116	6	202	1,829	5.38
2016	March	2,467	2,265	202	8.19	75	11	156	2,023	3.31
2016	Apr	2,120	1,915	205	9.67	71	17	131	1,696	3.71
2016	May	1,871	1,698	173	9.25	54	2	149	1,493	3.2
2016	June	2,265	2,069	196	8.65	63	3	150	1,853	3.04
2016	July	2,289	2,066	223	9.74	196	11	126	1,733	9.48
2016	Aug	2,231	2,058	173	7.75	186	9	115	1,748	9.03
2016	Sept	1,519	1,375	144	9.48	63	7	106	1,199	4.58
2016	Oct	2,178	1,973	205	9.41	80	10	212	1,671	4.05
2016	Nov	1,954	1,730	224	11.16	62	4	189	1,475	3.58
2016	DEC	2,154	1,866	288	13.37	109	1	263	1,493	6.46
		25,514	23,067	2,447	9.59%	1,147	93	1,978	19,849	4.97%

Yearly Totals of Answered Calls for 2016 by Logged Type

1. PDL	1,147
2. POS Rejection	2,247
3. PA for Drugs (Non PDL)	5,262
4. Eligibility	1,194
5. PA form	402
6. Pharmacist call	436
7. PEER	207
8. Nutritional	189
9. Other Programs	2,211
10. Medicare	1,978
11. MedWatch	93
12. Tier 2/Non preferred>18	124
13. Miscellaneous	7,079
14. MD Health Connections	498
TOTAL	23,067
Average per Month Calls Received in	2,126
Average per Month Calls Answered in	1,922

Time	Percentage of Calls
08:00-09:00	2.64%
09:00-10:00	8.47%
10:00-11:00	12.99%
11:00-12:00	13.65%
12:00-13:00	12.29%
13:00-14:00	12.76%
14:00-15:00	13.18%
15:00-16:00	12.34%
16:00-17:00	11.68%
Total	100.00%

Attachment BB has the following line added:

Interface Name	Direction	Frequency	Transition Method
State Actual Acquisition Cost	MDH to POS	Weekly	Secure FTP

Attachment CC Maryland Medicaid FDB Report Section now reads:

Maryland Medicaid FDB Report	
POS NDC MDSPAN UPDT RPRT – MediSpan Price change	Weekly
POS NDC UPDT RPRT – FDB Price change report	Weekly

Attachment CC KDP Interface Files Reports – Load/Update/Reconciliation Section has the following line added:

KDP Interface Files Reports – Load/Update/Reconciliation	
Provider Eligibility Update Report	Daily

Report Specifications Volume 1 from addendum 2 has the following report sample added. All other report samples have not changed:

Provider Eligibility Update Report (KDP)

***** PROVIDER UPDATE TOTAL *****

PROVIDER UPDATE PROCESSED ON 02/03/2018 00:24:42

TOTAL INPUT	ACCEPTED	ERROR	BYPASSED	OUTPUT
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1644	1487	157	0	1487

***** PROVIDER UPDATE ERROR *****

PROVIDER UPDATE ERROR PROCESSED ON 02/03/2018 00:24:42

NCPDP NBR	NPI NBR	MEDICAID NBR	ERROR MESSAGE
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RFP # MDH-OPASS #19-17712

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Attachment CC New Reports Section has the following reports added:

New Reports – The following reports are new to this RFP and do not have samples in the POS Procurement Library. Format and frequency for the following deliverables shall be established by the Contract Manager.	
Report Name	Frequency
Drug Formulary Load/Error Report	Weekly
Provider J-Code Claims FFS Load/Error Report	Monthly
Provider J-Code Claims BCCDT Load/Error Report	Monthly
J-Code Claims BCCDT Load/Error Report	Monthly
Diagnosis Code FFS Load/Error Report	Weekly
Diagnosis Code Encounters Load/Error Report	Daily
Drug Rebate Utilization MCO Notification Report	Quarterly
J-Code Crosswalk Notification Report	Monthly
Behavioral Health Carve-Out MCO Notification Report	Weekly
HIV/Aids Carve-Out MCO Notification Report	Weekly
Drug Rebate Quarterly Utilization Tape to CMS Notification Report	Quarterly
Drug Rebate Quarterly Utilization File for Supplemental Rebates Notification Report	Quarterly
State Actual Acquisition Cost Load/Error Report	Weekly
Prescriber MD Medicaid Load/Error Report	Daily
Patient Care Services Claims File Load/Error Report	TBD
Behavioral Health Substance Use Disorder Drug Utilization Report (Medicaid)	Quarterly

Added new Attachment NN – SPAP Pharmacy Rebate Agreement (Sample)

MARYLAND KIDNEY DISEASE PROGRAM

PHARMACY REBATE AGREEMENT

This Maryland Kidney Disease Program Pharmacy Rebate Agreement (the “Agreement”) is made effective as of the 1st day of **October, 1999** (the “Effective Date”), by and between the Kidney Disease Program of Maryland (the “Program”), a state pharmacy assistance program and a program of the Maryland Department of Health and Mental Hygiene, and the drug manufacturer identified in the signature line of this Agreement (“Manufacturer”).

I. DEFINITIONS

- (a) “Centers for Medicare and Medicaid Services (CMS)” means the agency of the U.S. Department of Health and Human Services.
- (b) “CMS Agreement” means Manufacturer’s drug rebate contract with CMS, entered pursuant to Section 1927 of the Social Security Act (42 U.S.C. Sec. 1396r-8).
- (c) “CMS Basic Rebate” means, with respect to the covered product(s), the Quarterly payment by Manufacturer pursuant to manufacturer’s CMS Agreement, made in accordance with Section 1927(c) of the Social Security Act (42 U.S.C. Sec. 1396r-8(c)).
- (d) “CMS CPI Rebate” means, with respect to the covered product(s), the Quarterly payment by Manufacturer pursuant to Manufacturer’s CMS Agreement, made in accordance with Section 1927(c)(2) of the Social Security Act (42 U.S.C. Sec. 1396r-8(c)(2)).
- (e) “Covered Outpatient Drug” will have the same meaning as set forth in 42 U.S.C. §1396r-8 (k)(2)-(4), *et seq.*, and with respect to the Manufacturer includes all such drug products meeting this definition. For purposes of coverage under this Agreement, all of those covered outpatient drugs are identified by the Manufacturer’s labeler code segment of the National Drug Code (NDC) number. Certain covered outpatient drugs may be restricted or excluded from payment at the Program’s option but will be included by the Manufacturer for purposes of this Agreement.
- (f) “Department of Health and Mental Hygiene (DHMH)” means the agency designated by the State of Maryland with the primary responsibility for providing health services, including: disease prevention; health promotion; indigent care; certain acute care services; health care facility regulation, excluding long-term care facilities; licensing of certain health professions; mental and substance abuse services; and other health-related services as provided by law.

- (g) “Manufacturer” will have the meaning as set forth in 42 U.S.C. §1396r-8(k)(5), *et seq.*, except, for purposes of this Agreement, it will also mean the entity holding legal title to or possession of the NDC number of the covered outpatient drug.
- (h) “National Drug Code (NDC)” is the identifying drug number maintained by the U. S. Food and Drug Administration. For the purposes of this Agreement the complete eleven (11) digit NDC number will be used including labeler code (which is assigned by the Food and Drug Administration and identifies the establishment), product code (that identifies the specific product or formulation), and package size code.
- (i) “Program” means the Kidney Disease Program of Maryland, a DHMH-administered and CMS qualified state-funded pharmacy assistance program.
- (j) “Program Utilization Information” means the information on the total number of Units of each dosage form and strength of the Manufacturer’s covered outpatient drugs reimbursed during a Quarter under Program. This information is based on claims paid by Program during a Quarter and not drugs that were dispensed during a Quarter. The Program Utilization Information to be supplied includes: 1) NDC number; 2) product name; 3) units paid for during the Quarter by NDC number; 4) total number of prescriptions paid for during the Quarter by NDC number, and 5) the total amount paid during the Quarter by NDC number. Program may, at its own option, compute the total rebate anticipated, based on its own records, but it will remain the responsibility of the Manufacturer to correctly calculate the rebate amount based on its correct determination under 42 U.S.C. §1396r-8, *et seq.* Program may, at its own option, delegate responsibility for determining Program Utilization Information to an appropriately authorized entity.
- (k) “Quarter” means calendar quarter unless otherwise specified.
- (l) “Rebate Payment” means, with respect to the Manufacturer’s Covered Outpatient Drugs, the Quarterly payment by the Manufacturer to the Program of the CMS Basic Rebate and the CMS CPI Rebate, as appropriate, in an amount equal to the Unit Rebate Amount multiplied by the number of Units reimbursed during a Quarter as determined by Program Utilization Information and as otherwise calculated in accordance with the provisions of this Agreement.
- (m) “Unit” means a drug unit in the lowest identifiable amount (e.g., tablet or capsule for solid dosage forms, milliliter for liquid forms, grams for ointments or creams).
- (n) “Unit Rebate Amount” for Covered Outpatient Drugs means the Unit amount computed by CMS to which the Program Utilization Information may be applied by the Program in invoicing the Manufacturer for the Rebate Payment due.

II. MANUFACTURER'S RIGHTS AND RESPONSIBILITIES

To become or remain reimbursable by Program for Covered Outpatient Drugs, the Manufacturer agrees to the following:

- (a) To timely and accurately calculate and, except as provided under section IV(b) of this Agreement, to timely make Rebate Payments to Program for the Manufacturer's Covered Outpatient Drugs paid for by Program during a Quarter. The Rebate Payments shall be made using the same unit type and rebate amount per Unit as those applied under 42 U.S.C. §1396r-8, *et seq.*;
- (b) Except as provided under section IV(b), to timely make such Rebate Payments for each Quarter within 38 days after receiving from Program the Program Utilization Information defined in this Agreement. Although a specific amount of information has been defined in section I(m) of this Agreement, the Manufacturer is responsible for timely payment of the rebate within 38 days of receiving, at a minimum, information on the number of units paid, by NDC number;
- (c) To comply with all applicable state and federal law, including DHMH's rules and regulations governing the Program, as amended or modified;
- (d) To continue to make a Rebate Payment on all of the Covered Outpatient Drugs for as long as the Manufacturer has legal ownership of the NDC number, for any Quarter covered by the term of this Agreement even when the Rebate Payment is made after the term has expired, and for as long as Program Utilization Information reports that payment was made for that drug, regardless of whether the Manufacturer continues to market that drug. If there are no sales by the Manufacturer during a Quarter, the Unit Rebate Amount last reported will be used in calculating rebates;
- (e) To have the option to audit the Program Utilization Information provided by Program;
- (f) To not report or recalculate pricing changes or dispute utilization or pricing data farther back than the execution date of this Agreement or twelve Quarters from the Quarter in which the data were due to CMS, whichever is the shorter time period, unless CMS, the Office of the Inspector General (OIG) or its designee reviews pricing data and determines that adjustments or revisions are necessary;
- (g) To maintain, and require its subcontractors to maintain, supporting financial information and documents that are adequate to ensure the accuracy and validity the Rebate Payments made pursuant to this Agreement. Such documents will be maintained and retained by the Manufacturer or its subcontractors for a period of five (5) years after the date of a Rebate Payment or until the resolution of all litigation, claim, financial management review or audit pertaining to such Rebate Payment, whichever is longer;

- (h) Upon reasonable notice, to provide, and cause its subcontractors to provide, the officials and entities identified in this section with prompt, reasonable, and adequate access to any records, books, documents, and papers that are directly pertinent to the scope of this Agreement;
- (i) To provide the access described in section II (g) and (h) upon DHMH's request. This request may be for, but is not limited to examination, audit, investigation, contract administration, or the making of copies, excerpts, or transcripts. The access required must be provided to the following officials and/or entities:
 - (i) United States Department of Health and Human Services;
 - (ii) CMS;
 - (iii) Comptroller General of the United States;
 - (iv) DHMH;
 - (v) any independent verification and validation contractor or quality assurance contractor, when acting on behalf of DHMH;
 - (vi) a state or federal law enforcement agency;
 - (vii) a special or general investigating committee of the Maryland Legislature; and
 - (viii) any other entity identified by DHMH; and
- (j) To provide the access described in Section II(g), (h) and (i) wherever it maintains such books, records, and supporting documentation. Manufacturer further agrees to provide such access in reasonable comfort and to provide any furnishings, equipment, or other conveniences deemed reasonably necessary to fulfill the purposes described in this Section. Manufacturer will require its subcontractor to provide comparable access and accommodations.

III. PROGRAM'S RIGHTS AND RESPONSIBILITIES

To induce the Manufacturer to make Rebate Payments hereunder, the Program agrees as follows:

- (a) The Program shall report Program Utilization Information to the Manufacturer within 60 days of the last day of each Quarter;
- (b) If the Manufacturer fails to comply with the terms of Section II, the Program may exclude a Covered Outpatient Drug or Drugs from coverage in the Program;
- (c) The Program is in compliance with all state pharmacy assistance program criteria of CMS as follows:

- (i) The Program is a Maryland developed program specifically for Maryland residents who are citizens of the United States or aliens lawfully admitted for permanent residence in Maryland who are diagnosed with end stage renal disease and who receive home dialysis or treatment in a certified dialysis or transplant facility and/or have received a renal transplant.
 - (ii) The Program is funded by Maryland; that is, no Federal dollars are involved.
 - (iii) The Program is set up such that payment is provided directly to providers.
 - (iv) The Program provides either a pharmaceutical benefit only or a pharmaceutical benefit in conjunction with other medical benefits or services.
 - (v) The Program does not allow for the diversion, resale or transfer of benefits reimbursed under the Program to individuals who are not beneficiaries of the Program.
 - (vi) The Program does not violate the non-discrimination provisions of Section 1860D-23(b)(2) of the Social Security Act;
- (d) The Program will promptly notify Manufacturer if any of the statements in Section III(c) change or need to be amended or modified;
 - (e) Rebate Payments are not available if any rebate, chargeback, or other form of discount is paid or payable by Manufacturer for the same Covered Outpatient Drug under a different state pharmacy assistance program or otherwise;
 - (f) No Rebate Payments shall be payable for any Covered Outpatient Drug provided to a Program enrollee for which Manufacturer has informed Program that it has already paid a Rebate Payment under the enrollee's Part D Plan (as provided for in Section 1860D-1 of the Social Security Act (42 U.S.C. 1395w-101)); and
 - (g) No Rebate Payments shall be payable for any prescriptions filled with Units of Manufacturer products sold at a discount pursuant to the federal supply schedule, TRICARE, the program established pursuant to Section 340B of the Public Health Service Act, as amended, or any other federal or Maryland program or contract pursuant to which Manufacturer provides discounted products.

IV. DISPUTE RESOLUTION -- PROGRAM UTILIZATION INFORMATION

- (a) If in any Quarter a discrepancy in Program Utilization Information is discovered by the Manufacturer which the Manufacturer and Program in good faith are unable to resolve, the Manufacturer will provide written notice of the discrepancy

by NDC number to Program prior to the due date set forth in Section II(b) of this Agreement.

- (b) The Program and the Manufacturer will use their best efforts to resolve the discrepancy within 180 days of receipt of such notification. If the Program and the Manufacturer are unable to resolve the discrepancy within 180 days, either party may request that the discrepancy be submitted to a non-binding mediation process administered by the American Arbitration Association under its Commercial Mediation Rules before resorting to litigation by sending written notice to the other party of such request. Any mediation held pursuant to this Section IV(f) shall be held in Baltimore, Maryland, before a single mediator selected by the parties. If the parties cannot agree on a mutually satisfactory mediator, the American Arbitration Association shall appoint a mediator.
- (c) If the Manufacturer in good faith believes the Program Utilization Information is incorrect, the Manufacturer will pay Program that portion of the Rebate Payment claimed which is not disputed within the required due date in section II(b). The balance due, if any, plus interest at the rate calculated in accordance with applicable Maryland law for interest owed on rebates in the Program, will be paid or credited by the Manufacturer to Program by the due date of the next Quarterly payment specified in Section II after resolution of the dispute.
- (d) Nothing in this Section will preclude the right of the Manufacturer to audit the Program Utilization Information reported or required to be reported by Program. The Manufacturer and Program will endeavor in good faith to develop mutually beneficial audit procedures.
- (e) Adjustments to Rebate Payments will be made if information indicates that either Program Utilization Information or Unit Rebate Amounts were greater or lesser than the amount previously specified.
- (f) Neither the occurrence of an event constituting an alleged breach of contract nor the pending status of any claim for breach of contract is grounds for the suspension of performance, in whole or in part, by Manufacturer of any duty or obligation under this Agreement.

V. CONFIDENTIALITY PROVISIONS

- (a) The Program shall not disclose information provided by the Manufacturer in connection with this Agreement in a form that identifies the Manufacturer or discloses prices charged for drugs by the Manufacturer, except as authorized by 42 U.S.C. §1396r-8(b)(3)(d).
- (b) The Manufacturer will hold Program Utilization Information confidential, especially with respect to any client identification information. If the Manufacturer audits this information or receives further information on such data, that information will also be held confidential. The Manufacturer will

observe state confidentiality statutes, regulations, and other properly adopted rules or policy.

- (c) The Program, its agents, employees and contractors shall not provide to the Manufacturer any patient identifiable information or protected health information or any other information prohibited or regulated by laws or regulations governing confidentiality of medical or other information.
- (d) Notwithstanding the nonrenewal or termination of this Agreement for any reason, these confidentiality provisions will remain in full force and effect, in accordance with applicable law.

VI. NONRENEWAL AND TERMINATION

- (a) Unless otherwise terminated by either party pursuant to the terms of this Agreement, this Agreement will be effective for an initial period of one year beginning on the Effective Date and will be automatically renewed for additional successive terms of one year unless the Manufacturer gives written notice of intent not to renew the Agreement at least 90 days before the end of the current period.
- (b) Either party to the Agreement may terminate the Agreement for any reason, and such termination will become effective the later of the first day of the first Quarter beginning 90 days after the Manufacturer gives written notice requesting termination, or the ending date of the term of the Agreement if notice has been given in accordance with section VI(a).
- (c) Any nonrenewal or termination will not affect rebates due before the effective date of termination.

VII. OVER/UNDERPAYMENT.

- (a) If either party discovers an error in the Rebate Payment, it shall notify the other of such error. The parties shall attempt to reconcile all differences through discussion and negotiation; if that attempt fails, the Parties will resolve their dispute in accordance with the terms of Article IV of this Agreement.
- (b) Any undisputed overpayment shall be deducted from one or more subsequent Rebate Payment(s) payable under this Agreement. In the event that no subsequent Rebate Payments are payable, DHMH will timely refund any such undisputed overpayment to Manufacturer after the parties' acknowledgement of the undisputed overpayment.
- (c) Manufacturer will remit any undisputed underpayment to DHMH within thirty (30) days of the parties' acknowledgement of such underpayment.

VIII. GENERAL PROVISIONS

- (a) Any notice required to be given pursuant to the terms and provision of this Agreement shall be sent in writing. Notice to the Program shall be sent to:

To the Program:

Kidney Disease Program of Maryland
Department of Health & Mental
Hygiene
201 West Preston Street
Room SS-3
Baltimore, MD 21201
Attention: Carol Manning

To the Manufacturer:

Manufacturer: _____
Address: _____

Attention: _____
Phone: _____

- (b) The parties expressly agree that no provision of this Agreement is in any way intended to constitute a waiver by the Program, DHMH or the State of Maryland of any immunities from suit or from liability that the Program, DHMH or the State of Maryland may have by operation of law.
- (c) Nothing in this Agreement will be construed as a waiver or relinquishment of any legal rights of the Manufacturer, the Program or DHMH under the U.S. Constitution; the Social Security Act; other federal laws, rules or regulations; or state laws, rules or regulations.
- (d) This Agreement will not be altered except by an amendment in writing signed by both parties. No person is authorized to alter or vary the terms unless the alteration appears by way of a written amendment, signed by the Manufacturer and the Program.
- (e) Nothing in this Agreement will be construed to require or authorize the commission of any act contrary to law. If any provision of this Agreement is construed to be illegal or invalid, such interpretation will not affect the legality or validity of any of its other provisions. The illegal or invalid provision will be deemed stricken and deleted to the same extent and effect as if never incorporated in this Agreement, but all other provisions will remain in full force and effect.
- (f) The Manufacturer will not have the right to assign this Agreement to a third party without the prior written consent of the Program, which consent shall not be unreasonably withheld. Any permitted assignee shall assume all obligations of its assignor under this Agreement. No assignment shall relieve the Manufacturer of

responsibility for the performance of any obligations that have accrued prior to such assignment.

- (g) Manufacturer will promptly notify the Program of any changes in ownership status. In the event of a change of ownership, the rebate obligation hereunder remains with the legal owner of the NDC number.
- (h) The failure of either party to insist upon the strict observation or performance of any provision of this Agreement or to exercise any right or remedy shall not impair or waive any such right or remedy in the future. Every right and remedy given by this Agreement to the parties may be exercised from time to time as often as appropriate.
- (i) The parties do not contemplate any circumstances under which indemnification of the other parties would arise. Nevertheless, should such circumstances arise, Manufacturer agrees to indemnify, defend and hold harmless the Program, its officers, agents and employees from any and all claims and losses accruing or resulting to any person, firm or corporation who may be injured or damaged by the Manufacturer in the performance of this Agreement.

[Signature Page Follows]

As evidence of their Agreement to the foregoing terms and conditions, the parties have signed below.

PROGRAM

By: _____ Date: _____

Name: _____

Title: _____

MANUFACTURER: _____

By: _____ Date: _____

Name: _____

Title: _____

Labeler Numbers _____

All other terms and conditions remain unchanged

February 7, 2018
Date

Dana Dembrow
Dana Dembrow, Procurement Officer

ADDENDUM # 4 ACKNOWLEDGEMENT OF RECEIPT FORM

I acknowledge receipt of Addendum #4 to MDH RFP OPASS #19-1712 “Pharmacy Point-of-Sale Electronic Claims Management Services (POSEMCS),” dated February 7, 2018.

Vendor’s Name

Authorized Signatory – (Print/Type)

Signature

Date

To be submitted with Offeror’s proposal response.