

<b>AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT</b>		1. CONTRACT ID CODE	PAGE OF PAGES 1 3
2. AMENDMENT/MODIFICATION NO. 000001	3. EFFECTIVE DATE See Block 16C	4. REQUISITION/PURCHASE REQ. NO. See Schedule	5. PROJECT NO. (If applicable)
6. ISSUED BY CMS, OAGM, AGG, DBSC 7500 SECURITY BLVD., MS: C2-21-15 BALTIMORE MD 21244-1850	CODE DBSC	7. ADMINISTERED BY (If other than Item 6) Chip Farmer Contract Specialist (410) 786-1997	CODE AGG/CF
8. NAME AND ADDRESS OF CONTRACTOR (No., street, county, State and ZIP Code) Strategic Health Solutions, L.L.C 10040 Regency Circle suite 150 Omaha NE 68114-3738		(x) 9A. AMENDMENT OF SOLICITATION NO.	9B. DATED (SEE ITEM 11)
CODE 4024523333	FACILITY CODE	x 10A. MODIFICATION OF CONTRACT/ORDER NO. GS-10F-0231T HHSM-500-2007-00311G	10B. DATED (SEE ITEM 13) 09/20/2007

**11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS**

The above numbered solicitation is amended as set forth in Item 14. The hour and date specified for receipt of Offers is extended. is not extended.  
Offers must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation or as amended, by one of the following methods: (a) By completing Items 8 and 15, and returning \_\_\_\_\_ copies of the amendment; (b) By acknowledging receipt of this amendment on each copy of the offer submitted; or (c) By separate letter or telegram which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGEMENT TO BE RECEIVED AT THE PLACE DESIGNATED FOR THE RECEIPT OF OFFERS PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER. If by virtue of this amendment you desire to change an offer already submitted, such change may be made by telegram or letter, provided each telegram or letter makes reference to the solicitation and this amendment, and is received prior to the opening hour and date specified.

12. ACCOUNTING AND APPROPRIATION DATA (If required) Net Increase: \$1,154,105.00  
See Schedule

**13. THIS ITEM ONLY APPLIES TO MODIFICATION OF CONTRACTS/ORDERS. IT MODIFIES THE CONTRACT/ORDER NO. AS DESCRIBED IN ITEM 14.**

CHECK ONE	A. THIS CHANGE ORDER IS ISSUED PURSUANT TO: (Specify authority) THE CHANGES SET FORTH IN ITEM 14 ARE MADE IN THE CONTRACT ORDER NO. IN ITEM 10A.
	B. THE ABOVE NUMBERED CONTRACT/ORDER IS MODIFIED TO REFLECT THE ADMINISTRATIVE CHANGES (such as changes in paying office, appropriation date, etc.) SET FORTH IN ITEM 14, PURSUANT TO THE AUTHORITY OF FAR 43.103(b).
X	C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF: FAR 52.217-9, Option to Extend the Term of the Contract
X	D. OTHER (Specify type of modification and authority) FAR 52.243-3, Changes - Time-and-Materials or Labor-Hours

E. IMPORTANT: Contractor is not. (X) is required to sign this document and return 1 copies to the issuing office.

**14. DESCRIPTION OF AMENDMENT/MODIFICATION (Organized by UCF section headings, including solicitation/contract subject matter where feasible.)**

Tax ID Number: 91-1773119  
DUNS Number: 622811847  
Refer to the attached pages.  
Period of Performance: 09/30/2007 to 09/29/2009

0002A Formulary Review - Option Year 1 515,000.00  
Requisition No: 765-8-656501

Accounting Info:  
85936565-7580511-252Z  
Funded: \$515,000.00  
Continued ...

Except as provided herein, all terms and conditions of the document referenced in Item 9A or 10A, as heretofore changed, remains unchanged and in full force and effect.

15A. NAME AND TITLE OF SIGNER (Type or print) <b>Peg Stessman</b>	16A. NAME AND TITLE OF CONTRACTING OFFICER (Type or print) DEBRA A. HOFFMAN
15B. CONTRACTOR/OFFEROR  (Signature of person authorized to sign)	16B. UNITED STATES OF AMERICA  (Signature of Contracting Officer)
15C. DATE SIGNED 08/27/08	16C. DATE SIGNED AUG 27 2008

**CONTINUATION SHEET**

REFERENCE NO. OF DOCUMENT BEING CONTINUED  
 GS-10F-0231T/HHSM-500-2007-00311G/000001

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NAME OF OFFEROR OR CONTRACTOR  
 Strategic Health Solutions, L.L.C

ITEM NO. (A)	SUPPLIES/SERVICES (B)	QUANTITY (C)	UNIT (D)	UNIT PRICE (E)	AMOUNT (F)
0002B	Formulary Review - Option Year 1 Requisition No: 765-8-653202  Accounting Info: 85936532-7580511-252Z Funded: \$212,865.00				212,865.00
0002C	Formulary Review - Re-negotiation Requisition No: 778-8-675375  Accounting Info: 85996753-7580511-252Z Funded: \$164,105.00				164,105.00
0002D	Formulary Review - Re-negotiation Requisition No: 765-8-653201  Accounting Info: 85936532-7580511-252Z Funded: \$262,135.00				262,135.00

**ORDER FOR SUPPLIES OR SERVICES**

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**IMPORTANT: Mark all packages and papers with contract and/or order numbers.**

1. DATE OF ORDER 09/20/2007		2. CONTRACT NO. (If any) GS-10F-0231T		6. SHIP TO:		
3. ORDER NO. HHSM-500-2007-00311G		4. REQUISITION/REFERENCE NO. See Schedule		a. NAME OF CONSIGNEE Not Applicable		
5. ISSUING OFFICE (Address correspondence to) CMS, OAGM, AGG, DBSC 7500 SECURITY BLVD., MS: C2-21-15 BALTIMORE MD 21244-1850				b. STREET ADDRESS		
c. CITY			d. STATE		e. ZIP CODE	
7. TO:				f. SHIP VIA		
a. NAME OF CONTRACTOR Strategic Health Solutions, L.L.C				8. TYPE OF ORDER		
b. COMPANY NAME				<input type="checkbox"/> a. PURCHASE		
c. STREET ADDRESS 10040 Regency Circle suite 150				REFERENCE YOUR:		
d. CITY Omaha				e. STATE NE		
				f. ZIP CODE 68114-3738		
9. ACCOUNTING AND APPROPRIATION DATA See Schedule				10. REQUISITIONING OFFICE CENTER FOR BENEFICIARY CHOICES		
11. BUSINESS CLASSIFICATION (Check appropriate box(es))				12. F.O.B. POINT Destination		
<input checked="" type="checkbox"/> a. SMALL				<input type="checkbox"/> b. DELIVERY		
<input type="checkbox"/> b. OTHER THAN SMALL				Except for billing instructions on the reverse, this delivery order is subject to instructions contained on this side only of this form and is issued subject to the terms and conditions of the above-numbered contract.		
<input type="checkbox"/> c. DISADVANTAGED				Please furnish the following on the terms and conditions specified on both sides of this order and on the attached sheet, if any, including delivery as indicated.		
<input checked="" type="checkbox"/> d. WOMEN-OWNED				<input type="checkbox"/> g. SERVICE-DISABLED VETERAN-OWNED		
<input type="checkbox"/> e. HUBZone				<input type="checkbox"/> f. EMERGING SMALL BUSINESS		

13. PLACE OF		14. GOVERNMENT B/L NO.		15. DELIVER TO F.O.B. POINT ON OR BEFORE (Date) 09/29/2008		16. DISCOUNT TERMS Net 30	
a. INSPECTION Destination		b. ACCEPTANCE Destination					

17. SCHEDULE (See reverse for Rejections)

ITEM NO. (a)	SUPPLIES OR SERVICES (b)	QUANTITY ORDERED (c)	UNIT (d)	UNIT PRICE (e)	AMOUNT (f)	QUANTITY ACCEPTED (g)
	Tax ID Number: 91-1773119 DUNS Number: 622811847 Pursuant to the terms and conditions of Contract No. GS-10F-0231T The contractor shall complete Formulary & Benefit Review per the attached Statement of Work (21 Continued ...					

18. SHIPPING POINT		19. GROSS SHIPPING WEIGHT		20. INVOICE NO.		17(h) TOTAL (Cont pages)
21. MAIL INVOICE TO:						
a. NAME DHHS, CMS, OFM, FSG						\$713,296.00
b. STREET ADDRESS (or P.O. Box) Div. of Financial Operations, P.O. Box 7520						
c. CITY Baltimore		d. STATE MD		e. ZIP CODE 21207-0520		\$713,296.00
22. UNITED STATES OF AMERICA BY (Signature)						17(i) GRAND TOTAL

*Debra A. Hoffman*

23. NAME (Typed)  
DEBRA A. HOFFMAN  
TITLE: CONTRACTING/ORDERING OFFICER

**ORDER SUPPLIES OR SERVICES  
SCHEDULE - CONTINUATION**

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**IMPORTANT:** Mark all packages and papers with contract and/or order numbers.

DATE OF ORDER 09/26/2007	CONTRACT NO. GS-10F-0231T	ORDER NO. HHSM-500-2007-00311G
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ITEM NO. (A)	SUPPLIES/SERVICES (B)	QUANTITY ORDERED (C)	UNIT (D)	UNIT PRICE (E)	AMOUNT (F)	QUANTITY ACCEPTED (G)
	pages). Period of Performance: 09/30/2007 to 09/29/2008					
0001A	Formulary & Benefit Review Requisition No: 765-7-251201  Accounting Info: 75932512-7578393-252Z				364,296.00	
0001B	Formulary & Benefit Review Requisition No: 765-7-656501  Accounting Info: 75936565-7570511-252Z  Total amount of award: \$713,296.00. The obligation for this award is shown in box 17(i).				349,000.00	

TOTAL CARRIED FORWARD TO 1ST PAGE (ITEM 17(H))

The purposes of this Modification are as follows:

- I. Re-negotiate Option Year 1 to allow for an increased level of effort for task B.4 of the SOW, Review of Plan Formularies.

The following table portrays the additional cost for the increased level of effort.

Labor Category	Rate	Hours	Total NTE Cost
Senior Consultant II			\$31,044
Senior Consultant I			\$375,014
Analyst III		(b)(4)	\$20,183
<b>Total NTE Amount</b>			<b>\$426,241</b>

The totals for each line item may vary as required; however, the total Not-to-Exceed amount shall not be exceeded. Travel and Other Direct Cost shall be reimbursed at actual costs incurred in accordance with FAR 52.216-7 Allowable Cost and Payment, and the Federal Travel regulation as applicable.

- II. Obligate funding to exercise Option Year 1, including the Re-negotiation, Sep 30, 2008 - Sep 29, 2009.

Obligation (Option Year 1 - Previously Approved)	\$727,864
Obligation (Increased level of effort)	\$426,241
<b>Total Obligation</b>	<b>\$1,154,105</b>

All other terms & conditions remain unchanged.

END OF MODIFICATION

Conduct Part D Formulary and Benefits Review

**I. TASK ORDER PRICE SUMMARY**

The allocation of hours for labor categories outlined in the Schedule of Services, in the following table, are estimates only and may vary within individual categories. However, the total value shall not exceed the total amount specified for labor under this order. Any Other Direct Costs (ODC) associated with this task order (specifically hardware/software costs & those items not outlined in the schedule below) shall be approved by the Project Officer and the Contracting Officer prior to any costs being incurred by the contractor.

**SCHEDULE OF SERVICES – 09/30/2007 – 09/29/2012**

**Base Year:** September 30, 2007 – September 29, 2008

Labor Category	Hourly Rate	Hours - Base Tasks	Subtotal Cost	Hours - Optional Task / Total Hours	Total Cost
Project Manager					\$ 66,801.41
Senior Consultant II					\$281,250.90
Senior Consultant I					\$212,491.18
Analyst II					\$ 73,023.66
Analyst III			(b)(4)		\$ 28,332.20
Admin II					\$ 30,850.80
<b>Subtotal Direct Labor</b>					<b>\$692,750.58</b>
Travel					\$ 5,422.98
ODCs					\$ 15,121.68
<b>Total Cost</b>					<b>\$713,295.24</b>

The award for the base year of the task order includes the optional task, Benefit Design Review.

Contract No: GS-10F-0231T  
 Task Order No: HHSM-500-2007-00311G

Option Year 1: September 30, 2008 – September 29, 2009

Labor Category	Hourly Rate	Hours – Base Tasks	Subtotal Cost	Hours – Optional Task / Total Hours	Total Cost
Project Manager					\$ 69,139.00
Senior Consultant II					\$291,091.77
Senior Consultant I					\$219,935.08
Analyst II					\$ 76,795.29
Analyst III			(b)(4)		\$ 31,395.00
Admin II					\$ 32,135.62
<b>Subtotal Direct Labor</b>					<b>\$720,491.76</b>
Travel					\$ 2,250.58
ODCs					\$ 5,121.68
<b>Total Cost</b>					<b>\$727,864.02</b>

Option Year 2: September 30, 2009 – September 29, 2010

Labor Category	Hourly Rate	Hours – Base Tasks	Subtotal Cost	Hours – Optional Task / Total Hours	Total Cost
Project Manager					\$ 71,557.08
Senior Consultant II					\$301,282.02
Senior Consultant I					\$227,636.30
Analyst II					\$ 79,472.25
Analyst III			(b)(4)		\$ 32,494.28
Admin II					\$ 33,261.36
<b>Subtotal Direct Labor</b>					<b>\$745,703.29</b>
Travel					\$ 2,250.58
ODCs					\$ 5,121.68
<b>Total Cost</b>					<b>\$753,075.55</b>

**Option Year 3: September 30, 2010 - September 29, 2011**

Labor Category	Hourly Rate	Hours - Base Tasks	Subtotal Cost	Hours - Optional Task / Total Hours	Total Cost
Project Manager					\$ 74,060.84
Senior Consultant II					\$311,821.65
Senior Consultant I					\$235,594.84
Analyst II					\$ 82,255.68
Analyst III			(b)(4)		\$ 33,629.96
Admin II					\$ 34,424.94
<b>Subtotal Direct Labor</b>					<b>\$771,787.91</b>
Travel					\$ 2,250.58
ODCs					\$ 5,121.68
<b>Total Cost</b>					<b>\$779,160.17</b>

**Option Year 4: September 30, 2011 - September 29, 2012**

Labor Category	Hourly Rate	Hours - Base Tasks	Subtotal Cost	Hours - Optional Task / Total Hours	Total Cost
Project Manager					\$ 76,655.04
Senior Consultant II					\$322,749.48
Senior Consultant I					\$243,847.46
Analyst II					\$ 85,145.58
Analyst III			(b)(4)		\$ 34,805.68
Admin II					\$ 35,626.36
<b>Subtotal Direct Labor</b>					<b>\$798,829.60</b>
Travel					\$ 2,250.58
ODCs					\$ 5,121.68
<b>Total Cost</b>					<b>\$806,201.86</b>

The totals for each line item may vary as required; however, the total Not-to-Exceed amount shall not be exceeded. Travel and Other Direct Cost shall be reimbursed at actual costs incurred in accordance with 52.216-7 Allowable Cost and Payment, and the Federal travel regulation as applicable.

## II. SCOPE

### A. Background

In January 2005, the Centers for Medicare & Medicaid Services (CMS) issued a proposed rule on the Medicare prescription drug benefit. This new voluntary prescription drug benefit program was enacted into law in December 2003, in Section 101 of the Medicare Prescription Drug, Improvement and Modernization act of 2003 (MMA). The addition of a prescription drug benefit to Medicare represents a landmark change to the Medicare program that will significantly improve the health care coverage available to millions of Medicare beneficiaries. The prescription drug benefit program or Part D became available to beneficiaries beginning on January 1, 2006. The drug benefit is offered to Medicare beneficiaries through Medicare Advantage drug plans (MA-PDs) and stand-alone prescription drug plans (PDPs).

Through this scope of work, CMS desires to obtain a contractor that will assist the agency in reviewing plan formularies and benefits related to the prescription drug program. This initiative will assist CMS in achieving its objective of reviewing plan formularies and benefits to ensure compliance with the guidelines outlined in Chapter 6 of The Medicare Part D Manual ([http://www.cms.hhs.gov/PrescriptionDrugCovContra/Downloads/PDBMChap6FormularyReqrmts\\_03.09.07.pdf](http://www.cms.hhs.gov/PrescriptionDrugCovContra/Downloads/PDBMChap6FormularyReqrmts_03.09.07.pdf)) and to ensure compliance with CMS' benefit guidelines. Review of plan formularies and benefits shall include the following types of activities, at a minimum:

- Compare each plan's formulary to the U.S. Pharmacopeia (USP) Model Guidelines;
- Ensure the inclusion of at least two distinct drugs in each of the plan sponsor's formulary categories and classes;
- Compare each plan's formulary to the top drug classes used by Medicare beneficiaries and dual eligible beneficiaries;
- Determine if appropriate access is granted for all or substantially all drugs within the six therapeutic classes of clinical concern;
- Determine if plans have included drugs or drug classes referenced in widely accepted treatment guidelines;
- Determine if drug class placement within tier structure is appropriate within a formulary;
- Determine if prior authorization criteria, quantity limits, and step therapy are being utilized appropriately within the formulary and as compared to all submitted plans;
- Determine if the benefit design and cost-sharing tier for a plan are discriminatory, and
- Participate in discussions with plans to address issues with formulary and benefit design.

Definitions:

Formulary: A formulary contains the list of approved medications for plan beneficiaries. In addition, the formulary will also contain the tier structure of the benefit and utilization management tools that support the appropriate utilization of medications among beneficiaries.

Formulary Guidelines: These guidelines outline how CMS will review Medicare prescription drug benefit plans to assure that beneficiaries receive clinically appropriate medications at the lowest possible cost. Two key requirements in the MMA are to assure that drug plans provide access to medically necessary treatments for all and do not discriminate against any particular types of beneficiaries, and to encourage and support the use of approaches to drug benefit management that are proven and in widespread use in prescription drug plans.

Health Plan Management System (HPMS): Interface that will enable plans to upload their formulary and benefit submissions to CMS. HPMS will perform a series of electronic edits on the formulary to determine any potential outliers within the formulary. Reports will then be generated from within HPMS to identify the potential outliers for the pharmacist.

**III. Requirements**

The contractor shall furnish all of the necessary services, qualified personnel, material, equipment and facilities, not otherwise provided by CMS, as needed to perform the requirements of this Statement of Work (SOW). This shall include ensuring access to HPMS for all key personnel.

**A. Key Personnel Requirements**

Project Manager

This position requires a thorough knowledge of and extensive experience with supervision and management of multi-disciplined work groups. Experience shall include project management roles with government and/or private sector entities focused on development of operational guidelines and the processing of work related items over an extended period of time (i.e., experience in supervising projects with ongoing review activity is essential). Knowledge and experience of pharmacy benefits management practice, Medicare and Title 1 and review of formularies and benefits are also required.

Pharmacist

Pharmacist(s) shall have a pharmacy license in good standing, which permits them to practice pharmacy in at least one state. Pharmacist(s) shall have knowledge and experience with pharmacy benefit management practices including the review/operations of formularies, tier structures, cost-sharing and drug utilization management (DUM) tools including prior authorization, step therapy and quantity limits. Pharmacists shall also have a strong clinical background that will enable them to identify and make recommendations for changes in a formulary. Pharmacist(s) shall review plan formularies including drug lists, classification systems, tier structures, cost-sharing arrangements and utilization management tools to ensure compliance with formulary standards outlined within the MMA as well as those outlined in Chapter 6 of the Medicare Part D Manual and other pertinent documents.

Analyst – Optional Task

Middle or senior level analyst(s) will have a background in pharmacy benefits, including tier structures, cost-sharing, and DUM tools. The analyst(s) shall be knowledgeable about the Medicare Part D program, the definition of a covered Part D drug, and the Part D plan benefit models. The analyst(s) shall review the cost sharing structure for each formulary tier in plan benefit packages to ensure the benefit structure is non-discriminatory and complies with CMS benefit guidance.

**B. Specific Tasks to be Performed**

B.1 Conduct and Attend Meetings

- The Contractor shall conduct an initial kickoff meeting and orientation to introduce project staff to key government personnel and to establish a timeline for completion of the project. The meeting shall take place within one week of the award.
- The Contractor shall be responsible for daily project update reports and meetings with the Government Task Leader (GTL). The purpose of these meetings is to track progress of the formulary and/or benefit reviews.
- The Contractor shall participate in negotiation calls with Plans, as needed, to communicate formulary and/or benefit issues discovered.

B.2 Attend Training Session

- The Contractor's Project Manager, Pharmacists, and Analysts will attend a training session. The training session will be conducted by CMS in order to teach the process and procedures on how to review the formulary and/or benefits according to CMS and how to access HPMS to review formularies and/or benefits.
- All key personnel involved in reviewing formularies and/or benefits shall be required to attend the training session.

**B.3 Develop Work Management Plan**

The Contractor shall develop a Work Management Plan that includes planning for each of the requirements of this Task Order and highlights each step of implementation of this Task Order. The Contractor shall include a measure of inter-rater reliability to ensure consistent formulary and/or benefit reviews across all Pharmacists and/or Analysts. The intent of this measure is to ensure accurate and consistent reviews. To achieve this the contractor shall consider preliminary data analysis and review of the formulary's inter-relations such as pharmacy benefit managers and identification of duplicate formularies to ensure the same reviewer is assigned to review similar formularies for inter-rater reliability. It is the intention of CMS that the lead pharmacist will perform quality checks on the formulary reviewer's work but CMS does not expect that every formulary will undergo more than one separate pharmacist review due to the time frames required in the formulary review cycle. The Contractor shall develop a draft within one (1) week and a final work management plan within three (3) weeks of the initial meeting. The Work Management Plan shall include, at a minimum, the following information:

- Descriptions of Contractor methods for satisfying task requirements or task protocol including:
  - Resource planning by activity (description of the activity, anticipated results, activity implementation schedule, and delivery schedules/completion dates).
  - Activity interdependency and critical path for completion of all tasks.
  - Key staff types devoted to each task or activity, if appropriate, and time allocation for each.
  - Key milestones signifying successful completion of each task and periodic internal assessment/progress reports planned.
  - Potential problems and proposed solutions.
  - Quality assurance process to ensure that formularies and/or plan benefit packages are reviewed accurately and consistently.

**B.4 Review Plan Formularies**

The Contractor shall review plan formularies to ensure they meet the standards outlined in Chapter 6 of the Medicare Part D Manual. The pharmacist will utilize reports generated by HPMS to review plan formularies against the standards set forth by CMS. This review will consist of reports that contain "potential issues" listed for the pharmacist to review for discrimination, access or clinical issues. Reviews need to be consistent across reviewers and plans. The contractor shall include a measure of inter-rater reliability (e.g., 95% of the materials reviewed by lead pharmacist result in the same finding as the original review). The Contractor shall develop and provide to the GTL an approach for ensuring quality formulary and/or benefits review throughout this project. CMS will provide quality assurance of this process by random spot reviewing of formularies to assure consistency and quality of reviews. The Contractor's review shall include, but is not limited to, the following modules:

- Compare plan formulary to the USP Model Guidelines. Potential issues report will identify drug categories or classes that do not contain at least two example drugs.
- Compare the number of formulary drugs to the plan's classification system. Potential issues report will identify drug classes that do not contain at least two drugs, regardless of the classification system.
- Compare plan formulary to the top drug classes used by Medicare beneficiaries by cost and utilization. Potential issues report will identify those drugs or drug classes that are not included on the formulary.
- Determine if appropriate access is granted for certain drug classes. Potential issues report will identify those drug classes which do not represent appropriate access. Within the review of certain drug classes one of the reviews focuses on the six classes of clinical concern. To ensure that this review is performed accurately the Contractor shall update the list of six class drugs. The Contractor shall develop a methodology for this review and have the methodology reviewed and approved by CMS. Medications shall be reviewed for labeled indications only. The Contractor shall submit a list of "required drugs" at the generic name, dosage form, strength, and route of administration level. This list must be produced utilizing the format in the current Formulary Reference NDC File, and be grouped by unique required drug category. The report must be provided in the format specified in Appendix A.
- Determine if plans have included drugs or drug classes included in widely accepted treatment guidelines. To ensure that this review is performed accurately the contractor shall update the list of necessary drugs based on treatment guidelines to ensure all appropriate drugs are included within the review. The Contractor shall submit a list of the drugs at the generic name, dosage form, strength, and route of administration level. This list must be produced utilizing the format in the current Formulary Reference NDC File, be grouped by treatment guideline (disease state), formulary requirement, and a drug listing that would fulfill the requirement. This report must be provided in the format specified in Appendix A. A summary of the methodology and the specific treatment guidelines used for review must be developed, reviewed, and approved by CMS. Potential issues will identify those drugs or drug classes which are not included on the formulary.
- Determine if drug placement within tier structure is appropriate within a formulary and as compared to all submitted plans. Potential issues report will identify drug classes where tier placement may be discriminatory.
- Determine if prior authorization criteria, quantity limits, and step therapy are being utilized appropriately within the formulary and as compared to all submitted plans. To determine if the prior authorization criteria, quantity limits, and step therapy are being utilized appropriately, the contractor shall review each criteria submitted for each formulary. After review the contractor shall submit a report summarizing the findings in the format specified by CMS. The Contractor shall develop a methodology to be utilized in the review of plan-submitted utilization management criteria. Potential issues will identify drugs that may not meet best practices.

- Determine if inclusion of a drug is appropriate within a formulary and as compared to all submitted plans.
- After these items are reviewed by a pharmacist, each module will be documented in HPMS as "pass" or "not pass" and documentation for each item found will be required in the system.
- As determined by the GTL, a pharmacist shall use clinical judgment and/or CMS guidelines to make decisions as to whether an issue that does not pass needs to be negotiated with the plan.
- As determined by the GTL, the pharmacist shall participate on negotiation calls with the plans.
- Complete review of resubmitted formulary information and clinical justification for plans that do not pass the initial review.
- Complete monthly review of plan changes. Plans will submit changes to the formulary, if any, each month during a set time frame. HPMS will produce a report of the changes and the Contractor shall ensure that any changes made by the plan are: 1) approved by CMS and 2) do not make the formularies discriminatory.
- The workload estimate for formularies to be reviewed is as follows:

Estimated Number of Formularies	Number of Months	Estimated Review Time per Formulary
450 initial formulary submissions	2	1 hour and 30 minutes
300 monthly update submissions	5	25 minutes

**B.5 Benefit Design Review: Cost Sharing per Formulary Tier – Optional Task**

The Contractor shall review the cost sharing structure for each formulary tier to ensure plans do not have a benefit structure that is discriminatory. The analyst will utilize data generated by HPMS to review cost sharing per tier against the standards set forth by CMS. This review will consist of data analysis that focuses on "outliers" to review for potential discrimination. The benefit review will require the contractor to coordinate and complete the following processes:

- Maintain a spreadsheet of the outcomes of the benefits review.
- Participate in benefit negotiations with plan sponsors, about Part D benefits, as directed by the GTL.
- Secondary benefit review.
- Tests and analyses to assure review consistency (e.g., 95% of the materials reviewed by the lead reviewer result in the same finding as the original review).
- The estimated number of plan benefit packages to be reviewed is 2500.

**B.6 Ad-hoc Requests**

CMS may need information on an ad hoc basis regarding formulary review criteria, formulary sub-reviews and/or benefit sub-reviews. The contractor

shall provide such information upon request. It is anticipated that approximately 6 ad hoc requests will be made per year.

**B.7 Reporting**

• **Project Summary Report**

The Contractor shall provide a monthly project summary report on the status of projects in progress that will include a Financial Report, as described below, as well as additional information negotiated between the contractor and CMS. At a minimum, this status report shall include the following additional information:

1. Project schedule;
2. Summary of project requirements;
3. Estimated cost and level of effort information necessary to manage workloads.

• **Financial Report**

The Contractor shall provide monthly financial reports to reflect the work performed by both the prime contractor and any subcontractors. The financial report shall report the content of pending invoices and shall include the following information:

1. Contract name;
2. Period of performance;
3. Current month, hours and cost expended for each labor category;
4. Cumulative hours and cost expended for each labor category;
5. Projected monthly hours and costs for the remainder of the contract period; and
6. Summary of the work completed by each contractor staff.

The financial report shall also include with it the following variance information to reflect the work performed. The variance information shall report the content of actual and proposed spending and shall include the following information:

1. Analysis of budgeted activities versus actual expenses on a monthly basis;
2. Explanation of variances of greater than 10% of the budget monthly cost indicated in the cost proposal;
3. Any relevant analysis or information explaining an activity causing an unexplained variance that occurred during the month; and
4. As requested by the project officer, a section will also be included providing the budgeted cost of work scheduled and work performed; the actual cost of work performed, and associated variances.

**C. Project Deliverables**

CMS is requesting technical assistance for the review of plan formularies and/or benefits. The Contractor shall provide planning, coordination, and

clinical expertise to accomplish these goals. The Contractor shall work and interact on a regular basis with the Government Task Leader (GTL) and the CMS Medicare Drug Benefit Group, Division of Finance and Operations.

The Contractor shall submit to the GTL each deliverable via email in Microsoft Office 2003 format, with the exception of the Progress updates and Status reports which also need to be emailed to the Contract Specialist. The Contractor shall also submit a copy of the transmittal letter for each deliverable to the Contract Specialist at the address specified on the front of the task order.

**Schedule of Deliverables**

<b>Description</b>	<b>Distribution</b>	<b>Due Date</b>
1) Initial kick-off meeting		1 week after award
2) Work management plan	(4) copies to GTL	3 weeks after award
3) Progress updates/Status reports	(2) copies to GTL	End of each day after review begins
4) Monthly progress and financial reports including a variance report	(2) copies to the GTL + (1) copy to CS	No later than the 15 <sup>th</sup> day of the following month
5) Complete initial review of plan formularies		June 2, 2008
6) Participate in negotiations with plans		June 30, 2008 to August 29, 2008
7) Complete review of resubmitted formulary information		June 9, 2008 to June 30, 2008
8) Complete formulary changes reviews		Ongoing each month from the 3 <sup>rd</sup> business day to the 13 <sup>th</sup> business day of the month
9) List of required drugs for the six classes of clinical concern based on the Formulary NDC Reference File in the format specified in Appendix A.	Electronic Excel File	March 7, 2008
10) Report on the methodology for the required drug list for the six classes of clinical concern		February 15, 2008
11) List of drugs group by treatment guideline as specified in Appendix A	Electronic Excel File	January 7, 2008
12) Report on the methodology and references to specific treatment guidelines used to		December 17, 2007

developed the revised drug list.		
13) Report on the appropriateness of prior authorization, quantity limit, and step therapy criteria as specified by CMS.	Electronic Excel File	June 30, 2008
14) Report on the methodology used to perform the analysis in deliverable #13		April 14, 2008
<b>Optional Task</b> 15) Complete review of cost sharing structure per tier		June 6, 2008 to June 30, 2008

**IV. Period of Performance**

The period of performance for this task order is a base year, Sep 30, 2007 – Sep 29, 2008, plus four option years. During the period of performance, the Contractor will perform all the tasks identified in the SOW and turn over to CMS all the products, materials, and records associated with the tasks. The Contractor may not use any information gained from the SOW, for any purpose, unless prior approval is received from CMS.

- Base Year: Sep 30, 2007 – Sep 29, 2008
- Option Year 1: Sep 30, 2008 – Sep 29, 2009
- Option Year 2: Sep 30, 2009 – Sep 29, 2010
- Option Year 3: Sep 30, 2010 – Sep 29, 2011
- Option Year 4: Sep 30, 2011 – Sep 29, 2012

**V. Options**

The Government has the authority to exercise any option periods or the optional task during the period of performance of the task order.

**VI. Confidentiality**

As a result of this Task Order, the Contractor may have access to confidential information (i.e. information considered proprietary as well as information that may fall under the Privacy Act). The Contractor shall not disclose any such information or findings to any parties other than the Project Officer and staff assigned to this effort. Appropriate administrative, technical, procedural and physical safeguards shall be established by the GSA Schedule Contractor to protect the confidentiality of the data and to prevent unauthorized access to such data.

All contractor staff participating in the completion of this task order will be required to sign Attachment 1, Formulary and Benefits Conflict of Interest, Confidentiality and Non-disclosure Form.

## **VII. Code of Conduct**

Effective June 9, 2004, smoking is not permitted anywhere on the CMS single site campus. This includes all areas outside the building, such as off-site facility, entranceways, sidewalks and parking areas. Smoking will not be permitted anywhere in Regional Offices or Washington, D.C. Office locations unless permitted by GSA guidelines or local landlord requirements. Contractor employees are subject to the same restrictions as government personnel. Fines up to \$50 per occurrence will be issued and enforced by the Federal Protective Service.

The preferred dress codes at CMS facilities are professional attire, business attire or business casual attire.

## **VIII. HIPAA BUSINESS ASSOCIATE PROVISION II**

### **Definitions:**

All terms used herein and not otherwise defined shall have the same meaning as in the Health Insurance Portability and Accountability Act of 1996 ("HIPAA," 42 U.S.C. sec. 1320d) and the corresponding implementing regulations. Provisions governing the Contractor's duties and obligations under the Privacy Act (including data use agreements) are covered elsewhere in the contract.

"Business Associate" shall mean the Contractor.

"Covered Entity" shall mean CMS' Medicare Fee for Service program and/or Medicare's Prescription Drug Discount Care and Transitional Assistance Programs.

"Secretary" shall mean the Secretary of the Department of Health and Human Services or the Secretary's designee.

### **Obligations and Activities of Business Associate**

(a) Business Associate agrees to not use or disclose Protected Health Information ("PHI"), as defined in 45 C.F.R. § 160.103, created or received by Business Associate from or on behalf of Covered Entity other than as permitted or required by this Contract or as required by law.

(b) Business Associate agrees to use safeguards to prevent use or disclosure of PHI created or received by Business Associate from or on behalf of Covered Entity other than as provided for by this Contract. Furthermore, Business Associate agrees to use appropriate administrative, physical and technical safeguards that reasonably and appropriately protect the confidentiality, integrity and availability of the electronic protected health information ("E PHI"), as defined in 45 C.F.R. 160.103, it creates, receives, maintains or transmits on behalf of the Covered Entity to prevent use or disclosure of such E PHI.

(c) 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 Contract.

(d) Business Associate agrees to report to Covered Entity any use or disclosure involving PHI it receives/maintains from/on behalf of the Covered Entity that is not provided for by this Contract of which it becomes aware. Furthermore, Business Associate agrees to report to Covered Entity any security incident involving E PHI of which it becomes aware.

(e) Business Associate agrees to ensure that any agent, including a subcontractor, to whom it provides PHI received from Covered Entity, or created or received by Business Associate on behalf of Covered Entity, agrees to the same restrictions and conditions that apply

through this Contract to Business Associate with respect to such information. Furthermore, Business Associate agrees to ensure that its agents and subcontractors implement reasonable and appropriate safeguards for the PHI received from or on behalf of the Business Associate.

(f) Business Associate agrees to provide access, at the request of Covered Entity, to PHI received by Business Associate in the course of contract performance, to Covered Entity or, as directed by Covered Entity, to an Individual in order to meet the requirements under 45 CFR § 164.524.

(g) Business Associate agrees to make any amendment(s) to PHI in a Designated Record Set that Covered Entity directs or agrees to pursuant to 45 CFR § 164.526 upon request of Covered Entity.

(h) Business Associate agrees to make internal practices, books, and records, including policies and procedures and PHI, relating to the use and disclosure of PHI received from, or created or received by Business Associate on behalf of Covered Entity, available to Covered Entity, or to the Secretary for purposes of the Secretary determining Covered Entity's compliance with the various rules implementing the HIPAA.

(i) Business Associate agrees to document such disclosures of PHI and 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 CFR § 164.528.

(j) Business Associate agrees to provide to Covered Entity, or an individual identified by the Covered Entity, information collected under this Contract, to permit Covered Entity to respond to a request by an Individual for an accounting of disclosures of PHI in accordance with 45 CFR § 164.528.

#### **Permitted Uses and Disclosures by Business Associate**

Except as otherwise limited in this Contract, Business Associate may use or disclose PHI on behalf of, or to provide services to, Covered Entity for purposes of the performance of this Contract, if such use or disclosure of PHI would not violate the HIPAA Privacy or Security Rules if done by Covered Entity or the minimum necessary policies and procedures of Covered Entity.

#### **Obligations of Covered Entity**

(a) Covered Entity shall notify Business Associate of any limitation(s) in its notice of privacy practices of Covered Entity in accordance with 45 CFR § 164.520, to the extent that such limitation may affect Business Associate's use or disclosure of PHI.

(b) Covered Entity shall notify Business Associate of any changes in, or revocation of, permission by Individual to use or disclose PHI, to the extent that such changes may affect Business Associate's use or disclosure of PHI.

(c) 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 CFR § 164.522, to the extent that such restriction may affect Business Associate's use or disclosure of PHI.

#### **Permissible Requests by Covered Entity**

Covered Entity shall not request Business Associate to use or disclose PHI in any manner that would not be permissible under the HIPAA Privacy or Security Rules.

### **Term of Provision**

(a) The term of this Provision shall be effective as of June 1, 2006, and shall terminate when all of the PHI provided 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 it is infeasible to return or destroy PHI, protections are extended to such information, in accordance with the termination provisions in this Section.

(b) Upon Covered Entity's knowledge of a material breach by Business Associate, Covered Entity shall either:

(1) Provide an opportunity for Business Associate to cure the breach or end the violation consistent with the termination terms of this Contract. Covered Entity may terminate this Contract for default if the Business Associate does not cure the breach or end the violation within the time specified by Covered Entity; or

(2) Consistent with the terms of this Contract, terminate this Contract for default if Business Associate has breached a material term of this Contract and cure is not possible; or

(3) If neither termination nor cure is feasible, Covered Entity shall report the violation to the Secretary.

(c) Effect of Termination.

(1) Except as provided in paragraph (2) of this section, upon termination of this Contract, for any reason, Business Associate shall return or destroy all PHI received from Covered Entity, or created or received by Business Associate on behalf of Covered Entity. This provision shall apply to PHI that is in the possession of subcontractors or agents of Business Associate. Business Associate shall retain no copies of the PHI.

(2) In the event that Business Associate determines that returning or destroying the PHI is infeasible, Business Associate shall provide to Covered Entity notification of the conditions that make return or destruction infeasible. Upon such notice that return or destruction of PHI is infeasible, Business Associate shall extend the protections of this Contract to such PHI and limit further uses and disclosures of such PHI to those purposes that make the return or destruction infeasible, for so long as Business Associate maintains such PHI.

### **Miscellaneous**

(a) A reference in this Contract to a section in the Rules issued under HIPAA means the section as in effect or as amended.

(b) The Parties agree to take such action as is necessary to amend this Contract from time to time as is necessary for Covered Entity to comply with the requirements of the Rules issued under HIPAA.

(c) The respective rights and obligations of Business Associate under paragraph (c) of the section entitled "term of Provision" shall survive the termination of this Contract.

(d) Any ambiguity in this Contract shall be resolved to permit Covered Entity to comply with the Rules implemented under HIPAA.

### **IX. Security Clause -Background - Investigations for Contractor Personnel**

If applicable, Contractor personnel performing services for CMS under this contract, task order or delivery order shall be required to undergo a background investigation. CMS will initiate and pay for any required background investigation(s).

After contract award, the CMS Project Officer (PO) and the Security and Emergency Management Group (SEMG), with the assistance of the Contractor, shall perform a position-sensitivity analysis based on the duties contractor personnel shall perform on the contract, task order or delivery order. The results of the position-sensitivity analysis will determine first, whether the provisions of this clause are applicable to the contract and second, if applicable, determine each position's sensitivity level (i.e., high risk, moderate risk or low risk) and dictate the appropriate level of background investigation to be processed. Investigative packages may contain the following forms:

1. SF-85, Questionnaire for Non-Sensitive Positions, 09/1995
2. SF-85P, Questionnaire for Public Trust Positions, 09/1995
3. OF-612, Optional Application for Federal Employment, 12/2002
4. OF-306, Declaration for Federal Employment, 01/2001
5. Credit Report Release Form
6. FD-258, Fingerprint Card, 5/99, and
7. CMS-730A, Request for Physical Access to CMS Facilities (NON-CMS ONLY), 11/2003.

The Contractor personnel shall be required to undergo a background investigation commensurate with one of these position-sensitivity levels:

**1) High Risk (Level 6)**

Public Trust positions that would have a potential for exceptionally serious impact on the integrity and efficiency of the service. This would include computer security of a major automated information system (AIS). This includes positions in which the incumbent's actions or inaction could diminish public confidence in the integrity, efficiency, or effectiveness of assigned government activities, whether or not actual damage occurs, particularly if duties are especially critical to the agency or program mission with a broad scope of responsibility and authority.

Major responsibilities that would require this level include:

- a. development and administration of CMS computer security programs, including direction and control of risk analysis and/or threat assessment;
- b. significant involvement in mission-critical systems;
- c. preparation or approval of data for input into a system which does not necessarily involve personal access to the system but with relatively high risk of causing grave damage or realizing significant personal gain;
- d. other responsibilities that involve relatively high risk of causing damage or realizing personal gain;
- e. policy implementation;
- f. higher level management duties/assignments or major program responsibility; or
- g. independent spokespersons or non-management position with authority for independent action.

Approximate cost of each investigation: \$2,900

**2) Moderate Risk (Level 5)**

Level 5 Public Trust positions include those involving policymaking, major program responsibility, and law enforcement duties that are associated with a "Moderate Risk." Also included are those positions involving access to or control of unclassified sensitive,

proprietary information, or financial records, and those with similar duties through which the incumbent can realize a significant personal gain or cause serious damage to the program or Department.

Responsibilities that would require this level include:

- a. the direction, planning, design, operation, or maintenance of a computer system and whose work is technically reviewed by a higher authority at the High Risk level to ensure the integrity of the system;
- b. systems design, operation, testing, maintenance, and/or monitoring that are carried out under the technical review of a higher authority at the High Risk level;
- c. access to and/or processing of information requiring protection under the Privacy Act of 1974;
- d. assists in policy development and implementation;
- e. mid-level management duties/assignments;
- f. any position with responsibility for independent or semi-independent action; or
- g. delivery of service positions that demand public confidence or trust.

Approximate cost of each investigation: \$2,400

**3) Low Risk (Level 1)**

Positions having the potential for limited interaction with the agency or program mission, so the potential for impact on the integrity and efficiency of the service is small. This includes computer security impact on AIS.

Approximate cost of each investigation: \$550

The Contractor shall submit the investigative package(s) to SEMG within three (3) days after being advised by the SEMG of the need to submit packages. Investigative packages shall be submitted to the following address:

Centers for Medicare & Medicaid Services  
Office of Operations Management  
Security and Emergency Management Group  
Mail Stop SL-13-15  
7500 Security Boulevard  
Baltimore, Maryland 21244-1850

The Contractor shall submit a copy of the transmittal letter to the Contracting Officer (CO).

Contractor personnel shall submit a CMS-730A (Request for Badge) to the SEMG (see attachment in Section J). The Contractor and the PO shall obtain all necessary signatures on the CMS-730A prior to any Contractor employee arriving for fingerprinting and badge processing.

The Contractor must appoint a Security Investigation Liaison as a point of contact to resolve any issues of inaccurate or incomplete form(s). Where personal information is involved, SEMG may need to contact the contractor employee directly. The Security Investigation Liaison may be required to facilitate such contact.

SEMG will fingerprint contractor personnel and send their completed investigative package to the Office of Personnel Management (OPM). OPM will conduct the background investigation. Badges will not be provided by SEMG until acceptable finger print results are received; until then the contractor employee will be considered an escorted visitor. The Contractor remains fully responsible for ensuring contract, task order or delivery order performance pending completion of background investigations of contractor personnel.

SEMG shall provide written notification to the CO with a copy to the PO of all suitability decisions. The PO shall then notify the Contractor in writing of the approval of the Contractor's employee(s), at that time the Contractor's employee(s) will receive a permanent identification badge. Contractor personnel who the SEMG determines to be ineligible may be required to cease working on the contract immediately.

The Contractor shall report immediately in writing to SEMG with copies to the CO and the PO, any adverse information regarding any of its employees that may impact their ability to perform under this contract, task order or delivery order. Reports should be based on reliable and substantiated information, not on rumor or innuendo. The report shall include the contractor employee's name and social security number, along with the adverse information being reported.

Contractor personnel shall be provided an opportunity to explain or refute unfavorable information found in an investigation to SEMG before an adverse adjudication is made. Contractor personnel may request, in writing, a copy of their own investigative results by contacting:

Office of Personnel Management  
Freedom of Information  
Federal Investigations Processing Center  
PO Box 618  
Boyers, PA 16018-0618.

At the Agency's discretion, if an investigated contractor employee leaves the employment of the contractor, or otherwise is no longer associated with the contract, task order, or delivery order within one (1) year from the date the background investigation was initiated by CMS, then the Contractor may be required to reimburse CMS for the full cost of the investigation. Depending upon the type of background investigation conducted, the cost could be approximately \$550 to \$2,900. The amount to be paid by the Contractor shall be due and payable when the CO submits a written letter notifying the Contractor as to the cost of the investigation. The Contractor shall pay the amount due within thirty (30) days of the date of the CO's letter by check made payable to the "United States Treasury." The Contractor shall provide a copy of the CO's letter as an attachment to the check and submit both to the Office of Financial Management at the following address:

Centers for Medicare & Medicaid Services  
PO Box 7520  
Baltimore, Maryland 21207

The Contractor must immediately provide written notification to SEMG (with copies to the CO and the PO) of all terminations or resignations of Contractor personnel working on this contract, task order or delivery order. The Contractor must also notify SEMG (with copies to

the CO and the PO) when a Contractor's employee is no longer working on this contract, task order or delivery order.

At the conclusion of the contract, task order or delivery order and at the time when a contractor employee is no longer working on the contract, task order or delivery order due to termination or resignation, all CMS-issued parking permits, identification badges, access cards, and/or keys must be promptly returned to SEMG. Contractor personnel who do not return their government-issued parking permits, identification badges, access cards, and/or keys within 48 hours of the last day of authorized access shall be permanently barred from the CMS complex and subject to fines and penalties authorized by applicable federal and State laws.

#### Work Performed Outside the United States and its Territories

The contractor, and its subcontractors, shall not perform any activities under this contract at a location outside of the United States, including the transmission of data or other information outside the United States, without the prior written approval of the Contracting Officer. The factors that the Contracting Officer will consider in making a decision to authorize the performance of work outside the United States include, but are not limited to the following:

1. All contract terms regarding system security
2. All contract terms regarding the confidentiality and privacy requirements for information and data protection
3. All contract terms that are otherwise relevant, including the provisions of the statement of work
4. Corporate compliance
5. All laws and regulations applicable to the performance of work outside the United States
6. The best interest of the United States

In requesting the Contracting Officer's authorization to perform work outside the United States, the contractor must demonstrate that the performance of the work outside the United States satisfies all of the above factors. If, in the Contracting Officer's judgment, the above factors are not fully satisfied, the performance of work outside the United States will not be authorized. Any approval to employ or outsource work outside of the United States must have the concurrence of the CMS SEMG Director or designee.

#### **X. TIME AND MATERIALS - 5% WITHHOLDING**

In accordance with FAR 52.232-7(A)(2), unless otherwise prescribed in the Schedule, the Contracting Officer will withhold 5 percent of the amounts due under this task order, but the total amount withheld shall not exceed \$50,000. The amounts withheld shall be retained until the execution and delivery of a release by the Contractor is provided.

Please adjust invoices to reflect 5% withholding.

**XI. TRAVEL**

Travel costs are to be reimbursed based upon the Federal Travel Regulations. Payment for travel is based on actual expenses incurred and the contractor is to maintain all receipts/vouchers for expense verification.

**XII. KEY PERSONNEL**

The following individuals are identified as Key Personnel for this task order:

Project Manager – Peg Stessman  
Senior Consultant II – Fred Ham  
Senior Consultant II – Paul Nelson  
Senior Consultant I – Sheila Glencer  
Senior Consultant I – Shannon Nelson  
Senior Consultant I – Jennifer Baxter  
Analyst II – Pam Wittfeldt  
Analyst III – Irvin Philpot

Prior to diverting/changing any of the specified key personnel to other programs, the contractor shall notify the Contracting Officer and Project Officer reasonably in advance and shall submit justification (including proposed substitutions) in sufficient detail to permit evaluation of the impact on the program. No diversion/changes shall be made by the Contractor without the consent of the Project Officer and the Contracting Officer.

**XIII. CENTRAL CONTRACTOR REGISTRATION**

For the contractor to receive payment under this task order, the contractor must be currently registered in the Central Contractor Registration database.

**XIV. CONTRACTUAL CLAUSES**

All deliverables for this task order will adhere to the specifications, requirements and guidance as prescribed in the Task Order, Statement of Work, and GSA contractual clauses and content.

Appendix A

Example Drug Grouping

Six Classes Format

GENERIC NAME	DOSAGE FORM	ROUTE	STRENGTH
ABACAVIR SULFATE	SOLN	ORAL	20 MG/ML
ABACAVIR SULFATE	TABS	ORAL	300 MG
ENFUVRTIDE	KIT	SC	90 MG

Treatment Guidelines  
 Format

TREATMENT GUIDELINE	DRUG CLASS	GENERIC NAME	DOSAGE FORM	ROUTE	STRENGTH
ATRIAL FIBRILLATION	AMIODARONE	AMIODARONE HCL	TABS	ORAL	100 MG
ATRIAL FIBRILLATION	AMIODARONE	AMIODARONE HCL	TABS	ORAL	200 MG
ATRIAL FIBRILLATION	AMIODARONE	AMIODARONE HCL	TABS	ORAL	300 MG
ATRIAL FIBRILLATION	AMIODARONE	AMIODARONE HCL	TABS	ORAL	400 MG
ASTHMA	SHORT-ACTING BETA-AGONIST	ALBUTEROL SULFATE	AERS	INHL	108 MCG/ACT
ASTHMA	SHORT-ACTING BETA-AGONIST	LEVALBUTEROL TARTRATE	AERO	INHL	45 MCG/ACT

**Attachment 1**  
**Formulary and Benefits Review Process**  
**Contract number: GS-10F-0231T**  
**Task Order Number: HHSM-500-2007-00311G**

**Date:** September 26, 2007

**Title:** Formulary and Benefits Conflict of Interest, Confidentiality and Non-disclosure Rules

**Scope:** CMS Formulary and Benefits Review Team

**Policy:** Review of formulary applications and Part D Plan Benefit Packages (PBP) on behalf of the Centers for Medicare and Medicaid Services (CMS) shall be conducted in a manner which is void from any real or perceived conflict of interest.

**Procedure:**

- (1) No member of the formulary or benefit review team may participate in, review, or be present during any review of a formulary submission or Part D PBP in which, to the member's knowledge, any of the following has a financial interest: (i) The member or his or her spouse, parent, child or partner, (ii) any organization in which the member or his or her spouse, parent, child, or partner is serving as an officer, director, trustee, partner, or employee, or is otherwise similarly associated, or (iii) any organization with which the member or his or her spouse, parent, child, or partner is negotiating or has any arrangement concerning prospective employment or other similar association.
- (2) In the event that any member of the formulary or benefits review team or his or her spouse, parent, child or partner is currently or expected to be the principal or a member of the staff responsible for carrying out any research or development activities contemplated as part of the formulary submission or Part D PBP, that individual is disqualified and the review will be conducted by another individual with the expertise to do so.
- (3) No member of the formulary or benefits review team may participate in any review of a formulary submission or Part D PBP for which the member has or is expected to have any other responsibility or involvement, including a competing interest.
- (4) No member of the formulary or benefits review team will disclose to any individual or entity, other than those individuals expressly authorized to know within the formulary or benefits review team and CMS, any information that is learned through the formulary or benefits review program and is otherwise not publicly available including, but not limited to the formulary review process, Part D benefits review process, formularies that are submitted, Part D PBP that are submitted or information regarding plan sponsors.

**Certification**

I certify that I have read the attached "Formulary and Benefit Conflict of Interest, Confidentiality and Non-disclosure Rules". I certify to the best of my knowledge, that I will disclose all real and perceived conflicts of interest that I may have with the application and I fully understand the confidential nature of the formulary and benefits review process and agree: (1) not to disclose or discuss the materials associated with the review, my evaluation, or the review meetings with any other individuals except as authorized by the Centers for Medicare and Medicaid Services (CMS), and (2) to refer all inquiries concerning the review to CMS or other designated individual.

Signature: \_\_\_\_\_ Date: \_\_\_\_\_

## Statement of Work

### Medicare Prescription Drug Benefit Final Part D Payment Process

#### I. SCOPE

The Contractor shall provide a full range of statistical, analytical, audit, financial, formulary and/or professional business services to the Centers for Medicare & Medicaid Services (CMS). The Contractor shall assist with analyzing the Part D Payment Reconciliation results as determined by the Payment Reconciliation System (PRS) and establishing and implementing a process for determining final Part D Payment.

#### A. Background

In December 2003, the President signed the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA). In addition to many other changes, the MMA augments the Medicare Program by creating the Medicare Prescription Drug Benefit (Part D).

The Medicare Plan Payment Group, Division of Payment Systems is responsible for the business requirements for the national systems for payment of the Part D prescription drug organizations. PRS is the payment system that compares Part D prospective payment information to actual cost in order to perform the three required payment reconciliations, which are collectively known as the Part D Payment Reconciliation. The Part D Payment Reconciliation is performed at the Contract/Plan Benefit Package (PBP) level. The Division of Payment Systems will evaluate the results of the Part D Payment Reconciliation and will determine if the results are final or if the results should be re-evaluated based upon documentation that is provided by Part D sponsors. A process will need to be established to receive and evaluate cost estimates and other supporting documentation from Part D Sponsors to evaluate the final cost of providing Part D Prescription Drug Coverage. The additional documentation requested for this analysis may include but is not limited to Prescription Drug Event (PDE) Data and Direct and Indirect Remuneration amounts.

#### B. Purpose

The purpose of the SOW is to assist CMS with the intake and review of cost estimates and other supporting documentation provided by sponsors, and to assist CMS with all communications to sponsors that will result from the Final Part D Payment Process. The Contractor shall also assist with the organization and review of the Final Part D Payment Process. In addition, the Contractor shall assist in implementing and refining the project plan for the Final Part D Payment Process.

## C. Objectives

### **Task 1: Final Part D Payment Process**

The Contractor shall assist with designing and implementing a set of procedures for the Final Part D Payment Process and to provide CMS with the procedures in application form using Microsoft Office products.

### **Task 2: Supporting CMS Communications with Part D Sponsors**

The Contractor shall assist CMS in communicating with Part D Sponsors. This includes assisting CMS in receiving and responding to questions regarding the Part D Payment Reconciliation and the PRS Reconciliation Results Reports to Plans, the data collection process for dispute of the Reconciliation Results, and the outcome of the Final Part D Payment process.

### **Task 3: Intake of Part D Payment Reconciliation Cost Estimates and Supporting Documentation**

The Contractor shall develop a data collection tool for the intake process of obtaining cost estimates. This task involves developing and implementing a process for the intake of the cost estimates and other relevant documentation from the Part D Sponsors.

### **Task 4: Maintain a Secure Location for all Documents in the Final Part D Payment Process**

The Contractor shall provide support for the secure storage, filing and tracking of all documents in the Final Part D Payment process, which includes documentation of sponsor communication, sponsor cost estimates and supporting documentation received and filed at CMS.

### **Task 5: Statistical and Analytical Review of Cost Estimates and Supporting Documentation**

The Contractor shall assist with a comprehensive review of the cost estimates and supporting documentation received from Part D Sponsors, which involves identifying data differences between the information supplied by the sponsor and the cost estimates calculated by CMS and the potential causes of those data differences.

### **Task 6: Management Support and Ad Hoc Reporting**

The Contractor shall generate reports and briefing materials at any time, which will assist in the overall analysis of the Final Part D Payment Process. Management meetings, if necessary, shall be required to discuss ongoing issues with this process and the implementation of the business plan and strategy.

### **Task 7: Letter Generation**

The Contractor shall assist with the development of letters to request cost estimates, to request additional documentation from Part D sponsors in order to complete the analysis needed to make a decision in the Final Part D Payment process, and to inform the sponsors of the outcome of this process.

### **Task 8: Updates**

The Contractor shall submit weekly updates regarding the review of Part D Payment Reconciliation Results and other data generated by CMS compared to the data provided by sponsors and involves reporting to CMS regarding funding, any issues impeding progress toward completion of deliverables, and the status of the completion of the deliverables outlined in this SOW.

## **D. General Requirements**

The implementation of the Medicare Drug Benefit under the Medicare Modernization Act (MMA) of 2003 requires CMS to make payments after a coverage year after obtaining all of the cost data information necessary to determine the amount of payment. The payment calculation is performed by the Payment Reconciliation System. The MMA allows for revision of an initial or reconsidered final payment determination (including a determination on the final amount of the direct subsidy, final reinsurance payments, the final amount of the low income subsidy, or the final risk corridor payments). The Final Part D Payment Process will require a specialized team of evaluators to analyze CMS generated results and compare the results with information provided by sponsors. The contractor shall provide staff to be located at CMS to perform the tasks necessary to complete each step in the Final Part D Payment Process. The contractor shall be responsible for managing their workload, to include managing incoming sponsor cost estimates and supporting documentation, performing statistical and analytical review of the information provided by the sponsors compared to the CMS generated results, interacting with CMS team leaders, and supporting CMS communications with Part D sponsors.

The Contractor shall possess, at a minimum, the following expertise:

- Thorough understanding of (1) the development, implementation, and management of large-scale prescription drug benefit programs; (2) the purchasing of prescription drugs by large employers, state Medicaid agencies, and large health insurers (on a full risk, shared risk, and cost reimbursements basis); and (3) the dispensing of prescription drugs in retail, mail order, and long-term care settings.
- Thorough understanding of the standards governing the prescribing and dispensing of pharmaceuticals, including state regulation of pharmacies.
- Thorough understanding of the prescription drug benefit management industry including all aspects of claims processing, payments, enrollment, rebates and other price concession negotiations, and formulary creation.
- Thorough understanding of the sections of the Social Security Act (the Act) and the Code of Federal Regulations (CFR) governing the Part D program
- Thorough understanding of the Medicare Prescription Drug Benefit.

## **E. Specific Requirements**

The task and deliverable section is divided into eight functions: Final Part D Payment Process, Supporting CMS Communications with Part D sponsors, Intake of Part D Payment Reconciliation Cost Estimates and Supporting Documentation, Maintain a Secure Location for all Documents in the Final Part D Payment Process, Statistical and Analytical Review of Cost Estimates and Supporting Documentation, Management Support and Ad Hoc Reporting, Letter Generation, and Updates.

**Task 1: Final Part D Payment Process**

The Contractor shall create procedures and a project plan which outlines methods to streamline the Final Part D Payment process. As this process is conducted, the Contractor shall administer these strategies and evaluate the methods to determine effectiveness. Moreover, the Contractor shall refine the process to determine if other efficiencies can be implemented throughout the entire Final Part D Payment process.

**Task 2: Supporting CMS Communications with Part D Sponsors**

The Contractor shall assist in receiving and responding to questions related to the PRS Reconciliation Results Reports to Plans, the data collection process that will be used to collect cost estimates from sponsors, and the outcome of the Final Part D Payment process. The Contractor shall document any communication with sponsors.

**Task 3: Intake of Part D Payment Reconciliation Cost Estimates and Supporting Documentation**

The Contractor shall perform certain organizational and administrative tasks. This shall include assisting with the dissemination of information from the sponsor provided documents to specific government stakeholders to include certain reports and other written and electronic materials in an efficient and effective manner.

**Task 4: Maintain a Secure Location for all Documents in the Final Part D Payment Process**

The Contractor shall provide the secure storage of all documentation collected in the Final Part D Payment process. This includes filing, tracking, and storage of all sponsor provided documentation and communication with sponsors in a secured location.

**Task 5: Statistical and Analytical Review of Cost Estimates and Supporting Documentation**

The Contractor shall perform certain tasks to assist with the review of the sponsor provided documentation. This review shall consist of comparing the Part D Payment Reconciliation Results and other CMS cost estimates to the Sponsor provided documentation. The analysis shall identify data differences and evaluate the reasons behind those data differences. If necessary, the results of the review shall require additional supporting documentation from the sponsors.

**Task 6: Management Support and Ad-hoc Reporting**

The Contractor shall provide management support throughout the Final Part D Payment process. This shall require frequent meetings and staff at CMS to complete this process. The meetings shall be daily at the beginning of the process and then shall be as needed based on the status of the Final Part D Payment process being conducted. Meetings can be in person or by phone, which will depend on the sensitivity of the information, urgency of the meeting or other factors.

Ad-hoc reporting shall also be required. This shall include data collection tools, status reports, tracking tools, spreadsheets, vulnerability reports, summary reports, etc. These reports shall

assist CMS in completing the Final Part D Payment process and tracking the progress or issues identified. These reports shall be discussed with the Contractor as needed.

**Task 7: Letter Generation**

The Contractor shall generate any letters required to notify the sponsors of the Final Part D Payment process, the need for additional documentation supporting their dispute of the Part D Reconciliation Results, and the outcome of the Final Part D Payment process. This shall require populating the information, generating the letters and mailing them to the sponsors. The Contractor shall work with CMS to complete the letters and track their submission and receipt of any materials provided in response to the letters.

**Task 8: Updates**

The Contractor shall provide status reports to CMS. The reports will provide notification to the GTL of the completion of deliverables outlined in the SOW, any issues impeding progress, funding updates, and any issues which require CMS attention. The reports will be provided weekly at the beginning of the Final Part D Payment process. The frequency of status reports will be re-evaluated as CMS proceeds through the Final Part D Payment process. Meetings between the GTL and the Contractor will occur frequently as this process gets underway in order to keep communication open and to identify any issues, which require mitigation.

**F. Report Requirements**

1. Status reports shall include at a minimum:

- The prior week's activities by task and activity;
- High-level workload reports;
- Summaries of meetings and areas of concentration for the upcoming week;
- Issues of concern that should be addressed by CMS; and,
- Any unresolved issues from the prior week.

2. Ad-hoc Reports—the contractor shall submit reports throughout the Final Part D Payment process.

- Summary reports
- Excel spreadsheets
- Tracking reports
- Intake reports
- Any other reports, which will assist with the Final Part D Payment process

**II. QUALITY ASSURANCE**

The Government, through the Government Task Leader (GTL), shall review and approve all work products and deliverables submitted by the contractor. Progress meetings shall be held between the contractor and the GTL weekly. The meetings shall take place each week on a day mutually agreed upon by contractor and CMS. These meetings will be used to review the status of the project, upcoming events, outstanding issues and money expenditures.

**III. DELIVERABLES SCHEDULE****MONTHLY PROGRESS REPORT**

The Contractor shall submit to the GTL and Contract Specialist a monthly progress report on the 15<sup>th</sup> of every month. The Monthly Progress Report shall provide: an account of work accomplished; difficulties encountered during the reporting period; remedial action taken; unresolved issues; a statement of activity anticipated during the subsequent reporting period; any proposed changes of key personnel; the status of the budget (actual cost vs. projected, breakdown of cost for that month, percentage of cost expended); a summary of costs incurred during the previous month in business proposal format; cumulative costs incurred to date on the task order; funds remaining to be incurred on the task order; costs by labor category, labor hours, labor rates, travel, subcontracts, overheads, profit, etc.; itemization of Other Direct Costs incurred; and, a narrative report of expenditures that exceed 10% either above or below the estimated expenditures for the period of time that is being reported. The Monthly Progress reports shall discuss work accomplished on all of the tasks listed in the Statement of Work.

<b><u>Deliverables Schedule</u></b>	<b><u>Due Date</u></b>
New Timeline based on deliverables schedule with applicable staff assigned.	One week after the effective date of the contract
Progress Meetings with GTL	Weekly in the beginning of the Final Part D Payment Process (frequency to be evaluated during this process)
Status Reports	Weekly (frequency to be evaluated during this process)
Monthly Progress Reports	No later than the 15 <sup>th</sup> of the following month
Maintain a secured location for storing documentation	Ongoing
Preparation and generation of letters notifying sponsors of the Final Part D Payment process	10/01/07-10/15/07
Preparation for reviews	09/17/07 – 10/31/07
Statistical and Analytical review of data collected in the Final Part D Payment process compared to PRS generated Results, assistance with Sponsor communication and assistance with generation of letters reporting the results of the Final Part D Payment process: 1. Reviews (This is subject to change depending on complexity of reviews and the number of reviews) include intake of dispute documentation and the Final Part D Payment process. 2. Staffing: —	10/01/07-09/10/08

**ATTACHMENT 1**

3. Generation of Notice of Results of the Final Part D Payment letters	
4. Denial and appeals support	
Administrative Support	09/17/07-09/10/08
Ad-Hoc Reports—as needed.	09/17/07-09/10/08