Medicare Competitive Acquisition Program

Part B Drugs and Biologicals

Vendor Application and Bid Form

If the applicant submits any confidential information using this form or by associated attachments, it is the applicant's responsibility to mark any privileged or confidential information as such.

You are required to submit two electronic copies of the completed Vendor Application and Bid Form and the completed Drug Bid Form. Each copy should be submitted on compact disc (CD). You are also required to submit one signed paper copy of the Vendor Application and Bid Form and the Drug Bid Form.

According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0938-0955. The time required to complete this information collection is estimated to average 40 hours per response, including the time to review instructions, search existing data resources, gather the data needed, and complete and review the information collection. If you have comments concerning the accuracy of the time estimate(s) or suggestions for improving this form, please write to: CMS, 7500 Security Boulevard, Attn: PRA Reports Clearance Officer, Baltimore, Maryland 21244-1850.

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COMPETITIVE ACQUISITION PROGRAM (CAP) FOR MEDICARE PART B DRUGS APPROVED CAP VENDOR APPLICATION

If the applicant submits any confidential information using this form or by associated attachments, it is the applicant's responsibility to mark any confidential information as such.

Applicants seeking to supply drugs under the CAP must meet the conditions specified in this application and provide necessary supporting documentation. Applicants who cannot attest to the following, and/or provide necessary supporting documents, will not be considered in the bidding process. Applicants must meet all conditions specified in the following pages and must submit all information required by this form and its attachments. Identify each page of the completed application with the applicant's name; space at the bottom of each page is provided.

Part I - Certification

I, the undersigned, certify to the following:

1) I have read the contents of this application. My signature binds this organization to the laws, regulations, manuals, and program instructions of the Medicare program. By my signature, I certify that the information contained herein is true, correct, and complete, to the best of my knowledge.

2) I understand that if this organization is selected and accepts the contract to be an approved CAP vendor, the organization will be required to comply with the requirements applicable to approved CAP vendors under Section 1847B, 42 CFR Part 414, Subpart K, and the terms and conditions of the CAP contract.

3) I further attest that the organization meets each of the following qualifications:

   A. The organization, and any subcontractors, subsidiaries, or business affiliates who will be furnishing drugs for the CAP, have been supplying Medicare Part B injectable drugs for use incident to physicians' professional services in the United States for at least 3 years prior to the date of the application.

   B. The organization, its subcontractors, subsidiaries, or business affiliates who will be supplying drugs for the CAP shall be able to perform activities in compliance with the requirements of the CAP set forth at 42 CFR part 414, Subpart K .

   C. The organization, with any subcontractors, subsidiaries, and business affiliates involved in the CAP, will be in full compliance with State and Federal requirements, including State licensing requirements, in the entire geographic area where the organization supplies drugs for the CAP. Any subcontractor, subsidiary, and business affiliate must meet, in each of the areas it serves, all applicable State and Federal requirements relating to the services it provides under the CAP.

   D. The organization, its subcontractors, subsidiaries, and business affiliates shall adhere to the CAP conflict of interest standards and requirements found at 42 CFR Part 414, Subpart K and in the Federal Acquisition Regulation (FAR) subpart 9.5. The organization also agrees to provide financial and organizational conflict of interest reports annually to CMS, pursuant to the approved CAP vendor contract, throughout the term of the CAP agreement.

   E. The organization, its business affiliates, subsidiaries, subcontractors, any members of its board of directors, or any key management or executive staff (including without limitation the president, vice president, CEO, CFO, and CIO), are not currently sanctioned under any Federal health care program; have not been convicted of fraud, debarred, suspended, or excluded from participation in any Federal or State health care programs, including Medicare or Medicaid;, are not under investigation for fraud, criminal activity or other activities which could lead to sanction or exclusion from Federal or State health care programs; or have entered into a settlement agreement or corporate integrity agreement with any State or Federal Government agency related to a fraud issue.

   F. The organization shall conduct CAP related activity in conjunction with a compliance plan as described in 42 CFR §414.914(c).

4) I authorize CMS to verify the information contained herein. I attest that the organization agrees to notify CMS in writing of any changes that may jeopardize the organization's ability to meet the qualifications stated in this application prior to such change or within 15 days of the effective date of such change. Examples of changes include, but are not limited to, changes in ownership, changes in key personnel (including president, vice-president, CEO, CFO) significant changes in financial condition, such as bankruptcy, investigation for criminal activity or fraud, actions against licenses, suspension or exclusion from any Federal or State health care program, and discovery of errors or omissions in this application. I understand that such a change may result in termination of the approval and the resulting contract. If the organization becomes aware that any information in this application is not true, correct, or complete at any time during the application period (or during the contract period for approved CAP vendors), the organization shall notify the Medicare designated carrier and CMS in writing immediately.

5) I attest that the organization recognizes that CMS reserves the right to request and obtain additional documentation in order to verify the information contained herein. Should further information be required, the organization agrees to submit the documentation within 10 business days.

6) I understand that to qualify as a candidate to be an approved CAP vendor, the organization must complete the Medicare supplier enrollment process and become an approved Medicare supplier in the Medicare program. I also understand that if the organization fails to maintain approved enrollment status it will no longer be allowed to operate as, and bill the Medicare program as, a drug vendor under the CAP.

7) I understand that, in accordance with 18 U.S.C. Section 1001, any omission, misrepresentation, or falsification of any information contained in this application or contained in any communication supplying information to CMS to complete or verify this application may be punishable by criminal, civil, or other administrative actions including revocation of approval, fines, and/or imprisonment under Federal law.

8) I understand that if selected to participate in the CAP, the organization will agree to deliver CAP drugs to participating CAP physicians upon receipt of a prescription order in all cases, except when the conditions of 42 CFR 414.914(i) are met.

9) I understand that all approved CAP vendors will be required to submit claims electronically using a HIPAA-compliant standard electronic format (4010A or later). No paper claims will be accepted. All claims from an approved CAP vendor will be processed by the CAP designated carrier.

10) I certify that the submitted bid prices are accurate and that all information and statements made in this submission are true, complete, and current to the best of my knowledge and belief and are made in good faith. I understand that information contained in this submission may be used for Medicare reimbursement purposes.

11) I further certify that I am an authorized representative, officer, chief executive officer, or general partner of the business organization that is applying for the approval of a Medicare CAP contract.

_____	_____
Authorized Representative's Name (Print) and Title	Telephone Number
_____	_____
Authorized Representative's Signature	Date (MM/DD/YY)

Part II – Management and Operations

Identify your organization by providing the following information:

Full legal organization name:_____

Full address of your organization's headquarters office: _____
_____

Type of ownership (sole proprietorship, partnership, publicly-traded corporation, privately-held corporation):_____

Your organization's parent organization, if any: _____

State in which your organization is incorporated or otherwise organized to do business: _____

Federal taxpayer identification number: _____

Name and title of individual who will sign the Medicare CAP contract, if application and bid are successful. This person must be authorized to act for the organization:
_____

Name and title of company's contact person who can answer questions regarding your organization's proposal, including telephone number, fax number, and e-mail address:
_____

Names of Chief Executive Officer and Chief Financial Officer, and name and address of your organization's point of contact for the Competitive Acquisition Program:
_____

Part III - Experience and Capabilities

List any current Medicare Supplier Numbers and the corresponding carrier:
_____

_____

_____

_____

_____

❑ Check this box if you do not have a Medicare supplier number specific to the CAP, but have submitted a supplier enrollment form 855B specific to the CAP.

Please indicate the business volumes your organization has generated during its 3 most recent tax reporting years by completing the following table. If the entity underwent significant change during its most recent tax reporting year, or it expects to have substantially different business volumes during its next tax reporting year, please check the business volume comments attached box that follows this sentence, comment and provide projected volumes in addition to your business volumes for your next tax reporting year. ❑ Business volume comments attached.

Tax Reporting Year	$ Drug Volume Managed (Sales Volume)	Unit Drug Volume Managed

BALANCE SHEET/PROFIT AND LOSS STATEMENT

PART A. - LATEST BALANCE SHEET			PART B. - LATEST PROFIT AND LOSS STATEMENT		
1. DATE	2. FILED WITH		1. CURRENT PERIOD	2. AUDITED BY	
3. FINANCIAL POSITION			3. NET SALES	a. Most Recent Period	
a. Cash				b. First prior fiscal year	
b. Accounts Receivable				c. Second prior fiscal year	
c. Inventory			4. NET PROFIT BEFORE TAXES	a. Most Recent Period	
d. Other Current Assets				b. First prior fiscal year	
e. Total Current Assets				c. Second prior fiscal year	
f. Fixed Assets			PART C - OTHER		
g. Current Liabilities			1. FISCAL YEAR ENDS(Date):		
h. Long Term Liabilities			2. OTHER PERTINENT DATA		
i. Total Liabilities					
j. Net Worth					
4. WORKING CAPITAL *(Current assets less Current Liabilities)*					
5. RATIOS					
a.CURRENT ASSETS TO CURRENT LIABILITIES	b.ACID TEST	c.TOTAL LIABILITIES TO NET WORTH			

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Part IV –Licensure and Sanctions

1) Check the following box if it applies: ☐ The applicant (including subcontractors, subsidiaries, or business affiliates) is licensed in a manner that will allow the applicant to supply CAP drugs in all 50 States, the District of Columbia, Puerto Rico, The United States Virgin Islands, American Samoa, Guam and the Northern Mariana Islands if the applicant is selected as an approved CAP vendor.

2) Check the box that applies: Has the applicant (including subcontractors or other affiliates who will be supplying drugs for the CAP) ever had its license to distribute drugs restricted, revoked or suspended or otherwise sanctioned in any state, the District of Columbia, or any United States Territory?

❑ No ❑ Yes

If indicating yes, provide a brief description of the action including in which state the action was taken, the date of the action, the duration of the action, whether the action has been terminated and when the action was terminated (i.e., if and when the license was reinstated).

3) Check the box that applies: Has the applicant (or any subcontractors or other affiliates who will be supplying drugs for the CAP) ever had its pharmacy license restricted, revoked, suspended or otherwise sanctioned in any state, the District of Columbia, or any United States Territory?

❑ No ❑ Yes ❑ Not Applicable

If indicating yes, provide a brief description of the action including in which state the action was taken, the date of the action, the duration of the action, whether the action has been terminated, and when the action was terminated (i.e., if and when the license was reinstated).

4) Check the box that applies: Has the applicant, or its business affiliates, subsidiaries, subcontractors, any members of its board of directors, or any key management or executive staff (including without limitation the president, vice president, CEO, CFO, CIO), ever been sanctioned under any Federal health care program, been convicted of fraud, debarred, suspended; excluded from participation in any Federal or State health care programs, including Medicare or Medicaid; or been under investigation for fraud, criminal activity or other activities which could lead to sanction or exclusion from Federal or State health care programs; or entered into a settlement agreement or corporate integrity agreement with any State or Federal Government agency related to a fraud issue.

❑ No ❑ Yes

If indicating yes, please provide details including when the action was taken, the parties involved, jurisdiction (if applicable) and the resolution.

Part V- Compliance Plan

On a separate page that includes the applicant's name, the date, and is labeled "Part V: Compliance Plan," please provide a copy of your compliance plan, which includes the following:

- Written policies, procedures, and standards of conduct articulating your organization's commitment to abide by all applicable Federal and State standards;
- The designation of a compliance officer and compliance committee accountable to senior management;
- Effective training and education of the organization's employees, contractors, agents, and directors by the compliance officer;
- Effective lines of communication between the compliance officer and organization employees, contractors, agents and directors and members of the compliance committee;
- Disciplinary standards that are publicized;
- Procedures for internal monitoring and auditing; and
- Procedures for ensuring prompt response to detected offenses and development of corrective action initiatives, relating to the applicant's contract as a CAP drug vendor.

CMS also recommends to applicants that they include in their compliance plans provisions that require the reporting of fraud and abuse to the appropriate government authority. Approved CAP drug vendors that self-report violations will continue to receive the benefits of voluntary self-reporting found in the False Claims Act and Federal sentencing guidelines.

Part VI- Operational Aspects

On a separate page that includes the applicant's name, the date and is labeled "Part VI: Operational Aspects," please provide the following information or describe how the following will be accomplished in compliance with the CAP regulations:

Customer Service:

- Provide the address, telephone number (including toll free numbers), point of contact, weekday and weekend business hours (including time zone) of the main distribution location and any additional distribution locations. If these resources are not available or are pending, please indicate expected date of completion or availability, but provide as much detail as possible.
- Describe how the organization may be contacted in case of an emergency outside regular business hours and how back up is accomplished if the main distribution location is down.
- Describe how each location will function in times of emergency (i.e. loss of power, phone service, etc) and how prescription orders and inquiries will be handled.
- Describe your process for providing customer assistance in response to inquiries from individuals who are hearing impaired, disabled, or speak Spanish.

Prescription Order Processing and Shipping:

- Describe how you intended to receive, process and ship CAP prescription orders. Describe the personnel involved and the type of shipping methods that will be used to meet the timely delivery definitions for the CAP.
- Describe how items will be packaged and shipped. Discuss methods used to ship items that are stable at room temperature and items that require refrigeration. Discuss what steps are taken to ensure that product integrity is maintained during shipping.
- Describe how the timeframes for shipping and delivery of routine and emergency orders will be met and when split shipments (orders sent in more than one shipment) may be sent. Provide a timeline that illustrates the receipt, processing and packaging and shipping of each type of order.
- Describe how returns of unused or partially used products from a physician's office will be handled.

CAP Drug Vendor Application Form Attachments- Please provide the following information. Label each response with the corresponding attachment number, the applicant's name and the date.

Attachment 1

Provide a brief summary of the history, structure, and ownership of your organization, including a list of subcontractors, subsidiaries, or business affiliates.

Attachment 2

Provide a brief summary of the history, structure, and ownership for any subcontractors, subsidiaries, or business affiliates that will be directly involved in the wholesale acquisition of drugs under the CAP on your behalf. Describe the functions that the affiliate will perform.

Attachment 3

Provide an organizational chart for staff within your organization assigned to the CAP. Describe your staffing plan for the operation of your drug vendor contract. In the space below, provide the number of staff (in Full Time Equivalent (FTE) units) who would be assigned to the following activities for the CAP contract:

Financial Administration:	Product Management:
Marketing:	Grievance Process/Complaint Resolution:
Customer Service:	Shipping and Distribution:
Quality Assurance:	Total FTEs for CAP activities:

Attachment 4

Provide a list of Part B injectable drugs which your organization has distributed in the last 3 years by National Drug Code (NDC) number. Include the corresponding drug name and package size for each NDC.

Attachment 5

Describe the measures and standard operating procedures that your organization and subcontractors, subsidiaries, or business affiliates will use to ensure CAP product integrity. Which of these measures are currently being used in your drug distribution or dispensing activities?

Attachment 6

Describe how your organization and its subcontractors, subsidiaries, or business affiliates plan to conduct CAP drug acquisition, distribution and storage. Include the sources from which your entity will acquire CAP drugs.

Attachment 7

Identify potential organizational or financial conflicts of interest and briefly describe how mitigation will occur.

Attachment 8

Provide a copy of the previous year's audited financial statement. Indicate the exact time period that the statement covers.

Attachment 9

Please list three references from businesses or organizations to which your organization has supplied significant volumes of Medicare Part B injectables in the past 3 years. For each reference, please provide the business' name, address, telephone number, a contact person, and an approximate dollar volume of Medicare Part B injectable drugs furnished to the organization.

Attachment 10

Please provide descriptions of how your organization will accomplish the following operational aspects of furnishing CAP drugs in a manner that is in compliance with the regulation:

- a detailed description of how the organization's CAP coinsurance assistance program will operate.
- a copy of the organization's CAP grievance procedures which describe the organization's process for promptly addressing complaints from physicians, beneficiaries, and beneficiaries' caregivers.

The table below illustrates the format for submitting CAP drug bid prices. A spreadsheet version of the table CAP 2009 Drug Bid Form is available on the following CAP website:
http://www.cms.hhs.gov/CompetitiveAcquisforBios/03_infovendors.asp

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The table is derived from Addendum F and Addendum G of the final rule. The HCPCS codes, the long description of the HCPCS code and the drug's volume weight are provided by CMS. The bidder must fill in the bid price and list NDC numbers being offered for each HCPCS code. If more than one NDC is being supplied for a single HCPCS code, separate the NDCs in one cell with a comma.

Note that the spread sheet contains two tabs. One tab for drugs with weights, and one tab for new drugs that are not weighted. A bid price must be submitted for each HCPCS code on both tabs.

Please remember that for 2009 only one category of drugs and one competitive acquisition area are being bid.

Vendor Name:				
CAP Drug Category: SINGLE CATEGORY		**CAP Competitive Acquisition Area: NATIONAL**		
HCPCS Code	**Long Description**	**Weight**	**Bid Price**	**NDC number(s)**
Provided by CMS	Provided by CMS	Provided by CMS		

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