INITIAL APPLICATION FOR

EMPLOYER/UNION DIRECT CONTRACT PRIVATE FEE-FOR-SERVICE (PFFS) MEDICARE ADVANTAGE ORGANIZATION

January 16, 2007

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Centers for Medicare & Medicaid Services (CMS)
Center for Beneficiary Choices (CBC)
Employer Policy & Operations Group (EPOG)

2008

PURPOSE

The Centers for Medicare & Medicaid Services (CMS) is seeking applications from qualified employer/union entities, as described under Section 1857(i) of the Social Security Act (SSA) to enter into a new contract as a Direct Contract Private-Fee-for-Service (PFFS) Medicare Advantage Organization. Hereinafter, these entities will be referred to as "Direct Contract PFFS MAOs". In accordance with Section 1857(i), applicant must be an employer, a labor organization, or the trustees of a fund established by one or more employers or labor organizations (or combination thereof) to furnish benefits to the entity's employees, former employees (or combination thereof) or members or former members (or combination thereof) of the labor organizations.

BACKGROUND

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) provides employers and unions with a number of options for providing medical and prescription drug coverage to their Medicare-eligible employees, members, and retirees. Under the MMA, those options include making special arrangements with Medicare Advantage Organizations (MAOs) and Section 1876 Cost Plans to purchase customized benefits, including drug benefits, for their members; purchasing benefits from sponsors of standalone prescription drug plans (PDPs); and directly contracting with CMS to become a Direct Contract PFFS MAO or PDP sponsor themselves. Each of these approaches involves the use of CMS waivers authorized under Section 1857(i) of the SSA. Under this authority, CMS may waive or modify requirements that "hinder the design of, the offering of, or the enrollment in" employer or union-sponsored group plans.

OBJECTIVES AND STRUCTURE

This Application is to be used by an employer or union to directly contract with CMS to offer a Direct Contract MA PFFS Plan to its Medicare eligible active employees and retirees (hereinafter referred to as a "Direct Contract MA PFFS Plan"). This option involves the use of CMS employer/union-only group waivers authorized under Section 1857(i) of the Social Security Act. **This Application is only for to be used by employers and unions seeking to directly contract with CMS to sponsor and operate a Direct Contract MA PFFS Plan. Applications may be submitted up until March 12, 2007. Applicants must use the 2008 Application. CMS will not accept or review in any way those submissions using the 2007 Application.**

- Applications must be sent to:

  Centers for Medicare & Medicaid Services (CMS)
  Mail Stop: C1-22-06
  Attn: Direct Contract MA PFFS Application
  7500 Security Boulevard
  Baltimore, Maryland 21244-1850

- In order for CMS to receive your application in a timely manner, please note that Federal Express and the US Postal Service possess a CMS Security Clearance. Applications mailed through carriers that do not have CMS Security Clearance could be delayed due to clearance processing.

Note: MA PFFS Plans are not required to offer the Part D drug benefit. A Direct Contract PFFS MAO Applicant that wants to offer an MA-PD plan must also complete the Direct Contract MA-PD application which can be found at
http://www.cms.hhs.gov/EmpGrpWaivers/01_Overview.asp.
Specific instructions to guide Direct Contract PFFS MAO Applicants in applying to qualify to offer a Part D benefit for 2008 are provided in the separate Direct Contract MA-PD application.

CENTER FOR BENEFICIARY CHOICES
EMPLOYER POLICY & OPERATIONS GROUP
EMPLOYER/UNION DIRECT CONTRACT
PRIVATE FEE-FOR-SERVICE (PFFS) MEDICARE ADVANTAGE ORGANIZATION (MAO) APPLICATION

Type of DIRECT CONTRACT MEDICARE ADVANTAGE PLAN REQUESTED (Check all that apply):

Open Access (Non-Network) PFFS Plan ☐
Contracted Network PFFS Plan ☐
Product Name of each Medicare Advantage Plan(s):
H# (s) if available:

NAME OF LEGAL ENTITY:

TRADE NAME (IF DIFFERENT): MAILING ADDRESS:

CEO, EXECUTIVE DIRECTOR/TRUSTEE/EQUIVALENT OFFICIAL:
NAME AND TITLE:
MAILING ADDRESS (If different than above):

TELEPHONE NUMBER / E-MAIL ADDRESS:
FAX NUMBER:
ORGANIZATION'S WEB PAGE:

CONTACT PERSON THAT CAN ANSWER QUESTIONS REGARDING YOUR ORGANIZATION'S DIRECT CONTRACT PFFS MAO APPLICATION:
NAME: E-MAIL:

TITLE: FAX:

ADDRESS: TELEPHONE NO:

TAX STATUS For Profit ☐
Not For Profit ☐

IS APPLICANT SUBJECT TO ERISA?
Yes ☐ No ☐

TYPE OF ENTITY (Check All That Apply):

Employer ☐ Labor Union ☐ Fund Established by One or More Employers or Labor Organizations ☐

Government ☐ Church Group ☐ Publicly-Traded Corporation ☐ Privately-Held Corporation ☐

Other _____

I certify that all information and statements made in this application are true, complete and current to the best of my knowledge and belief and are made in good faith.

Signature CEO/ Executive Director /Trustee/Equivalent Official Date

Signature, Board Chairman/Trustee/Equivalent Official	Date

TABLE OF CONTENTS

The table of contents for the completed application is placed after the cover sheet. Each chapter and subsection title within the Narrative part is marked for automatic generation of the table of contents on this page. That table appears below with page numbering that reflects a "blank" application. The numbers will change when you generate the table again for the completed application. Please follow the directions in the Technical Instructions to generate the table for the Narrative part. Note that the table of contents for the Documents Section is not generated automatically, and is to be manually filled in after the table for the Narrative.

GENERAL INFORMATION

(See Medicare Managed Care Manual Chapter 4)

I. SUMMARY DESCRIPTION

Briefly describe the organization in terms of its history and its present operations. Cite significant aspects of its current financial, general management, and health services delivery activities. (Do not include information requested in the Legal Entity section.) Please include the following:

A. The extent of the current Medicare population served by the Applicant, if any, and the maximum number of Medicare beneficiaries that could be served as a Direct Contract MA PFFS Plan.

B. Include information about other Medicare contracts held by the Applicant, (i.e., 1876, fee for service, PPO, etc.) unless described in the Legal Entity Section. Provide the names and contact information for all CMS personnel with whom Applicant works on their other Medicare contract(s).

II. MEDICARE CONTRACT INFORMATION

A. For HPMS access, please complete and submit the appropriate CMS form located at:

http://www.cms.hhs.gov/AccesstoDataApplication/Downloads/Access.pdf

If you have questions about this form please contact Don Freeberger at (410) 786-4586.

B. Please complete the Payment Information form located at:

http://www.cms.hhs.gov/MedicareAdvantageApps/Downloads/pmtform.pdf

The document contains financial institution information and Medicare contractor data. If you have questions about this form please contact Yvonne Rice at (410) 786-7626 applicant. The completed form needs to be faxed to Yvonne Rice at (410) 786-0322.

Note: HPMS access is needed in the early stages of the application process to enable the Applicant to input application information into the HPMS application module. Combining the HPMS request with other system access requests will delay the HPMS access approval (access to other systems will be needed after application approval). Please submit a separate request for HPMS access, and use a separate form for other system access requests.

Place the signed forms in the Documents Section. Include the completed forms in both the electronic and hard copies of the application.

III. POLICYMAKING BODY - 42 CFR 422.503

In general, an entity seeking to contract with CMS as a Direct Contract PFFS MAO must have policymaking bodies exercising oversight and control to ensure actions are in the best interest of the organization and its enrollees, appropriate personnel and systems relating to medical services, administration and management, and an executive manager whose appointment and removal are under the control of the policymaking body.

An employer or union directly contracting with CMS as a Direct Contract PFFS MAO may be subject to other, potentially different standards governing its management and operations, such as ERISA fiduciary requirements, state law standards, and certain oversight standards created under the Sarbanes-Oxley Act. In most cases, they will also contract with outside vendors (i.e., business associates) to provide health benefit plan services. To reflect these issues and avoid imposing additional (and potentially conflicting) government oversight that may hinder employers and unions from considering applying to offer Direct Contract MA Plans, the requirements under 42 CFR 422.503 noted in this Section III are waived if the employer or union (or to the extent applicable, the business associate with which it contracts for health benefit plan services) is subject to ERISA fiduciary requirements or similar state or federal laws and standards. However, such entities (or their business associates) are not relieved from the record retention standards applicable to other MA Organizations.

A. List the members of the organization's policymaking body (name, position, address, telephone number, occupation, term of office and term expiration date). Indicate whether any of the members are employees of the Applicant.

B. If the Applicant is a line of business versus a legal entity, does the Board of Directors of the corporation serve as the policymaking body of the organization? If not, describe the policymaking body and its relationship to the corporate Board.

C. Does the Federal Government or State regulate the composition of the policymaking body? If yes, please identify all Federal and State regulations that govern your policymaking body (e.g., ERISA).

D. Indicate below the ways in which the policymaking body carries out its responsibilities:

1. What is the requirement for meeting frequency?
2. How many times has this body met in the last 12 months?
3. What is the required number of members of this body?
4. Are there term limits for the Board members?
5. What are the provisions for filling vacancies?
6. What are the quorum requirements?
7. Are the Applicant’s management decisions ratified by the full Board?
8. How often is the Chief Executive Officer's (CEO’s) performance formally evaluated?
9. Does this body have authority to appoint and remove the CEO?

E. List any policymaking committees and the chairperson and members of each committee. Provide an organizational chart(s) showing clear lines of authority, responsibility and delegation(s) of authority.

F. Describe the communication within the organization to assure coordination among its physicians, board, and between the Medical Director and key management personnel.

IV. KEY MANAGEMENT STAFF – 42 CFR 422.503

A. Indicate the individuals responsible for the key management functions.

Staff Function	Name	Title	Employed By
CEO/President			
Medicare Medical Director			
Utilization Management Director			
CFO			
Marketing Director			
Government Relations			
Management Information Systems Director			
Compliance/ Officer			
Quality Director			

B. In the Documents Section, provide brief position descriptions and resumes for the individuals listed above in A.

C. Provide an organizational chart(s) showing the relationships of the various departments, including the names of the managers or directors. Place the chart(s) at the end of this chapter.

V. MANAGEMENT INFORMATION SYSTEM - 42 CFR 422.503

A. Describe the use of the MIS for day-to-day management of the key plan functions as they apply to Medicare as well as long-term planning. Provide a list of key reports, which include a brief description of each report and indicates their distribution. Have MIS reports available on-site for evaluation by CMS staff. Indicate whether data can be collected on an individual patient basis and/or in aggregate.

B. Explain how the Applicant meets or will meet the Health Insurance Portability and Accountability Act (HIPPA) standards for electronic transactions.[45 CFR 160, 162, 164]

C. Describe the organizations MIS capabilities to track and update fee for service reimbursement and payments.

VI. SERVICE AREA - 42 CFR 422.2

In general, PFFS MAOs can only cover individuals in the service areas in which they operate. However, under CMS' waiver authority, for employers/unions that directly contract with CMS to offer a MA PFFS plans, coverage can extend to all of their Medicare eligible plan participants, regardless of whether they reside in one or more other MA regions in the nation.

VII. COMMUNICATION WITH CMS - 42 CFR 422.503

Describe the Applicant's ability to communicate with CMS electronically.

END OF CHAPTER DOCUMENTATION

1. CMS Access forms (II)
2. Organizational Chart(s) of policymaking committees (III.E)
3. Organizational Chart(s) of relationships of various departments (IV.C)

ORGANIZATIONAL AND CONTRACTUAL

(See Medicare Managed Care Manual Chapter 11)

I. LEGAL ENTITY - 42 CFR 422.4(a) (3) (b); 422.2- 422.4

A. Provide information regarding how the Applicant is organized under Federal or state laws. If the Applicant does business as ("d.b.a.") a name or names different from the name shown on its Articles of Incorporation, provide such name(s) and include a copy of Federal or State approval for the d.b.a. (s) in the Documents Section. Provide the name the plan will use to market its Medicare product.

B. Include in the Documents Section a copy of any articles of incorporation, bylaws and other legal entity documentation. If applicable, provide the Partnership Agreement in the Documents Section.

Describe any changes in the basic organizational structure since Federal approval, such as any changes in the corporate charter or the bylaws. Provide appropriate documentation as applicable. Place all documentation in the Documents Section.

II. STATE AUTHORITY TO OPERATE - 42 CFR 422.6(b) (i) and (2), 422.400, 422.501

In general, an MA Organization must be organized and licensed under State law as a risk-bearing entity eligible to offer health insurance or health benefits coverage in each State in which it offers a, MA plan. CMS has waived the state licensing requirement for Direct Contract PFFS MAOs; therefore any documentation concerning state licensing is not required for these applicants. However, these entities are required to meet all financial solvency requirements outlined in Appendix I of this application. If, however, the Applicant does not meet the standards described in Appendix I of this application, CMS may in its discretion approve, on a case-by-case basis, waivers of such requirements upon a demonstration from the entity that its fiscal soundness is commensurate with its financial risk and through other means the entity can assure that claims for benefits paid for by CMS and beneficiaries will be covered. In all cases, CMS will require that the Applicant's contracts and sub-contracts provide beneficiary hold harmless provisions described in Appendix I and other CMS guidance.

III. ORGANIZATIONAL AND FUNCTIONAL CHARTS

Provide the following organizational and functional charts at the end of this chapter:

A. The Direct Contract MA Organizational chart.

B. If the Applicant is a line of business of a corporation, describe and chart the relationship and show the line of business in relation to the corporation.

C. Show the relationship of the entity that will hold the MA Organization contract to any parent or subsidiary organization(s).

D. Contractual Relationships: If applicable, indicate current contractual relationships between the entity that will hold the MA Organization contract and any administrative, management, and/or marketing service entities.

IV. RISK SHARING (LEGAL-1 TABLE)

Legal-1 Table is a summary of insurance or other arrangements for major types of loss and liability. Complete the table to indicate the types of arrangements in effect, or to be in effect, for the proposed area when approved. [This table is a separate file: *legal-1.doc.* Place a hard copy in the Documents Section.] [42 CFR 422.503]

V. CONTRACTS FOR ADMINISTRATIVE/MANAGEMENT SERVICES – 42 CFR 422.504

A. Describe the Applicant's relationships with related entities, contractors and sub-contractors for the provision of health and/or administrative services specific to the Medicare product.

B. If using a contracted network, describe each of the specific functions (health delivery and/or administrative) that are now or will be delegated to medical groups, IPAs, or other intermediate entities. Describe how the Applicant will remain accountable for any functions or responsibilities that are delegated to other entities. Describe how the Applicant oversees and formally evaluates delegated functions.

C. Include a copy of each administrative service contract and/or delegation agreement in the Documents Section of the application.

D. Complete the administrative/management delegated contracting matrix (*matrixadm.doc)* for each delegated entity and include it in the Documents Section of the application.

VI. PROVIDER CONTRACTS & AGREEMENTS - 42 CFR 422.114, 422.504, 422.520(b)

The Applicant should determine whether it will offer a Network or Non-network model PFFS Plan. The Applicant should also determine if it is paying providers for any category of service at the Original Medicare allowable payment rates under Medicare Part A or Part B. Please check one of the responses below and follow instructions for each response

(☐) YES Applicant will be a Non-Network model PFFS product. Do not complete Section VI. Instead, describe the "deeming process" as described in 42 CFR 422.216 (f) and how providers will be paid. Include a terms and conditions of payment.

(☐) NO Applicant will be a network model PFFS product. Identify and complete the remainder of Section VI for those categories of service for which the Direct Contract MA PFFS Plan will be paying less than the Medicare allowable payment rates for those categories of service or a combination of the two.

Note: For purposes of simplicity in completing this application, the term "provider" means physicians, inpatient institutions and other ancillary practitioners. This definition departs from other Medicare definitions of "providers" (hospitals and other inpatient institutions, plus home health services) and "suppliers" (DME or other practitioners and other non-providers).

There must be full documentation of arrangements for health services in the requested service area(s) at the time that the application is submitted. Executed written agreements are considered evidence of an operational health delivery network which is able to provide access and availability to health services for Medicare enrollees. These arrangements are typically provider contracts, but may also include employment contracts and letters of agreement. CMS will accept any legally binding written arrangements. CMS does not accept letters of intent.

A. Complete "Provider Arrangements" Table - For each proposed service area or distinct delivery system(s) the Applicant must provide the provider contracts and/or agreements. Contracts and/or agreements must be executed at the time the application is submitted to CMS. [This table is a separate file -legal-2.xls; place a hard copy in the Documents Section. Instructions for this table are in the Guidelines.]

B. Provide a sample copy of each category of provider contract(s) and/or agreement(s) between the Applicant and its primary health care contractors (i.e., direct contract with physicians, medical group, IPA, PHO, hospitals, skilled nursing facilities, etc.) Place in the Documents Section.

C. Provide the signature pages and an alphabetical listing of contracted providers for each of the major provider(s) from actual contract(s) and /or agreement(s) with these provider entities (i.e., IPAs, medical groups, PHOs or similar entities and hospitals); place in the Documents Section.

   Note: All signature pages must be identifiable and if the provider cannot be identified by the signature page, then the first page of the contract and/or agreement along with signature page should be sent.

D. For provider contracts and agreements between medical groups, IPAs, PHOs, etc., including their subcontracting providers, provide a sample copy of each applicable subcontract in the Documents Section. (Example: If the Applicant contracts with an IPA, which contracts with individual physicians, then provide a sample copy of the contract and/or agreement between the IPA and physicians.) This table is a separate file *matrix1.doc*; place a hard copy in the Documents Section.

   NOTE: For this entire section, Applicants must demonstrate that all contractual provisions extend to the level of provider actually rendering the service to Medicare beneficiaries and that all levels of contracts and/or agreements meet the CMS requirements. If subcontracts do not mention which insuring organization members will be served, explain how the contracted hospital, IPA, etc., advised its subcontractors about which insuring organizations are covered by subcontractor, e.g., which MA Organization memberships will be served. [42 CFR 422.505(i)(3)]

VII. BUSINESS INTEGRITY

Give a brief explanation and status of each current and past legal action, for the past three years, if applicable, against the Applicant.

A. Applicant and its affiliated companies, subsidiaries or subcontractors, subcontractor staff, any member of its board of directors, any key management or executive staff, or any major shareholder of 5 percent or more agree that they are bound by 42 CFR Part 76 and attest that they are not excluded by the Department of Health and Human Services Office of the Inspector General or by the General Services Administration.

B. List any past or pending, if known, investigations, legal actions, or matters subject to arbitration brought involving the Applicant (and Applicant's parent firm if applicable) and its subcontractors, including any key management or executive staff, or any major shareholders (5 percent or more), by a government agency (state or federal) over the past three years on matters relating to payments from governmental entities, both federal and state, for healthcare and/or prescription drug services. Provide a brief explanation of each action, including the following:

1. legal names of the parties;
2. circumstances;
3. status (pending or closed); and
4. if closed, provide the details concerning resolution and any monetary payments, or settlement agreements or corporate integrity agreement.

C. Applicant will be required to provide financial and organizational conflict of interest reports to CMS, pursuant to instructions to be issued by CMS.

VIII. COMPLIANCE PLAN - 42 CFR 422.503

A. Describe the organization's internal compliance plan. Submit a copy of the MA Organization compliance plan by placing in the Documents Section.

B. Describe the reporting relationship of the MA compliance officer to the organization's senior management. Describe how the compliance officer and compliance committee is accountable to senior management. List all members of the compliance committee and their positions within the organization.

END OF CHAPTER DOCUMENTATION

1. Organizational and Functional chart of the Applicant

2. Organizational Chart between Corporation and MA Organization

3. Compliance Plan and Compliance Program

4. Chart of Contractual Relationship with other entities

5. Terms and Conditions of Payment for Non Network Model PFFS Plans

HEALTH SERVICES DELIVERY

(See Medicare Managed Care Manual Chapters 4, 5, 6, and 7)

If applying for a Direct Contract MA PFFS Plan, determine whether a Network or Non-Network model PFFS Plan. Is the Applicant paying providers, for any category of service, the Original Medicare allowable payment rates under Medicare Part A or Part B? (Check one response and follow instructions for each response)

(☐) YES If yes, it will be a Non-Network product. Do not complete Section I, II and III. Instead, describe the 'deeming process' (42 CFR 422.216 (f)) and how providers will be paid. Include a terms and conditions of payment.

(☐) NO It will be a network model PFFS product. Identify and complete for those categories of service for which the Applicant will be paying less than the Medicare allowable payment rates Sections I, II and III. For those categories of service or a combination of the two, complete Sections I, II, and III.

I. HEALTH CARE PROVIDERS - Physician Services, Hospital Admitting Privileges – 42 CFR 422.114

If the Applicant pays providers less than the Medicare allowable payment rates:

A. Describe the health services delivery system through which the organization will furnish covered Medicare services.

B. Complete the tables "*matrix1.doc"* and place a hard copy in the Documents Section.

C. Complete HSD-1 Table, County Summary of Providers by Specialty. [Complete this table in its file and place a hard copy in the Documents Section.]

D. Please address whether the MA Organization will use the same delivery systems of providers for each requested MA plan. If not, clearly delineate variations in the networks.

E. Explain how the MA Organization will ensure that the number and type of providers will be sufficient to meet the needs of the projected enrollment and to cover all MA benefit plans. For example, state how the MA Organization will identify shortages in the physicians' specialties or in-patient beds in hospitals or skilled nursing facilities. If the maintenance of a network has been delegated or subcontracted, explain how the Applicant will oversee the adequacy of the network.

F. Will the MA Organization use the same delivery systems for the new service area? If so, how does the MA Organization assure sufficient providers for projected enrollment? If not, how will services be rendered in the new area?

II. LOCATIONS OF HEALTH SERVICES PROVIDERS - 42 CFR 422.114

Complete HSD-2 Table, Provider List – List of Physicians and other Practitioners by County. Submit Microsoft electronic Excel spreadsheet format (electronic copy) only, not in hard copy. [Complete this table in its file on the disk.]

Complete HSD-2A Table, PCP/Specialist Contract Signature Page Index [Complete this table in its file HSD.xls; place a hard copy in the Documents Section.]

III. MEDICARE HEALTH BENEFITS - 42 CFR 422.101

A. Describe your benefits which will be provided. Address each of the following items for the Parts A & B, supplemental, and additional benefits:

1. deductible and cost sharing provisions,
2. enrollee premium amount and billing method,
3. allowable medical expenses and rate of those expenses which will be applied toward meeting the deductible,
4. payment arrangements for all providers of health benefits after the deductible is met, e.g., note whether providers will be paid more than the Medicare allowable amount, thereby reducing the enrollee's liability under balance billing.

B. Complete HSD-3 Table, Arrangements for Medicare Required Services by County. [Complete this table in its file *HSD.xls*; place a hard copy in the Documents Section.]

C. Complete HSD–3A Table, Ancillary/Hospital Contract Signature Page Index Complete this table in its file HSD.xls; place a hard copy in the Documents Section.]

D. Complete HSD-4 Table, Arrangements for Mandatory Supplemental Benefits by County. [Complete this table in its file *HSD.xls*; place a hard copy in the Documents Section.]

E. Complete HSD-5 Table, Signature Authority Grid [Complete this table in its file HSD.xls; place a hard copy in the Documents Section]

F. Describe how the MA Organization will provide for or arrange for all the health care services (that are covered under Part A and Part B of Medicare) for their enrollees. [42 CFR 422.112]

IV. PROCEDURES FOR BILLING AND PAYMENT (Reimbursement Grid)

A. Describe the billing and payment process for all categories of Medicare Part A and Medicare Part B services and any additional services offered. Please include:

1. Who will bill the Direct Contract PFFS Plan and to whom will the Direct Contract PFFS Plan make payment (e.g., the enrollee and/or the provider)?
2. Procedures should also address when the provider bills the plan directly versus when members will be liable to pay providers, before being reimbursed by the plan.

3. Provide a copy of the Applicant's Reimbursement \Grid in the documents section.
4. Describe Provider Education Strategy for all provider types.

B. Describe the mechanism by which the plan will notify CMS of violations of the limits on charges to plan enrollees by non-contracting or deemed providers.

C. Describe the process by which the plan will make available the terms and conditions of plan payment to all providers in a category of service. Provide a copy of the terms and conditions for review by CMS in the documents section.

D. Describe the mechanism the plan will use to enforce the limits on charges by contract providers (including deemed contractors) to plan enrollees.

E. Describe any preauthorization procedures (if applicable) or other requirements for coverage that the plan proposes.

F. Describe the Applicant's provider dispute resolution process.

V. HEALTH SERVICES MANAGEMENT

(Areas of this section are applicable to both network and non network PFFS model unless otherwise noted)

A. Service Management

1. How will the MA Organization use CMS's national coverage decisions and written decision of carriers and intermediaries (LMRP) in the geographic area in which services are covered under the MA plan? [42 CFR 422.101(b)]
2. Describe and provide policies for ensuring that health services are provided in a culturally competent manner to enrollees of different backgrounds.

B. Service Authorization

Describe the MA Organization's written policies and procedures, reflecting current standards of medical practice, for referral authorizations and processing requests for initial authorization of services, or requests for continuation of services.

C. Practice Guidelines

1. Describe how the MA Organization ensures compliance with Federal requirements prohibiting employment or contracts with individual excluded from participation under Medicare or Medicaid. [42 CFR 422.204]
2. Describe procedures, if any, for monitoring utilization, controlling costs and achieving utilization goals for Medicare members for the following:

(a) In-plan and out-of-plan physician services

(b) Laboratory services
(c) X-ray services
(d) Hospital services, including admitting practices and length of stay
(e) Out-of-area hospital services

The Applicant's utilization review protocol should be (1) based on current standards of medical practice and (2) should incorporate mechanisms to detect both under- and over-utilization of services. Provide the MA Organization's written protocols for utilization review in the Documents Section. [42 CFR 422.152(e) (3)]

D. Enrollee Health Records and Confidentiality - 42 CFR 422.118

1. How does the Applicant ensure appropriate and confidential exchange of information among providers?
2. What are the policies and procedures for sharing enrollee information with any organization with which the enrollee may subsequently enroll?
3. How does the Applicant assure that enrollees will have timely access to records and information that pertain to them?
4. Describe the organizations record keeping system through which pertinent information relating to health care of enrollees is accumulated and is readily available to appropriate professionals.
5. Provide a copy of the tool for conducting an initial assessment of each enrollee's health care needs. Place this in the Documents Section.
6. Encounter Data - 42 CFR 422.257
   Describe how the Applicant meets (or will meet) CMS requirements on the electronic submission of encounter data regarding the following:

   (a) Inpatient hospital care data for all discharges
   (b) Physician, outpatient hospital, skilled nursing facility and home health agency data and other data deemed necessary by CMS

Describe any changes that are specific to the requested area for Sections II through III.

VI. QUALITY IMPROVEMENTS INITIATIVES

Although, Direct Contract MA PFFS Organizations are exempted from the majority of QI requirements, they must meet the following requirements:

A. Maintain health information systems,
B. Ensure information from providers is reliable and complete,
C. Make all collected information available to CMS,
D. Conduct quality reviews; and
E. Take corrective action for all problems that come to the organization's attention.

Describe how the organization will meet the above quality improvement initiatives.

MEDICARE

(See Medicare Managed Care Manual Chapters 2, 3, 4, 13, and 14)

I. MARKETING

CMS has waived the review and approval requirements for marketing materials and election forms contained in 42 CFR 422.80 for Direct Contract Medicare Advantage Organizations. This waiver applies to all marketing materials, including the marketing materials requirements contained in the Medicare Marketing Guidelines.

Disclosure/Dissemination

CMS will waive the disclosure requirements of 42 CFR 422.111 and the dissemination requirements of 42 CFR 423.128 for Direct Contract PFFS MAOs when the employer or union plan sponsor is subject to alternative disclosure requirements (e.g., ERISA) and the Direct Contract PFFS MAO complies with such alternative requirements. However, these alternative disclosure materials (including summary plan descriptions and all other beneficiary communications that provide descriptions of the benefit offerings) must be provided to CMS at the time of use and to beneficiaries on a timely basis. CMS will presume that timely disclosure/dissemination to beneficiaries has been met if the alternative disclosure materials are provided to the enrollees pursuant to the Medicare timeframes outlined in the Medicare Marketing Guidelines (e.g., at the time of enrollment and during the month within which an enrollee utilizes their prescription drug benefits).

If you are subject to alternative disclosure requirements, please identify below the other governing standards which would make your organization eligible for these waivers:

_____

If you are not subject to alternative disclosure requirements, you must complete the below requirements.

A. Marketing strategy - 42 CFR 422.62 & 422.100(g) -- Describe the Applicant's Medicare communication and dissemination strategy, including:

1. Overall dissemination approach including communication materials and how materials will be developed and used to communicate the program.
2. Dissemination approach and channels that will be used to enroll (e.g. Internet, paper and automatic enrollment with opt out provisions).
3. Plans for education\outreach and public relations.
4. Systems for managing inquiries and servicing members.
5. Allocation of resources and efforts to accommodate and to disseminate plan information to disabled and socially disadvantaged persons.
6. The anticipated enrollment date for each MA plan.
7. Enrollment and dissemination training on CMS Medicare Guidelines.

8. All open enrollment periods for each Direct Contract MA PFFS Plan, including the initial coverage election period; the mandatory annual election period; and any special election periods.
9. Standard and fast track appeal notices.

B. Submit policies and procedures for informing members regarding changes in provider network.

II. ENROLLMENT and DISENROLLMENT

A. Describe your enrollment history for the last 3 years.

B. Enrollment and Disenrollment Processes:

1. Describe how the Applicant will enroll Medicare beneficiaries in accordance with CMS requirements. Include the date the Applicant plans to begin enrolling Medicare members.
2. Describe the Applicant's process for receiving and processing enrollments and disenrollments, including beneficiary notification. Include a flow chart that shows each stage of the process for your MA Organization, including the responsible entity.

3. Does the Applicant currently offer a Medicare "wrap around" or supplement? If so, how will the Applicant ensure that there is no health screening of members transferring from a wrap around product to Medicare Advantage product?
4. Describe the systems, policies and procedures for identifying and reporting Medicare working aged enrollees.
5. Describe your process for receiving and acting upon membership notifications from CMS.

III. CLAIMS

A. Direct Contract MA PFFS Plans must demonstrate compliance with 42 CFR 422.114 - Access to services under a MA PFFS Plan. In Non-Network Direct Contract MA PFFS models, the access requirement is met when a Direct Contract MA PFFS Plan chooses to pay a particular category of health care providers' payment rates that are not less than the rates that apply under original Medicare for the provider in question. To demonstrate the ability to pay claims on a Fee-For-Service (FFS) basis, all Direct Contract MA PFFS Organizations must submit a reimbursement grid for approval by CMS and must validate a claims system that pays FFS rates accurately and on a timely basis.

Reimbursement Grid

All Direct Contract MA PFFS Organizations must submit an electronic and hard copy of the Reimbursement Grid to CMS for approval. Applicants must provide in the Documents Section a grid that outlines how the Direct Contract PFFS MAO will be paying each category of health care provider for Medicare benefits. The link to the CMS

MA payment document is: http://www.cms.hhs.gov/healthplans/rates/out-of-network/default.asp

B. Claims System - Validation

The Applicant can validate the claims systems in the following ways:

1. Maintain a current claims system that has been previously tested by CMS and has demonstrated the ability to pay Medicare FFS payments (for example, using a third party claims administrator that CMS has tested previously); or
2. Utilize a claims system that has been CMS approved for a PFFS product; or
3. Validate the Applicant's claims system – Provide in the Documents section reports and/or narrative that clearly substantiates the process used by the Applicant to test the claims system that will be paying PFFS claims. This documentation must demonstrate the ability to accurately pay providers of all Medicare services an amount not less than the amount the providers would receive under Original Medicare. In addition, the Direct Contract MA PFFS Organization must agree to:

   (a) Sign an Attestation to the Direct Contract PFFS MAO Contract indicating the Applicant has in place the necessary operational claims systems, staffing, processes, functions etc. to properly institute the Reimbursement Grid and pay all providers of Medicare services an amount not less than Original Medicare; (See copy at the end of this chapter) and
   (b) Submit complete and thorough Provider Dispute Resolution Policies and Procedures (P&Ps) with the application to address any written or verbal provider dispute/complaints, particularly regarding the amount reimbursed. This P&P must be extremely clear in all provider materials. The Applicant must submit how it is integrated into all staff training – particularly in Provider Relations, Customer Service and in Appeals/Grievance; and
   (c) Submit a biweekly report, to the CMS Central Office plan manager, data which outlines all provider complaints (verbal and written), particularly where providers or beneficiaries question the amount paid for six months following the receipt of the first claim. This report will outline the investigation and the resolution including the completion of a CMS designed worksheet; and
   (d) Submit a biweekly report, to the CMS Central Office plan manager, data which outlines all beneficiary appeals and/or complaints (verbal and written) related to claims for the six months following the receipt of the first claim. This report will outline the investigation and the resolution including the completion of a CMS designed worksheet.

   NOTE: Should the data indicate that the Direct Contract PFFS MAO offering the PFFS Plan is not meeting the access requirements as outlined above, the CMS may institute a Claims Payment test, a Corrective Action Plan requiring the Direct Contract PFFS MAO to come into compliance and/or move to the initiation of Enforcement Actions as provided in 42 CFR 422.752.

All Direct Contract MA PFFS Organizations must answer the following sections regardless of which option is chosen for Validation of Meeting Access Standards.

C. Describe the claims processing workflow and who is responsible for each stage of the process for the Direct Contract PFFS MAO. Include a flow chart and all Policies and Procedures of this process and place at the end of this chapter.

Provide a list of: all claim denial codes and reasons for denial used in the Medicare contract (do not include commercial).

Describe the Applicant's ability to document interest payment requirements on claims, which are not paid on a timely manner.

Answers to the following questions are needed if the Applicant is paying providers payment rates that are equal to or greater than the rates that apply under Original Medicare (Non-Network PFFS Plan):

1. Describe in detail the system in place that allows the Applicant to obtain payment information for any Medicare approved provider throughout the nation.
2. Provide an electronic and hard copy of the Direct Contract MA PFFS Plan's Terms and Conditions in the Documents Section that will be made available to potential providers. Describe how providers will be able to access the terms and conditions.

3. Will providers be allowed to balance bill the beneficiary? If balance billing is allowed, describe the organizational requirements and processes. Include all communications to beneficiaries and providers. Provide Policies and Procedures and how the Direct Contract MA PFFS Plan will inform the beneficiaries and providers of this requirement. Provide the Policies and Procedures in the Documents Section.
4. How will the Direct Contract MA PFFS Plan monitor the amount collected by non-contract providers to ensure that these amounts do not exceed the amounts permitted to be collected under law?
5. How will the Direct Contract MA PFFS Plan provide to enrollees an appropriate explanation of benefits for each claim filed by the enrollee or provider? The explanation must include a clear statement of the enrollee's liability for deductibles, coinsurance, co-payment and balance billing. Describe and attach a copy.
6. Describe the provider payment appeal process. Provide a flow chart, Policies and Procedures, education materials, etc. of this process.

IV. ENROLLEE RIGHTS AND RESPONSIBILITIES
(Areas of this section may be applicable to both network and non network Direct Contract MA PFFS Organization model)

A. Explain the Applicant's member complaints and grievance procedures and how this will be available to Medicare enrollees. Provide a flow chart of the Applicant's Medicare enrollee complaint and grievance procedures. [42 CFR 422.564]

B. Explain how the Applicant will handle Medicare reconsideration and appeals procedures, including expedited determinations and expedited reconsideration. Provide a flow chart of the Applicant's Medicare reconsideration and appeals procedures (including expedited determinations). Describe how the organization will respond to reversals of Medicare reconsideration determinations by the Independent-Review Entity. [42 CFR 422.566, 422.618(b)]

C. Provide the Applicant's policies and explain projected procedures for implementing those policies with respect to enrollee rights. This includes detailing mechanisms for communicating policies to enrollees at the time of enrollment, and thereafter on a yearly basis; how the organization will ensure its compliance with Federal and state laws affecting the rights of Medicare enrollees. [42 CFR 422.112(a) (8), 422.112(a) (8) (I), 422.112. (a)(10)(I), 422.100(G)]

Describe how:

1. The Direct Contract PFFS MAO will handle Medicare enrollees' privacy with regards to each enrollee being treated with respect, dignity including the protection of any information that identifies a particular enrollee.
2. The Direct Contract PFFS MAO will ensure the confidentiality of health and medical records of other information about enrollees. [42 CFR 422.118(a)]
3. The Direct Contract PFFS MAO will ensure that enrollees are not discriminated against in the delivery of health care services based on race, ethnicity, national origin, religion, sex, age, and mental or physical disability. [42 CFR 422.110(a)]
4. The Direct Contract PFFS MAO will ensure that all services both clinical and non-clinical are accessible to all including those with limited English proficiency or reading skills, and those with diverse cultural and ethnic backgrounds. [42 CFR 422.112(a)(9)]
5. The Direct Contract PFFS MAO will ensure that enrollees participate in decision-making regarding the enrollee's health care and if unable to do so, the Direct Contract PFFS MAO provides for the enrollees representative to facilitate care or treatment decision when the enrollee is unable to do so. [42 CFR 422.206(b), 422.128(a), 422.128(b)]
6. The Direct Contract PFFS MAO will ensure that the enrollee will receive information on available treatment options (including the option of no treatment) or alternative sources of care. The Direct Contract PFFS MAO must ensure that information provided by health care professionals regarding treatment options are in a language that the enrollee understands. [42 CFR 422.206(a)(1)i), 422.206(a)(2)]

7. The Direct Contract PFFS MAO will follow to ensure enrollees' will have access to one's medical records in accordance with applicable Federal and State laws. [42 CFR 422.118(a), 422.118(d)]
8. The Direct Contract PFFS MAO will ensure prompt resolution, of issues, raised by the enrollee, including complaints or grievances and issues relating to authorization, coverage or payment for services. [42 CFR 422.118(d)]

D. A written statement must be provided including information that is readable and easily understood for each area described below (refer to regulations at 42 CFR 422.111 (a) (1-3), 422.111(b) (1)-(10), 422.113. Describe how the Applicant will ensure that the following enrollee information is received at the time of enrollment and at least annually:

1. The Applicant will ensure that all enrollee information on benefits and services including mandatory and supplemental benefits will be provided in an appropriate manner. [42 CFR 422.111(b)(2), 422.111(b)(6)]
2. The Applicant will ensure that enrollees have information on the number, mix and distribution of providers including out-of-network coverage, point-of-service etc. [42 CFR 422.111(b)(3)]
3. The Applicant will ensure that enrollees are provided information on emergency coverage, including the appropriate use of emergency services, and policies and procedures. [42 CFR 422.111(b)(5)(I-IV)]
4. The Applicant will ensure the right to access emergency health care services is consistent with the determination of the need for services by a prudent layperson. [42 CFR 422.113]
5. The Applicant will ensure that enrollees are informed of prior authorizations and review rules. [42 CFR 422.111(b)(7)]
6. The Applicant will ensure that all enrollee's rights have been provided on the grievance and appeals procedures. [42 CFR 422.111(b)(8)]
7. The Applicant will ensure that enrollees are informed of the organization's quality assurance program. [42 CFR 422.111(b)(9)]
8. The Applicant will provide for enrollees' disenrollment rights and responsibilities. Explain how the MA Organization will provide to the enrollee upon request any disclosures. [42 CFR 422.111(b)(10), 422.111(c)(1-5)]

E. For each of the following, describe the Applicant's system for resolution of enrollee issues which are raised by enrollees, including complaints and grievances; issues related to authorization of, coverage of, or payment of services; and issues related to discontinuation of service [Note: references to an enrollee in these standards include reference to an enrollee's representative]. [42 CFR 422.564(a) (2), 422.152(c), 422.562(a) (I), 422.562(a) (ii)]

Explain how:

1. The Applicant will ensure that it follows its own written procedures for processing all issues raised by enrollees.
2. The Applicant will implement procedures (with clearly explained steps and time limits for each step) for the resolutions of a compliant or grievance by enrollees. [42 CFR 422.564(a)(1), 422.564(a)(2), 422.564(b)(1)]
3. The Applicant will implement procedures (with clearly explained steps and time limits for each step) for reviewing coverage and payment requests for reconsideration of initial decisions that the MA Organization chooses not to provide or pay for a particular service. [42 CFR 422.564(b)(4), 422.564(b)(iii)]

4. The Applicant will monitor the resolution of enrollee issues. How will the Applicant ensure that it maintains, aggregates and analyzes the resolution of enrollee issues? [42 CFR 422.152(f) (1)]

F. Patient Self-Determination Act - Explain the Applicant's process of providing information regarding advance directives to members at the time of a member's enrollment.

G. Describe how the Applicant will comply with the prohibitions against Direct Contract PFFS MAO interference with health professional advice to enrollees regarding enrollees' care and treatment options.

H. Describe the process for assuring a "best effort" to conduct an initial assessment of each enrollee's health care needs within 90 days of effective date of enrollment [42 CFR 422.112(b)(4)(i)]

V. MORAL OR RELIGIOUS EXCEPTION - 42 CFR 422.206(b)

If the Direct Contract PFFS MAO is requesting an exception to covering a particular counseling or referral service due to moral or religious grounds, state the service and explain the reasons for the request.

VI. MEDICARE MATERIAL - 42 CFR 422.80

Review and Approval

CMS has waived the prior review and approval requirements for marketing materials and election forms contained in 42 CFR 422.80 for Direct Contract PFFS MAOs. This waiver applies to all marketing materials, including the marketing materials requirements contained in the Medicare Marketing Guidelines.

Disclosure/Dissemination

CMS will waive the disclosure requirements of 42 CFR 422.111 and the dissemination requirements of 42 CFR 423.128 for Direct Contract PFFS MAOs when the employer or union plan sponsor is subject to alternative disclosure requirements (e.g., ERISA) and the Direct Contract PFFS MAO complies with such alternative requirements. However, these alternative disclosure materials (including summary plan descriptions and all other beneficiary communications that provide descriptions of the benefit offerings) must be provided to CMS at the time of use and to beneficiaries on a timely basis. CMS will presume that timely disclosure/dissemination to beneficiaries has been met if the alternative disclosure materials are provided to the enrollees pursuant to the Medicare timeframes outlined in the Medicare Marketing Guidelines (e.g., at the time of enrollment and during the month within which an enrollee utilizes their prescription drug benefits).

A. Please identify if you are subject to alternative disclosure requirements which would make your organization eligible for these waivers. If you are not subject to alternative disclosure requirements, you must complete the below requirements.

1. Definitions: 42 CFR 422.80(b)
2. Marketing materials include any applicable informational materials targeted to Medicare beneficiaries which:

   (a) Promote the Direct Contract PFFS MAO, or any Direct Contract MA PFFS Plan offered by the MA Organization;
   (b) Inform Medicare beneficiaries that they may enroll, or remain enrolled, in a Direct Contract MA PFFS Plan offered by the Direct Contract PFFS MAO;
   (c) Explain the benefits of enrollment in a Direct Contract MA PFFS Plan or rules that apply to enrollees;
   (d) Explain how Medicare services are covered under Direct Contract MA PFFS Plan including conditions that apply to such coverage and are not dependent on the annual bidding process.

MEDICARE
END OF CHAPTER DOCUMENTATION

1. Reimbursement Grid and Policy and Procedures for quarterly updates to CMS.
2. Substantiation of claims system capabilities to pay claims – Flow chart of claims processing workflow with responsibility outlined
   (a) Narrative on how the test process was conducted to pay all PFFS claims
   (b) Provide five actual test claims as examples for each provider type with a results report for each provider type. Describe the plan's evaluation process (how did the plan determine the amount was accurate to FFS payments), discrepancies noted and corrective actions taken.
   (c) Policies and Procedures on payment processes for all provider types represented in the Reimbursement Grid. Describe edits used.
   (d) List of Claim denial codes and reasons
   (e) List of Public Use Files accessed and loaded into the claims system.
3. Terms and Conditions of Payment for Non Network Model Direct Contract MA PFFS Plan
4. Provider Dispute Resolution Policies and Procedures
5. All Provider education materials
6. Policies and Procedures for Balance Billing
7. Copies of Beneficiary and Provider notifications of payments (Explanation of Benefits and Payment Advice)
8. All Marketing Materials, if applicable

ON SITE DOCUMENTS

1. Policy and Procedure Manuals for claims processing, appeals, enrollment, provider relations, reimbursement.
2. Staffing plans for all operational areas.

3. Provider appeal flowchart

FINANCIAL

I. FINANCIAL SOLVENCY

In general, a MA Organization must be organized and licensed under State law as a risk-bearing entity eligible to offer health insurance or health benefits coverage in each State in which it offers coverage. CMS has waived the state licensing requirement for Direct Contract PFFS MAOs; therefore any documentation concerning state licensing is not required for these applicants. However, these entities are required to meet all financial solvency requirements outlined in Appendix I. If, however, the employer or union does not meet the standards described in Appendix I of this application, CMS may in its discretion approve, on a case-by-case basis, waivers of such requirements upon a demonstration from the entity that its fiscal soundness is commensurate with its financial risk and through other means the entity can assure that claims for benefits paid for by CMS and beneficiaries will be covered. In all cases, CMS will require that the Direct Contract PFFS MAO's contracts and sub-contracts provide beneficiary hold harmless provisions described in Appendix I and other CMS guidance.

A. Please provide a copy of the Applicant's most recent independently certified audited statements and complete Appendix I – Financial Solvency Document.

B. Please submit an attestation signed by the Chairman of the Board, Chief Executive Officer and Chief Financial Officer or Trustee or other Equivalent Official attesting to the following:

1. The Applicant will maintain a fiscally sound operation and will notify CMS within 10 business days if it becomes fiscally unsound during the contract period.
2. The Applicant is in compliance with all applicable Federal and State requirements and is not under any type of supervision, corrective action plan, or special monitoring by the Federal or State government state regulator. **NOTE: If the Applicant cannot attest to this compliance, a written statement of the reasons must be provided.**

APPENDIX I
Financial Solvency Documentation
For Employer/Union Direct Contract MA PFFS Organization

I. FINANCIAL DOCUMENTATION

A. Minimum Net Worth at the Time of Application -
Documentation of Minimum Net Worth

At the time of application, the Applicant must demonstrate financial solvency through furnishing two years independently audited financial statements to CMS. These financial statements must demonstrate a required minimum net worth at the time of application of the greater of $3.0 million **or** the number of expected individuals to be covered under the Direct Contract MA PFFS Plan times $800.00. Complete the following:

1. Minimum Net Worth: $_____
2. Number of expected individuals to be covered under the Direct Contract MA PFFS Plan _____ times $800.00 = $ _____.

NOTE: In addition to the requirements in this Appendix, if the Direct Contract PFFS MAO Applicant is also applying to offer a Direct Contract MA PFFS Plan that provides Part D coverage (i.e., MA-PD), it must complete and submit the corresponding Direct Contract MA-PD application with this application and meet the Part D Minimum Net Worth requirements stated in the separate Direct Contract MA-PD application.

If the Applicant has not been in operation at least twelve months, it may choose to: 1) obtain independently audited financial statements for a shorter time period; or 2) demonstrate that it has the minimum net worth through presentation of un-audited financial statements that contain sufficient detail to allow CMS to verify the validity of the financial presentation. The un-audited financial statements must be accompanied by an actuarial opinion from a qualified actuary regarding the assumptions and methods used in determining loss reserves, actuarial liabilities and related items.

A "qualified actuary" for purposes of this application means a member in good standing of the American Academy of Actuaries, a person recognized by the Academy as qualified for membership, or a person who has otherwise demonstrated competency in the field of actuarial science and is satisfactory to CMS.

If the Direct Contract PFFS MAO Applicant's auditor is not one of the 10 largest national accounting firms in accordance with the list of the 100 largest public accounting firms published by the CCH Public Accounting Report, the Applicant should enclose proof of the auditor's good standing from the relevant state board of accountancy.

B. Minimum Net Worth On and After Effective Date of Contract

A Applicant must have net worth as of the effective date of the **greater** of the following financial thresholds; $3.0 million; or, an amount equal to eight percent of annual health care expenditures, using the most recent financial statements filed with CMS; or the number of expected individuals to be covered under the Direct Contract MA PFFS Plan times $800.00.

C. Liquidity -

Liquidity at the Time of Application ($1.5 Million)

The Applicant must have sufficient cash flow to meet its financial obligations as they become due. The amount of the minimum net worth requirement to be met by cash or cash equivalents is $1.5 million. Cash equivalents are short-term highly liquid investments that can be readily converted to cash. To be classified as cash equivalents, investments must have a maturity date not longer than 3 months from the date of purchase.

NOTE: In addition to the requirements in this Appendix, if the Direct Contract PFFS MAO Applicant is also applying to offer a Direct Contract MA PFFS Plan that provides Part D coverage (i.e., MA-PD), it must complete and submit the corresponding Direct Contract MA-PD application with this application and meet the Part D Liquidity requirements stated in the separate Direct Contract MA-PD application.

D. Liquidity On and After Effective Date of Contract

After the effective date of the contract, an Applicant must maintain the **greater** of $1.5 million **or** 40 percent of the minimum net worth requirement outlined in Section I.B above in cash or cash equivalents.

In determining the ability of an Applicant to meet the requirements of this paragraph D, CMS will consider the following:

1. The timeliness of payment;
2. The extent to which the current ratio is maintained at 1:1 or greater, or whether there is a change in the current ratio over a period of time; and
3. The availability of outside financial resources.

CMS may apply the following corresponding corrective remedies:

1. If a Direct Contract PFFS MAO fails to pay obligations as they become due, CMS will require the Direct Contract PFFS MAO to initiate corrective action to pay all overdue obligations.
2. CMS may require the Direct Contract MA Organization to initiate corrective action if any of the following are evident:
   (a) The current ratio declines significantly; or
   (b) A continued downward trend in the current ratio. The corrective action may include a change in the distribution of assets, a reduction of liabilities, or alternative arrangements to secure additional funding to restore the current ratio to at least 1:1.
3. If there is a change in the availability of outside resources, CMS will require the Direct Contract PFFS MAO to obtain funding from alternative financial resources.

E. Methods of Accounting

The Direct Contract PFFS MAO generally must use the standards of Generally Accepted Accounting Principles (GAAP). Generally Accepted Accounting Principles (GAAP) are those accounting principles or practices prescribed or permitted by the Financial Accounting Standards Board. However, a Direct Contract PFFS MAO whose audited financial statements are prepared using accounting principles or practices other than GAAP, such as a governmental entity that reports in accordance with the principles promulgated by the Governmental Accounting Standards Board (GASB), may utilize such alternative standard.

F. Bonding and Insurance

An Applicant may request a waiver in writing of the bonding and/or insurance requirements set forth at 42 CFR 422.503(b) (4) (iv) and (v) in accordance with Appendix II to this application. Relevant considerations will include demonstration that either or both of the foregoing requirements are unnecessary based on the entity's individualized circumstances, including maintenance of similar coverage pursuant to other law, such as the bonding requirement at ERISA Sec. 412. If the waiver request is based on the existence of alternative coverage, the Applicant must describe such alternative coverage and enclose proof of the existing of such coverage.

G. Additional Information

A Direct Contract PFFS MAO Applicant must furnish the following financial information to CMS to the extent applicable:

1. **Self-Insurance/Self Funding**- If the Direct Contract PFFS MAO Applicant's PFFS Plan(s) will be self-insured or self-funded, it must forward proof of stop-loss coverage (if any) through copies of policy declarations.
2. **Trust**- If the Direct Contract PFFS MAO Applicant maintains one or more trusts with respect to its health plan(s), a copy of the trust documents, and if the trust is intended to meet the requirements of Section 501(c)(9) of the Internal Revenue Code, the most recent IRS approval letter.
3. **Forms 5500 and M-1**- The two most recent annual reports on Forms 5500 and M-1 (to the extent applicable) for the Direct Contract PFFS MAO Applicant's health plans that cover prescription drugs for individuals who are Part D eligible.
4. **ERISA Sec. 411(a) Attestation**- The Direct Contract PFFS MAO (including a Direct Contract PFFS MAO that is exempt from ERISA) must provide a signed attestation that no person serves as a fiduciary, administrator, trustee, custodian, counsel, agent, employee, consultant, adviser or in any capacity that involves decision-making authority, custody, or control of the assets or property of any employee benefit plan sponsored by the potential Direct Contract PFFS MAO if he or she has been convicted of, or has been imprisoned as a result of his or her conviction of, one of the felonies set forth in ERISA Sec. 411(a), for 13 years after such conviction or imprisonment (whichever is later).
5. **Defined Benefit Pension Plan-** If the potential Direct Contract PFFS MAO sponsors one or more defined benefit pension plans (within the meaning of ERISA Sec. 3(35)) that is subject to the requirements of Title IV of ERISA, the latest actuarial report for each such plan.

6. **Multi-Employer Pension Plan-** If the potential Direct Contract PFFS MAO is a contributing employer with respect to one or more multi-employer pension plans within the meaning of ERISA Sec. 3(37), the latest estimate of contingent withdrawal liability.
7. **Tax-Exempt Direct Contract PFFS MAOs Only**- a copy of the most recent IRS tax-exemption.

II. INSOLVENCY REQUIREMENTS

A. Hold Harmless and Continuation of Coverage/Benefits.
The Direct Contract PFFS MAO shall be subject to the same hold harmless and continuation of coverage/benefit requirements as other Medicare Advantage contractors.

B. Deposit Requirements -
Deposit at the Time of Application
A Direct Contract PFFS MAO generally must forward confirmation of its establishment and maintenance of a deposit of at least $1.0 million to be held in accordance with CMS requirements by a qualified U. S. Financial Institution. A "qualified financial institution" means an institution that:

1. Is organized or (in the case of a U.S. office of a foreign banking organization) licensed, under the laws of the United States or any state thereof; and
2. Is regulated, supervised, and examined by the U.S. Federal or State authorities having regulatory authority over banks and trust companies.

The purpose of this deposit is to help assure continuation for services, protect the interest of Medicare enrollees, and pay costs associated with any receivership or liquidation. The deposit may be used to satisfy the minimum net worth requirement set forth in Section I above.

A Direct Contract PDP Sponsor may request a waiver in writing of this requirement in accordance with Appendix II to this application.

NOTE: In addition to the requirements in this Appendix, if the Direct Contract PFFS MAO is also applying to offer a Direct Contract MA PFFS Plan that provides Part D coverage (i.e., MA-PD), it must complete and submit the corresponding Direct Contract MA-PD application with this application and meet the Part D Deposit requirements stated in the separate Direct Contract MA-PD application.

Deposit On and After Effective Date of Contract

Based on the most recent financial statements filed with CMS, CMS will determine the adequacy of the deposit under this Section and inform the Direct Contract PFFS MAO as to the necessity for any increased deposit. Factors CMS will consider shall include the total amount of health care expenditures during the applicable period, the amount of expenditures that are uncovered, and the length of time necessary to pay claims.

Rules Concerning Deposit

1. The deposit must be held in trust and restricted for CMS' use in the event of insolvency to pay related costs and/or to help assure continuation of services.
2. All income from the deposit are considered assets of the Direct Contract PFFS MAO and may be withdrawn from the deposit upon CMS, approval, such approval to not be unreasonably withheld.
3. On prior written approval from CMS, a Direct Contract PFFS MAO that has made a deposit under this Section may withdraw such deposit or any part thereof if:

   (a) a substitute deposit of cash or securities of equal amount and value is made;
   (b) the fair market value of the assets held in trust exceeds the required amount
   (c) for the deposit; or
   (d) the required deposit is reduced or eliminated.

III. GUARANTEES (this Section only applies to a Direct Contract PFFS MAO that submits a request to utilize a Guarantor)

A. General policy

The Direct Contract MA Organization, or the legal entity of which the Direct Contract MA Organization is a component, may apply to CMS to use the financial resources of a Guarantor for the purpose of meeting the requirements of a Direct Contract PFFS MAO set forth above. CMS has the sole discretion to approve or deny the use of a Guarantor.

B. Request to use a Guarantor

To apply to use the financial resources of a Guarantor, a Direct Contract PFFS MAO must submit to CMS:

1. Documentation that the Guarantor meets the requirements for a Guarantor under paragraph (C) of this section; and
2. The Guarantor's independently audited financial statements for the current year-to-date and for the two most recent fiscal years. The financial statements must include the Guarantor's balance sheets, profit and loss statements, and cash flow statements.

C. Requirements for Guarantor

To serve as a Guarantor, an organization must meet the following requirements:

1. Is a legal entity authorized to conduct business within a State of the United States.
2. Not be under Federal or State bankruptcy or rehabilitation proceedings.
3. Have a net worth (not including other guarantees, intangibles and restricted reserves) equal to three times the amount of the Direct Contract PFFS MAO guarantee.
4. If a State insurance commissioner or other State official with authority for risk-bearing entities regulates the Guarantor, it must meet the net worth requirement in Section I above with all guarantees and all investments in and loans to organizations covered by guarantees excluded from its assets.
5. If the Guarantor is not regulated by a State insurance commissioner or other similar State official, it must meet the net worth requirement in Section I above with all

guarantees and all investments in and loans to organizations covered by a guarantee and to related parties (subsidiaries and affiliates) excluded from its assets.

D. Guarantee document

If the guarantee request is approved, a Direct Contract PFFS MAO must submit to CMS a written guarantee document signed by an appropriate Guarantor. The guarantee document must:

1. State the financial obligation covered by the guarantee;
2. Agree to:
   (a) Unconditionally fulfill the financial obligation covered by the guarantee; and
   (b) Not subordinate the guarantee to any other claim on the resources of the Guarantor;
3. Declare that the Guarantor must act on a timely basis, in any case not more than 5 business days, to satisfy the financial obligation covered by the guarantee; and
4. Meet any other conditions as CMS may establish from time to time.

E. Ongoing reporting requirements

A Direct Contract PFFS MAO must submit to CMS the current internal financial statements and annual audited financial statements of the Guarantor according to the schedule, manner, and form that CMS requires.

F. Modification, substitution, and termination of a guarantee

A Direct Contract PFFS MAO cannot modify, substitute or terminate a guarantee unless the Direct Contract PFFS MAO:

1. Requests CMS's approval at least 90 days before the proposed effective date of the modification, substitution, or termination;
2. Demonstrates to CMS's satisfaction that the modification, substitution, or termination will not result in insolvency of the Direct Contract MA Organization; and
3. Demonstrates how the Direct Contract PFFS MAO will meet the requirements of this section.

G. Nullification

If at any time the Guarantor or the guarantee ceases to meet the requirements of this section, CMS will notify the Direct Contract PFFS MAO that it ceases to recognize the guarantee document. In the event of this nullification, a Direct Contract PFFS MAO must:

1. Meet the applicable requirements of this section within 15 business days; and
2. If required by CMS, meet a portion of the applicable requirements in less than the 15 business days in paragraph (G.1.) of this section.

IV. ONGOING REPORTING REQUIREMENTS

An approved Direct Contract PFFS MAO is required to update the financial information set forth in Sections I and II above to CMS on an ongoing basis after approval. The schedule, manner, form and type of reporting, will be in accordance with CMS requirements.

APPENDIX II

REQUEST FOR ADDITIONAL WAIVER/MODIFICATION OF REQUIREMENTS (OPTIONAL):

As a part of the application process, Applicants may submit individual waiver/modification requests to CMS. The Applicant should submit these additional waiver/modification requests via hard copy to:

Centers for Medicare & Medicaid Services (CMS)
Mail Stop: C1-22-06
Attn: 2008 Case-by Case Waiver Request (Contract #: EXXXX)
7500 Security Blvd.
Baltimore, MD 21244-1850

These requests must be identified as requests for additional waivers/modifications and must fully address the following items:

- Specific provisions of existing statutory, regulatory, and/or CMS policy requirement(s) the entity is requesting to be waived/modified (please identify the specific requirement (e.g., "42 CFR 422.66," or "Section 40.4 of Chapter 2 of the Medicare Managed Care Manual (MMCM)") and whether you are requesting a waiver or a modification of these requirements);

- How the particular requirements hinder the design of, the offering of, or the enrollment in, the employer-sponsored group plan;

- Detailed description of the waiver/modification requested including how the waiver/modification will remedy the impediment (i.e., hindrance) to the design of, the offering of, or the enrollment in, the employer-sponsored group plan;

- Other details specific to the particular waiver/modification that would assist CMS in the evaluation of the request; and

Contact information (contract number, name, position, phone, fax and email address) of the person who is available to answer inquiries about the waiver/modification request.

DRAFT - ATTACHMENT D

CERTIFICATION OF CLAIMS PAYMENT SYSTEMS RELATING TO THE MEDICARE ADVANTAGE ORGANIZATION'S ABILITY TO PAY PROVIDER CLAIMS ACCURATELY ON A FEE-FOR-SERVICE BASIS

Pursuant to the contracts(s) between the Centers for Medicare & Medicaid Services (CMS) and (INSERT NAME OF DIRECT CONTRACT MEDICARE ADVANTAGE ORGANIZATION), hereafter referred to as the Direct Contract PFFS MAO, governing the operation of the following Direct Contract PFFS MAO Plan (INSERT CONTRACT IDENTIFICATION NUMBERS HERE), hereby makes the following certification to CMS. The Direct Contract PFFS MAO acknowledges that the information described below is accurate, complete and truthful and that misrepresentations to CMS about the accuracy of such information may result in Federal civil action and/or criminal prosecution.

The Direct Contract PFFS MAO has an operational claims payment system that, is duly tested, and has the ability to pay providers rates that are not less than rates that apply under original Medicare for the provider in question. For services that currently have no Medicare fee schedules, the Direct Contract PFFS MAO will pay providers rates that CMS has approved on the Direct Contract PFFS MAO's reimbursement grid.

_____

(INDICATE TITLE [CEO, CFO, or delegate])

On behalf of

_____

(INDICATE NAME OF DIRECT CONTRACT PFFS MAO)

PART D PRESCRIPTION DRUG BENEFIT - 42 CFR 422.252

Note: Direct Contract PFFS MAOs are not required to offer the Part D drug benefit.

I. PART D PRESCRIPTION DRUG BENEFIT

If the Direct Contract PFFS MAO seeks to offer a PFFS Plan that provides Part D coverage (i.e., is a MA-PD), it must complete and submit **in addition to this application** a Direct Contract MA-PD application, which can be found at http://www.cms.hhs.gov/EmpGrpWaivers/01_Overview.asp. Specific instructions to guide Direct Contract PFFS MAOs in applying to qualify to offer a Part D benefit during 2008 are provided in the MA-PD application.

The MA-PD application is an abbreviated version of the application used by stand-alone Prescription Drug Plan (PDPs), as the regulation allows CMS to waive provisions that are duplicative of MA requirements or where a waiver would facilitate the coordination of Part C and Part D benefits. Further, the MA-PD application includes a mechanism for Medicare Advantage organizations to request CMS approval of waivers for specific Part D requirements under the authority of 42 CFR 423.458 (b)(2).

DOCUMENTS TABLE OF CONTENTS

To add the page numbers for the Documents table of contents, place cursor at the end of each line (using the End key) and type in the page number. Do not press ENTER, just place the cursor at the end of the next line for the next page entry.

ADMINISTRATIVE CONTRACTING REQUIREMENTS FOR MANAGEMENT/DELEGATION OF CONTRACTS AND/OR AGREEMENTS

For contracts and/or agreements that directly relate to MA Organization's core functions under its contract with CMS

NAME OF CONTRACTOR (FIRST TIER & DOWNSTREAM)			
42 CFR 422	**Section & Page #**	**Section & Page #**	**Section & Page #**
Person or entity must agree to comply with all applicable Medicare laws, regulations, and CMS instructions. 422.504(i)(4)(v)			
Agrees to comply with all state & Federal requirements for accuracy & confidentiality of enrollee records, including the requirements established by the MAO and the MA program. 422.118; 422.504(a)(13)			
Agrees to grant HHS, etc. the right to inspect information related to the contract for up to 10 years from the final date of the contract period and in certain instances described in the MMA regulation, periods in excess of 10 years or more. 422.504(e)(2); 422.504(e)(3); 422.504(e)(4); 422.504(i)(2)(ii)			
Contract must clearly state the responsibilities of the administrative services provider and its reporting arrangements. 422.504(a)(8)			
MAO has the right to revoke the contract if any first tier and/or downstream entity does not perform the services satisfactorily and if reporting and disclosure requirements are not timely. 422.504(i)(4)(ii)			
Any services performed will be consistent with and comply with the MAO's contractual obligations with CMS. 422.504(i)(1); 422.504(i)(3)(iii)			
If credentialing is delegated, the entity must meet all MAO credentialing requirements, and the credentials of medical professionals will be either reviewed by the MAO **or** the credentialing process will be reviewed, approved, & audited by the MAO on an ongoing basis. 422.504(i)(4)(iv)(A)/(B)			
If MAO delegates selection of providers written arrangements must state that the MAO retains the right to approve, suspend, or terminate any such arrangement. 422.504(i)(5)			
The contract must acknowledge that the responsibilities performed by an administrative services entity and/or any delegated administrative service entities are monitored by the MAO on an ongoing basis and that the MAO is ultimately responsible to CMS for the performance of all services. 422.504(i)(1) & (4)			
Contracts between MAOs and first tier entities and first tier entities and downstream entities must contain provisions specifying MAO delegation requirements specified at section 422.504(i)(3)(iii); 422.504(i)(4) and 422.504(i)(5)			
Dated & signed.			

REGULATORY REQUIREMENTS THROUGH POLICIES, STANDARDS & MANUALS

(These provisions must be included in provider procedures, standards or manuals, etc.)

Provide Title of Manual:				
CMS REGULATION - 42 CFR 422	**Section/Page#**	**Section/Page#**	**Section/Page#**	**SectionPage#**
Permanent "out of area members to receive benefits in continuation area 422.54(b)				
Prohibition against discrimination based on health status 422.110(a)				
Pay for emergency and urgently needed care consistent with provisions 422.112(a)(9); 422.100(b)				
Pay for renal dialysis for those temporarily out of service area 422.100(b)(1)(iv)				
Direct access to mammography screening and influenza vaccinations 422.100(g)(1)				
No copay for influenza and pneumoccocal vaccines 422.100(g)(2)				
Agreements with providers to demonstrate "adequate" access. Network must be sufficient to provide access to covered services 422.112(a)(1)				
Direct access to in-network women's health specialist for routine and preventive services 422.112(a)(3)				
Services available 24 hrs/day, 7 days/week 422.112(a)(7)				
Suspension or termination of plan-contracted providers 422.204				
Safeguard privacy and maintain records accurately and timely 422.118				
Adhere to CMS marketing provisions 422.80(a), (b), (c)				
Ensure services are provided in culturally competent manner 422.112(a)(8)				

Provide Title of Manual:				
CMS REGULATION - 42 CFR 422	**Section/Page#**	**Section/Page#**	**Section/Page#**	**SectionPage#**
Conduct a health assessment of all new enrollees within 90 days of the effective date of enrollment 422.112(b)(4)				
Document in a prominent place in medial record if individual has executed Advance directive 422.128(b)(1)(ii)(E)				
Provide covered benefits in a manner consistent with professionally-recognized standards of health care 422.504(a)(3)(iii)				
Payment and incentive arrangements specified between MAO, providers, first tier, & downstream entities be specified in all contract(s) 422.504				
Subject to laws applicable to federal funds 422.504(h)				
Disclose to CMS all information necessary to (1) administer & evaluate the program (2) establish and facilitate a process for current and prospective beneficiaries to exercise choice in obtaining Medicare services 422.64: 422.504(a)(4): 422.504(f)(2)				
Must make good faith effort to notify all affected members of the termination of a provider contract within 30 days of notice of termination by plan or provider 422.111(e)				
Submission medical records and certify completeness and truthfulness 422.504(a)(8); 422.504(d)-(e); 422.504(i)(3)-(4);422.504 (l)(3)				
Comply with medical policy, QM and MM. MAO must develop such standards in consultation with contracting providers 422.202(b); 422.504(a)(5)				
Disclose to CMS quality & performance indicators for plan benefits re: disenrollment rates for benes enrolled in the plan for the previous two years 422.504(f)(2)(iv)(A)				
Disclose to CMS quality & performance indicators for the benefits under the plan regarding enrollee satisfaction 422.504(f)(2)(iv)(B)				
Disclose to CMS quality & performance indicators for the benefits under the plan				

Provide Title of Manual:				
CMS REGULATION - 42 CFR 422	**Section/Page#**	**Section/Page#**	**Section/Page#**	**SectionPage#**
regarding health outcomes 422.504(f)(2)(iv)(C)				
Notify provider in writing of reason for denial, suspension & termination 422.204(c)(1)				
Provide 60 days notice (terminating contract without cause) 422.204(c)(4)				
Comply with Civil Rights Act, ADA, Age Discrimination Act, federal funds laws 422.504(h)(1)				
Prohibits MAO, first tier & downstream entities from employing or contracting with individuals excluded from participation in Medicare under section 1128 or 1128A of the SSA 422.752(a)(8)				
Adhere to appeals/grievance procedures 422.562(a)				

PROVIDER PARTICIPATION CONTRACTS AND/OR AGREEMENTS

COUNTY:_____

IPA/Group/Provider Name **First Tier & Downstream Contracts and/or Agreements**					
CMSREGULATIONS – 42 CFR 422	**Section/Page**	**Section/Page**	**Section/Page**	**Section/Page**	**Section/Page**
All Provider Contracts					
Gives HHS, GAO and designees right to audit etc. for 6 years or periods exceeding 6 years or completion of an audit, whichever is later 422.504(e)(2); 422.504(e)(3); 422.504(i)(2)(ii); 422.504(e)(4)					
Comply with all confidentiality and enrollee record accuracy requirements 422.504(a)(13); 422.118					
Hold harmless provisions 422.504(g)(1)(i)					
Specify delegation requirements in manner consistent with reg 422.504(i)(3)(iii); 422.504(i)(4)					
Prompt payment 422.520(b)					
Comply with reporting requirements in 422.516 and 422.257 422.504(a)(8)					
Accountability provisions 422.504(i)(3)(ii)					
Comply with applicable Medicare laws and Regulations 422.504(i)(4)(v)					
Benefit continuation 422.504(g)(2)(i); 422.504(g)(2)(ii); 422.504(g)(3)					
Dated and Signed 422.505					
Term 422.505					

license.doc - State License

State	Applicant Licensed? Yes or No	Type of License	Does State Regulate Medicare? Yes or No	Which Medicare Activities are Regulated by the State?[i]	Restricted Reserve Requirements If yes, give amount	State Regulator=s Name, Address Phone #

i. Include activities such as Medicare marketing, financial performance, benefits, grievances, etc.

County Name: _____

LEGAL-2 PROVIDER ARRANGEMENTS

Category	Type of Agreement	Number of Agreements	Various Dates Executed	Automatic Renewal of Agreements	Page Number for Contract Template in this Application
Staff					
Physicians					
Non-Physicians					
Non-staff Physicians					
Group					
Member Physicians					
Member Non-Physicians					
Non-Member Physicians					
Non-Member, Non-Physicians					
IPA					
Member Physicians					
Member Non-Physicians					
Non-member Physicians					
Non-member, Non-Physicians					
Direct Contract HMO Physicians					
Lab Services					
X-ray Services					
Hospitals					
Home Health					
Other (specify)					

Prepare a separate table for each county requested

PROVIDER ARRANGEMENTS **TABLE: Legal-2**

Instructions:

Provide a separate table for each county or partial county.

Column Explanations:

1. Category - Staff/Group/IPA/PHO/Direct:

Member Physicians - Licensed Medical Doctors (M.D.) and Doctors of Osteopathic Medicine (O.D.) who are members of the entity.
Member Non-Physicians - Mid-wives, nurse practitioners, or chiropractors, etc. who are members of the entity.
Non-Member Physicians - Licensed M.D. and D.O. who are subcontracted to provide services to the. entity.
Non-Member, Non-Physicians - Mid-wives, nurse practitioners, or chiropractors, etc. who are subcontracted to provide services to the entity but are not members of the entity.
Direct Contract HMO Physicians - Licensed M.D. and D.O. who have entered into a contract with the HMO.

2. Type of Agreement - Only contracts or Letters of Agreement (LOA) are acceptable. *Letters of* intent are not acceptable.

3. Number of Agreements - List the total number of signed agreements.

4. Automatic Renewal of Agreements - Provide "Yes" or "No" response.

5. Date Executed - Enter the date all agreements were finalized for the particular category.

6. Page Number in Contract - List the page number where the agreement is located in the application package.

Legal-1 INSURANCE COVERAGE

Type	Carrier	Entity Covered	Description: Deductibles, Co-insurance, Minimum & Maximum Benefits	Premiums	Period Policies are in Effect	Other Arrangements to Cover These Risks
Reinsurance						
Risk of insolvency						
Out-of-area emergency						
Malpractice 1. Plan						
2. Affiliated Providers						
General Liability						
Casualty						
Fire						
Theft						
Fidelity bond						

HSD-2 PROVIDER LIST - LIST OF PHYSICIANS AND OTHER PRACTITIONERS BY COUNTY

Date Prepared:

Applies to plan(s):

Name of Physician or Mid-Level Practitioner	Specialty	Contract Type	Service Address: Street Address	City	State	Zip Code	County	Provider Previously Listed? Y or N	Contracted Hospital Where Privileged	May Provider Serve as PCP? Y or N	If PCP, Accepts New Patients? Y or N	If PCP, Accepts Only Established Patients? Y or N	Does MCO Delegate Credentialing? Y or N	If Credentialing is Delegated, List Entity	Medical Group Affiliation MGA or DC	Employment Status