SUPPORTING STATEMENT: CMS-901
OMB: 0938-0470

QUALIFICATION APPLICATION (CMS 901-A); MEDICARE AGREEMENT APPLICATION FOR HEALTH CARE PREPAYMENT PLAN (CMS 901-D) Regulations in 42 CFR Section 417.143 and 422.6

A. Background -- The nature of the collection.

We are requesting regular OMB approval extension of collection requirement contained in 42 CFR Section 417.143 and 422.6, Medicare Advantage Program. The collection documents are application forms, CMS-901 A and CMS 901-D; the user will be either a new applicant or a currently qualified HMO or contracting health plan requesting an expansion of its service area. Application titled Qualification Application Initial and Service Area Expansion CMS 901-A & Medicare Agreement Application Health Care Prepayment Plan CMS 901-D was approved under OMB number 0938-0470. Additionally, Applications 901-B and 901-C approved under OMB number 0938-0470 are being removed from this collection, due to their inclusion in OMB collection 0938-0935.

Title XIII of the Public Health Service Act was established by Public Law 93-222, the Health Maintenance Organization Act of 1973. This Act established a major federal initiative in the private sector to change the emphasis of the health service system. The HMO Act also established requirements for HMO's performance and a mechanism for continued regulation.

The Office of Health Maintenance Organizations (OHMO) was developed and designated as the implementing agent of the legislation. As a result of an organizational change, which took place in March 1986, the OHMO program functions were transferred into the Office of Prepaid Health Care (OPHC), Health Care Financing Administration (HCFA). A subsequent organizational change in 1991 transferred these functions to the Office of Prepaid Health Care Operations and Oversight (OPHCOO); another change in 1994 transferred the HMO program to HCFA's Office of Managed Care (OMC). After HCFA's reorganization in 1997, federal qualification is regulated at the Center for Health Plans and Providers, Health Plan Administration Group. The most recent change placed federal qualification in the Center for Medicare & Medicaid Services, Center for Beneficiary Choices, Division of Qualifications and Plan Management.

The Balanced Budget Act of 1997 (Public Law 105-33) established a new Medicare Advantage Program that significantly expanded the health care options available to Medicare beneficiaries. The two options (CMS-901-A and CMS 901-D) have sufficiently different requirements that a separate application format for each is needed to allow the Centers for Medicare and Medicaid Services (CMS) (formerly HCFA) to determine compliance with requirements. The different requirements are listed below:

CMS 901-A
An organization may apply to enter into a Federal Qualification agreement with CMS only

if:

(1) A Prepaid Health Plan seeking federal qualification as a health maintenance organization (HMO) under the Title XIII of the Public Health Service Act. An applicant may request one or more regional components in its initial application.

Each regional component must provide substantially; the full range of basic health services and may establish a separate community rate for each component based on the different costs of providing health services; see 42 CFR 417.104(b) for a full definition.

(2) A Federally Qualified HMO seeking to expand its qualified service areas or to establish one or more additional regional components.

Please note that if the health plan is a separate legal entity, then it is the applicant. If the health plan is a line of business of a legal entity, then the legal entity is the applicant.

CMS 901-D

An organization may apply to enter into a Medicare Advantage Private Fee For Service (PFFS) agreement with CMS only if it is eligible as defined in the Balance Budget Act of 1997 '4002. Specifically PFFS is defined as being a Medicare Advantage plan that:

(1) Reimburses providers and suppliers on a fee for service basis without placing the provider or supplier at financial risk;
(2) Does not vary the payment rate based on the utilization relating to such a provider/supplier; and
(3) Does not restrict the selection of providers/suppliers among those who are lawfully authorized to provide the covered services and agree and agree to accept the terms and conditions established by the plan.

B. Justification

1. *Need and Legal Basis*

Prepaid health plans may be considered to be federally qualified if they meet federal criteria that include financial soundness, provision of medical services, quality assurance, managerial arrangements, disclosure to subscribers, and member protection. An entity seeking a contract as a Medicare Advantage organization must be able to provide the Medicare basic benefits plus meet the organizational requirements of the regulations. An applicant must demonstrate that it can meet the criteria within the specific geographic area it is requesting.

The application forms are designed to give federal staff the information they need about the health plan to determine compliance with federal regulations. Section 42 CFR 417.143 gives the application requirements for federal qualification; section 42 CFR 422.6 includes the application requirements for Medicare Advantage. These regulations mandate the application process that begins with submission of an application in the form and manner that the Secretary provides. The regulations are attached.

2. *How, by whom, and for what purpose the information is to be used. Actual use the agency has made of the information received from the current collection.*

A federal qualification application form has been in continuous use since 1974 to collect information from prepaid health plans requesting federal approval. It is used by federal staff to gain information about the applicant and enable a decision to be rendered. The information serves as a justification of CMS'determination to approve or not approve a request for federal qualification.

The Medicare Advantage application forms will be used by federal staff to determine whether to enter into a contract with such entities to provide services to Medicare beneficiaries.

3. *The use of technological collection techniques.*

The applications are in MS Word97. Essentially, for the Narrative Section of the form, the user fills in responses to questions and fills in the cells on formulated tables. The text is marked so that pagination is automatic and the user can generate a table of contents automatically. Tables that are to be inserted into the Documents part are on separate files. This technology greatly simplifies application preparation because the user neither retypes questions nor formulates table formats. Technological instructions are included in the beginning of the application.

4. *Efforts to identify duplication.*

Each application is unique to the prepaid health plan applying and CMS must evaluate all information related to regulatory requirements. Specific information about each HMO is not collected or available in any form other than this application form.

When a network of health plans, operated by one "parent" company, all use certain systems that are essentially the same; CMS does not require submission of the standard material by new applicants from that network. An applicant requesting an expansion of its approved service area also need not submit sections of the form if they are essentially the same as the earlier submission.

5. *Impact on small businesses or other small entities.*

Each HMO desiring Federal Qualification must complete the application as a one-time submission regardless of their business designation. There is no difference for small or larger businesses.

6. *Consequence if the collection is not conducted or is conducted less frequently.*

Not applicable. Each organization desiring federal qualification or an expansion, or a Medicare Advantage contract or expansion, must complete the application as a one-time submission.

7. *Special circumstances causing information collection to be conducted, as listed.*

The only circumstance that applies here is confidentiality; see B.10.below for response.

8. *Federal Register notice, if applicable.*

A 60 day Federal Register notice was published on January 26, 2007.

9. *Any payment or gift to respondents, other than remuneration of contractors or grantees.*

There are no gifts or payments from CMS to applicants.

10. *Assurance of confidentiality to respondents and the basis for the assurance.*

Subpart D (Application for Federal Qualification) at 42 CFR 417.143(h) and Subpart A (Application requirements for Medicare Advantage) at 42 CFR 422.6(e) state:

> "Disclosure *of the application information under the Freedom of Information Act.* An applicant submitting material that he or she believes is protected from disclosure under 5 U.S.C 552, the Freedom of Information Act, or because of exceptions provided in 45 CFR part 5, the Department's regulations providing exceptions to disclosure, should label the material "privileged" and include a concise explanation of the applicability of an exception described in 45 CFR Part 5."

The application forms require submission of financial information which is of a confidential nature. The data is necessary to evaluate the fiscal soundness of the applicant. Section 1301 of the Public Health Service Act and 42 CFR 417.120 require that HMOs demonstrate a fiscally sound operation and adequate provision against the risk of insolvency. Potential applicants are apprised of the regulations and the statutes relating to the Freedom of Information Act.

11. *Justification for any questions of a sensitive nature.*

No data is collected dealing with sensitive areas such as religious beliefs, sexual behavior, or other matters commonly of a private nature.

12. *Estimates of the hour burden of the collection of information*.

CMS 901-A

The respondent burden is estimated to be 40 hours per application. This estimate is based on consultations with applicants and consultants who work with prepaid health organizations.

CMS 901-D

The respondent burden is estimated to be 40 hours per application. This estimate is based on consultations with applicants and consultants who work with prepaid health organizations.

The total annual hours requested is an average of the two application types (CMS 901-A & CMS 901-D) calculated as follows; total hours per application 40 hours+ 40 hours= 80 hours, divided by 2 =40 hours; then multiplied that by 55 to give us a total of 2200 annual hours.

There is no annualized cost since an application is submitted only when the health plan requests approval as a federal qualified plan.

13. *Estimate of total annual cost burden to respondents from collection of information - (a) total capital and start-up cost; (b) total operation and maintenance.*

Not applicable. The entities that apply are ongoing health organizations that voluntarily elect to become federally qualified.

14. *Annualized cost to federal government*

The estimated cost for an average application review is $850.36 each application:

Plan Manager:	2 days @ 248/day x 40	$ 19,840
Specialty reviewers (in-house):	1 day @ 248/day x 40	9,920
Specialty reviewers (health services):	1 day @ 248/day x 40	9,920
Supervisory review:	0.25 day @ 303/day x 40	3,030
Support staff:	0.25 day @ 106/day x 40	1,060
Travel for site visits		3,000
Total		$46,770

Total cost to the government for 55 applications	55 @ $850.36=	$46,770
Net cost to government =		**$46,770**

15. *Program/Burden Changes*.

The decrease in burden is due to the revision of this collection to include only applications CMS 901-A and 901-D. CMS applications CMS 901-B and CMS 901-C approved under this collection OMB 0938-0470 are removed from this collection; due to a prior submission of these applications under OMB 0938-0935.

16. *Plans for publication*.

Not applicable. The application forms are used for determining compliance with regulations, not for data collection.

17. *Reasons for not displaying the OMB approval expiration date*

We are not seeking this exemption.

18. *Reasons for exception to certification statement*

There are no exceptions.