#2

HealthPartners

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OMB 0937

OMB Human Resources and Housing Branch
Attention: Carolyn Lovett
New Executive Office Building,
Room 10235
Washington, DC 20503

Re Part D Service Area Expansion Application
Medicare Advantage Master Application

Dear Ms. Lovett,

Attached, please find our comments regarding the proposed applications.

If you have any questions, please feel free to contact me at 952-967-5183.

Sincerely,

Tracy Pederson

Tracy Pederson
Senior Medicare Programs Coordinator
HealthPartners

Attachments: Medicare Advantage Master Applications Comment Document
Part D SAE Application Comment Document

First, We would like to commend CMS on the automation and streamlining of the application process.

Page	Section	Subject	Comment
		Overall	1. Will all users have access to the application module or will there be a separate process for requesting security for certain HPMS Users? 2. Will plans have an opportunity to view the application tool on HPMS and provide comments? 3. Will the application tool have a tracking page so we can see which elements or uploads are missing? 4. There should be sensitivity added to the yes/no answers in attestation boxes. 5. If we upload a document on HPMS on 3/1 and need to submit a revised version on 3/9, does that functionality exist?
10	10.3	Protecting Confidential Information	We used to define specific sections of our applications as confidential and proprietary in the cover letter that accompanied the application. How will this designation be made in an online (HPMS) submission?
12	1.2	Administrative Management	Number 10 – replace "executive manager" with "chief executive officer"
15	1.5	Compliance Plan	The instructions should specify that the provisions in application will be implemented by 01/01/09 unless specifically noted in individual attestations.
18	1.7.3.	Fiscal Soundness	We have a concern about the word "any" financial concerns. This is too broad. Need definitive language.
19	1.9.2, 3, 4	Provider Contracts & Agreements	N/A for PFFS. Plans use Terms and Conditions. Please provide allowance in attestations.
21	1.10.9	Contracts and Administration and Management Services	This statement specifies Part C. Does that mean the other statements apply to both Parts C and D? Please specify.
29	1.13.2.A.19	Enrollment, Disenrollment and Eligibility	Spelling error – "disembroils"
29	1.13.2.A.21	Same	How is this different than #1, #2 and #4?

29	1.13.3.2	Working Aged Membership	Please add limiting language, example "...to the extent we are aware of other coverage."
30	1.13.4	Claims	Please define prompt.
30	1.13.4.3	Claims	Please clarify "denial." Denial of what??
30	1.14	Minimum Enrollment	References refer to same section.
31	1.15	Communication between MA plan and CMS	Please clarify date action must be completed. We are assuming before January 1st.
35	1.20	Medicare Advantage Certification	Typically, the application is completed by staff not authorized to bind the organization. Will CMS separate this piece for officers? Will this be a printed document? Do officers need HPMS access?
40	3.1.B.	Access to Services	Is this for network plans only? PFFS plans do not have networks hence, no HSD tables.
45	1.2.2	State Licensure	Please remove "some type" language is too broad.
50	1.5	HSD	PFFS plans do not have a contracted provider network.
53	D.		Spelling error "are" should be "area"

MA/PD Employer Group Application

Page	Section	Name	Comment
3		Application Instructions	HPMS data is performed by staff not authorized to bind the organization through certifications or attestations. Does CMS have recommendations for this or do our executives need HPMS access?

Page	Section	Name	Comment
7	2.4	Instructions and Format of Qualifications	Please clarify if time given is EST or local time.
16	3.2.4	Licensure and Solvency	Regarding the "CMS-published financial solvency and capital adequacy requirements," Where are these posted? Can CMS provide link or statute?
16	3.2.5	Same	"some type" is too broad. Can language be "Corrective Action Plan and Special Monitorings"?
16	3.3	PFFS Pharmacy Access	A N/A column should be added given the nature of some questions.
17	3.4.1.3	Retail Pharmacy Access	Will the file "Medicare Beneficiaries by State, Region, Zip 09302006" be updated?
18	3.4.1.E.	Retail Pharmacy Access	Why is N/A needed here?
18	3.4.1.G. and H	Retail Convenient Access Standards	Please define – does this mean all scripts, scripts for our members only, not other plans, scripts for Part D and/or commercial? 2007 run out claims data may not be available in early March 2008.
20	3.4.3	Home Infusion Pharmacy	Please provide measure of "adequate access" Is there are statute, guidance that can be referenced?
20	3.4.4.A.5.	LTC Pharmacy Access	Please define "sufficient access"

COVENTRY
Health Care

#3

November 12, 2007

CMS-10137

Carolyn Lovett
OMB Human Resources and Housing Branch
New Executive Office Building, Room 10235
Washington, DC 20503

Dear Ms. Lovett:

I would like to thank the Centers for Medicare and Medicaid Services (CMS) for this opportunity to review and submit comments related to the draft of 2009 MA, MA-PD and PDP Applications. After reviewing CMS' revisions, we request the following clarifications to assist plans in completing the applications.

Section 3.6.A.8 page 43 of MA-PD application
Section 3.5.A.18 page 42 of PDP application
We suggest that CMS add the following clarification, after the requirement : "Applicant agrees to provide CMS with the 4 Rx data for all their enrollees as part of the enrollment transaction. The reports should verify that the Applicant's plan demonstrates the ability to have 4 Rx data in place for 95% of its prospective dual eligible enrollees." *For those cases in which the enrollee was auto assigned, facilitated, or otherwise a CMS generated enrollment., the 4Rx data would be submitted via a change transaction, after receiving the enrollment transaction from CMS.*

HSD table instructions in the 2009 MA Application (starting page 107 of MA application)
We requests clarification for three of the elements in the HSD tables:

- HSD-1, Medicare Provider Breakdown-Nos. 2 & 3 on the table instructions. The table requires a breakdown of physicians by specialty into physicians who are 'Direct with MAO' and 'Downstream Arrangement'. We are requesting clarification as to whether the term 'Direct with MAO' would include only single, directly contracted providers (i.e. a one-to-one agreement between the MAO and physician) or if it would also include a contract between the MAO and a physician practice where the providers did not sign individual agreements, but are signatories to a group agreement.

- HSD-2, Medical Group Affiliation, No. 12 on the table instructions. The instructions state that "For example, if you have a provider with a direct contract that is affiliated with a 'XYZ' medical group/IPA you must input 'DC' in column number 3 and the name of 'XYZ' medical group/IPA in column 16". There is no 'DC' in the Contract Type instructions under No. 3. We request that CMS clarify if this means 'D' for direct since that is how it is designated elsewhere on the table.

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- HSD-2, Employment Status, No. 13 on the table instructions. The instructions state to "Indicate whether the provider is an employee of a medical group/IPA or whether a downstream contract is in place for that provider. Insert 'E' if the provider is an employee. Insert 'DC' if a downstream contract is in place for the provider." We are asking for clarification in the event that this is not a mutually exclusive arrangement. There may be instances in which an employee of a medical group is still in a downstream relationship to the MAO. Is this element asking whether the physician is an employee of or has a downstream contract with *their* medical group/IPA? Please clarify how the physician should be listed if they are both an employee of the medical group/IPA and delegated with the MAO.

Again, thank you for the opportunity to provide input into the 2009 application process. We appreciate all of the work that CMS put into these documents. And we look forward to our continued partnership with CMS.

Sincerely,

Cheryl A. Powell
Director, Policy and Compliance

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Health Care

(4)

CVS CAREMARK

CMS-10137

November 12, 2007

Kerry Weems
Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health & Human Services
Attn: CMS-10137
7500 Security Boulevard
Mail Stop: C4-26-05
Baltimore, MD 21244-1850

Re: Comments on Draft 2009 Part C Medicare Advantage, Draft 2009 Part D, and the Employer/Union-Only Group Waiver Plan (EGWP) Applications

Dear Mr. Weems:

CVS Caremark is the largest provider of prescriptions and related healthcare services in the nation. The Company fills or manages more than one billion prescriptions annually. It operates 6,200 CVS/pharmacy stores; a pharmacy benefit management, mail pharmacy and specialty pharmacy division, Caremark Pharmacy Services; its retail-based health clinic subsidiary, MinuteClinic; and its online pharmacy, CVS.com. SilverScript Insurance Company, a national Part D Sponsor, and SilverScript, Inc., a Part D pharmacy benefit management company (PBM), are both affiliates of Caremark.

SilverScript Insurance Company (SSIC) is one of only 10 national PDPs servicing the Part D market. We have united with distribution partners, including health plans and Medicare Supplement providers, in the sales of our products nationwide. We bring substantial prescription drug benefit management experience through operating our own PDP (SSIC) as well as through our affiliate SilverScript, Inc. (SSI), a PBM offering prescription drug management services to Part D plans. SSI supports over 30 of our health plan clients, which have a combined membership of 2 million lives in Medicare Advantage and PDP programs.

1. Section 2.8.1 Retail Pharmacy Access

We believe that this is an area where CMS can significantly reduce the administrative burden on plans and itself by setting up a process to allow subcontractors that establish and manage the retail pharmacy network on behalf of multiple Part D applicants to submit one set of access reports on behalf of all their Part D applicant clients. Since most

Part D applicants in a given service area that use the same PBM subcontractor also use the identical pharmacy networks, the identical reports will be generated multiple times for multiple Part D applicants by the subcontractor. Currently, it takes SilverScript approximately 1800 man-hours to prepare access reports for its Part D clients' annual application process. This time commitment could be significantly reduced if it were not necessary to run a separate geo-access report for each client that utilizes the SilverScript network.

In light of this enormous expenditure of resources to submit essentially duplicative reports, we urge CMS to consider a more streamlined approach to submitting the geo-access reports on behalf of multiple Part D sponsors. This would greatly reduce the administrative burden and the time and effort associated with this application requirement – from about 1800 hours annually to less than 100 hours. Specifically, we recommend that a certification process be established such that a subcontractor may submit its access report to CMS once on behalf of all its Part D applicant clients. While we understand that the current access reporting requirements are specific to an applicant's proposed service area, a subcontractor could submit a national geo-access report or, at least, a geo-access report covering all the service areas of its various Part D applicants, broken down to the county level if need be to address local plans. Adopting this approach will satisfy the CMS concern that retail pharmacy access be reviewed and monitored, but will make the information reporting and review process much more efficient by eliminating duplicative reports and redundant administrative work inherent in the current process, and will accomplish the same outcome at far less cost to all concerned.

Recommendation: Develop a process to allow a subcontractor to submit one set of retail pharmacy access reports for all Part D sponsor applicants that will use its retail pharmacy network. This report can cover all relevant service areas and be broken down to the county level where required.

2. Section 3.9 and 3.21 – Coverage Determinations and Paper Claims

We are concerned that the references in Section 3.9 to the time frames for standard coverage determinations does not address or take into account the standard time frame for processing paper claims, as stated in Section 3.21. While we understand that Section 3.21 can be interpreted to refer only to those paper claims received from non-network pharmacies, and that Chapter 18 of the Part D Manual has been interpreted to require that beneficiaries be notified of the plan's determination on a paper claim submission within 72-hours, we believe that such an interpretation would be inconsistent with CMS' intent as stated in the preamble, the realities of paper claims processing, and existing industry standards. Each of these issues is discussed in greater detail below.

First, limiting the language in Section 3.21 of the Application to only those paper claims submitted by non-network pharmacies is inconsistent with the realities of paper claims processing. The time and process to make a determination on a paper claim is the same whether the claim is submitted by a non-network pharmacy or a beneficiary, and requires a full adjudication of the claim. Unlike POS electronic claims, paper claims are typically submitted by the beneficiary, either because they paid cash at a network pharmacy for

some reason or because they went to an out-of-network pharmacy. Although it is possible for non-network pharmacies to submit paper claims directly to us (using a Universal Claim Form), this is very rare, and most non-network claims are submitted by the beneficiary. These claims are adjudicated manually by clerical staff using the identical plan design criteria as the automated process, with no additional discretion or judgment.

Thus, it is not possible to notify an enrollee whether his/her claim will be paid without first fully adjudicating the claim. A full adjudication involves at least the following steps, each of which must be done manually in the case of a paper claim: processing and sorting of all inbound mail, handwritten data keyed from the claim form, run a system adjudication process run for eligibility and drug coverage editing, obtain incomplete data (such as looking up the NDC number if only the drug name is provided), among several other tasks that must be completed before a decision can be reached as to whether the claim will be paid or denied.

In light of the fact that the processing time for a claim depends not on who submitted it, but whether it is submitted by paper vs. electronically, there is no rational basis for interpreting the 15/30 day timeframe specified in Section 3.21 of the Application to only those submitted by a non-network pharmacy. From a plan's perspective, the sender is irrelevant in terms of the steps and time required to process a paper claim. While we understand that in the case of beneficiary-submitted claim the beneficiary is out-of-pocket as opposed to the pharmacy, even under the 72-hour turnaround time frame, actual payment to the beneficiary is only required to be made within 30 days. So the beneficiary does not receive reimbursement any quicker, whether the plan is required to process the claim within the 72-hour time frame or 15 to 30-day timeframe. Thus, we read the reference to non-network pharmacies in Section 3.21 as simply a reflection of CMS' assumption that this was the most likely circumstance in which paper claims would be received by a plan. But a paper claim is a paper claim for processing purposes, and the overall processing time doesn't change based on who sends it in. Indeed, from a health care industry perspective, it would be quite unprecedented to require that a paper claim be processed in 72 hours.

Second, the stated purpose and intent behind the 72-hour determination time frame, namely to protect beneficiaries who had not yet obtained their medications from suffering serious adverse effects, does not apply in the case of paper claims, since the beneficiary has in every case already obtained the medication. In the preamble, CMS explained the rationale behind the 72-hour time frame as follows:

There is too much risk for an enrollee's health if determinations are not made sooner than 14 days from the date the request is received, since an enrollee often will not be able to pay out-of-pocket for a prescribed medication and thus must forgo necessary therapy until a determination is made. . . . Clearly, Part D enrollees are likely to suffer significant adverse consequences if medications are not received quickly.

This rationale simply does not apply to paper claims, where the enrollee has always already obtained the drug, and is simply seeking reimbursement. In providing for the 15 and 30-day turnaround time for paper claims from non- network pharmacies, CMS, like DOL, recognized that paper claims take considerably more time to process than do POS claims, and do not warrant the tighter time frames required when the beneficiary is awaiting the medication.

Finally, a 72-hour timeframe for processing paper claims would be unprecedented in the health care industry, and inconsistent with the paper claims processing times required by DOL and the FEHP program, both of which are viewed as models for Part D. In the preamble, CMS references with approval the approach to coverage determinations in the Department of Labor (DOL) claim procedure regulation for ERISA plans under 29 CFR 2560.503-1. In the ERISA claims procedure, however, the DOL clearly distinguished between claims for urgent care, pre-service and post-service claims. For post-service claims (i.e. claims where the service has already been received and that are thus not awaiting plan approval), the regulation states that the time frame is 30 days, with the option to extend it for up to 15 days . The DOL clearly recognized that expedited time frames are not warranted once the care or service has already been provided and it is simply a matter of reimbursement. Beneficiary - submitted paper claims clearly fall into this category.

Similarly, paper claims submitted by beneficiaries under various state and government plans are generally required to be adjudicated within 30 days. Thus, changes in processes and staffing in order to perform this extremely manual process within a 72 "real time" hours for Part D claims would require an enormous and unprecedented ramp up in resources at a significant cost to the program, and in a situation where there would be little practical benefit or impact to the beneficiary - namely, simply knowing payment status but not receiving payment.

Recommendation : Clarify that the time frames for standard coverage determinations applies only to requests for drugs that have not yet been dispensed as well as requests for payment made after and in response to a paper claim adjudication, and that the time frame for an initial paper claim adjudication is the 15/30-day time frame set forth in Section 3.21, regardless of the party that submits the paper claim.

3. **Section 3.18.B and Appendix XI – Data Use Agreement**

Part D sponsor applicants and existing Part D sponsors, are required to sign a data use agreement that limits their use of data (and that of their subcontractors and related parties) obtained from CMS information systems to those "directly related to the administration of the Medicare benefits". We are concerned that this would restrict Part D sponsors not only from improper uses of PHI, such as to support other lines of business, but also from legitimate and entirely proper uses of PHI that are expressly permitted by HIPAA, and indeed, in many cases mandated by other laws. For example, if a Part D sponsor is named in a lawsuit or a government investigation by a government

agency other than CMS, it may be required to maintain information obtained from CMS' systems for these purposes, even though these purposes do not relate to administration of the Part D benefit. Similarly, a subcontractor may be required to provide access to this data to its auditors for financial reporting purposes, even though this is not directly related to the administration of the Part D benefit. There are many other legitimate uses and disclosures (e.g. to law enforcement) that do not fall within the very narrow confines of the data use agreement, and that are permitted under the HIPAA Privacy Rule and that should similarly be permitted here.

While we understand that CMS intends this agreement to apply only to that information obtained from its information systems, as a practical matter it will be extremely difficult for Part D sponsors to (i) determine which data is uniquely obtained from a CMS information system, and (ii) isolate this information from other information it maintains about beneficiaries. In light of this, we urge CMS to add language to the data use agreement making clear that Part Sponsors may use the information as otherwise required by law and, in the case of Protected Health Information, as otherwise permitted by HIPAA.

Recommendation: Revise the data use agreement to allow the use and disclosure of CMS data as otherwise required by law and, for data that also constitutes PHI, to those uses and disclosures permitted by the HIPAA Privacy Rule and 42 CFR 423.136.

We appreciate the opportunity to provide these comments. If you have any questions or would like discuss our comments, please do not hesitate to contact me at 202-772-3501.

Sincerely,

Russell C. Ring
Sr. Vice President
Government Affairs