CENTERS FOR MEDICARE AND MEDICAID SERVICES
HEARING OFFICER DECISION

IN THE MATTER OF:

Harvard Pilgrim Health Care, Inc. (HPHC)	*	
	*	
Denial of Service Area Expansion Application	*	DOCKET NOS.
Medicare Advantage/Prescription Drug Plan Organization	*	2014 MA/PD APP. 6 (H1660)
	*	& APP. 7 (H6750)
Contract Year 2015, Contract Nos. H1660 and H6750	*	

ORDER GRANTING SUMMARY JUDGMENT

I. JURISDICTION

The Medicare Advantage (MA or Part C) program offers Medicare beneficiaries the option of receiving health care benefits through a privately-operated coordinated care delivery system.[1] The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 made changes to MA and allowed beneficiaries to elect a voluntary outpatient prescription drug benefit within a Part C plan.[2] Plans offering both the Part C and Part D benefits are known as Medicare Advantage-Prescription Drug (MA-PD) plans. Organizations that are approved to offer MA-PD benefits are required to maintain a provider network that ensures "adequate access to covered services" for plan enrollees in each operative service area.[3] Each organization's network must include a variety of providers, including primary care physicians, specialists, and hospitals,[4] and must offer an outpatient prescription drug benefit in the service areas in which it offers a Part C benefit.[5]

The Secretary of the United States Department of Health & Human Services (the Secretary) is authorized to contract with entities seeking to offer MA and MA-PD benefits.[6] Through regulation, the Secretary has delegated this contracting authority to the Centers for Medicare and Medicaid Services (CMS), which has established the general provisions for entities seeking to qualify as MA-PD plans.[7]

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[1] *See* 42 U.S.C. § 1395w-21 *et seq.*
[2] *See, generally,* Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Public Law 108-173, Sec. 231 (codified at 42 U.S.C. § 1395w-28(b)(6)).
[3] 42 C.F.R. § 422.112(a).
[4] 42 C.F.R. § 422.112(a)(1).
[5] 42 C.F.R. § 422.4(c)(1). *See also, generally,* 42 U.S.C. § 1395w-112 (Medicare Part D).
[6] 42 U.S.C. § 1395w-27.
[7] 42 C.F.R. §§ 422.400 *et seq.*, 422.503(b) *et seq.* 42 C.F.R. § 422.502(a). The analogous provision for Part C and Part D appear at 42 C.F.R. Parts 422 and 423 respectively. Throughout this Order, unless otherwise indicated, references to regulations governing Part C should be read to include the analogous regulations for Part D.

If CMS denies a MA-PD application, the applicant organization is entitled to a hearing before a CMS Hearing Officer.[8] The regulation at 42 C.F.R. § 422.660(b)(1) dictates that "the applicant has the burden of proving by a preponderance of the evidence that CMS' determination was inconsistent with the requirements of [42 C.F.R. §§ 422.501-502 and 423.502-503]."[9] The regulations governing the hearing process provide that either party may ask the Hearing Officer to rule on a motion for summary judgment.[10] In exercising his or her authority, the CMS Hearing Officer must comply with the provisions of Title XVIII and related provisions of the Social Security Act, regulations issued by the Secretary, and general instructions issued by CMS in implementing the Act.[11]

II. FACTUAL AND PROCEDURAL BACKGROUND

HPHC represents that it has a history of 30 years of Medicare managed care initiatives, as well as various MA and PD products and contracts between 1998 and 2010.[12] HPHC entered into a contract with CMS to provide Part C and Part D services in Massachusetts, New Hampshire, and Maine effective January 1, 2014. In November 2013, HPHC submitted a Notice of Intent to Apply for a service area expansion (SAE) for contract year 2015 under its MA-PD contracts,

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[8] 42 C.F.R. § 422.660.

[9] The regulations at 42 C.F.R. §§ 422.501-502 and 423.502-503 establish the contract application requirements and review procedures.

[10] 42 C.F.R. §§ 422.684 and 423.662. *See also* Medicare Program; Revisions to the Medicare Advantage and Part D Prescription Drug Contract Determinations, Appeals, and Intermediate Sanctions Processes, 72 Fed. Reg. 68700, 68714 (Dec. 5, 2007) (Preamble to final rule stating, "In ruling on such a [Summary Judgment] motion, we propose that the hearing officer would be bound by the CMS regulations and general instructions. Where no factual dispute exists, the hearing officer may make a decision on the papers, without the need for a hearing.").

[11] 42 C.F.R. § 422.688.

[12] HPHC Appeal Brief at 2, 4. HPHC indicates that it:

> [I]s a not-for-profit health plan founded under the name of Harvard Community Health Plan in affiliation with professors at Harvard Medical School. It is one of the oldest serving Medicare managed care plans. *See* Exhibits 15 and 16. Through the years it has demonstrated consistently sound compliance in federal managed care programs and has been acknowledged for exemplary consumer satisfaction and quality of care across its products. For example, in 2014, HPHC's commercial plans were named by NCQA for the tenth year in a row as the nation's #1private health plan in its annual health insurance rankings. *See* NCQA Private Health Plan Rankings 2013-2014, Exhibit 17. . . .
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> - From 1986 through 1998, HPHC and its affiliates offered Medicare risk products in Massachusetts and subsequently in New Hampshire (Contract Nos. H2204 and H2206).
> - From 1998 through 2006, HPHC and its affiliates held contracts with CMS to offer HMO Medicare+ Choice Plans (becoming MA-PD Plans) to Massachusetts and New Hampshire members under the aforementioned contracts.
> - From 2007 through 2010, HPHC offered a Private Fee-for-Service ("PFFS") MA-PD plan in Massachusetts, New Hampshire and Maine under Contract No. H7226.
> - HPHC voluntarily non-renewed its PFFS plan at the end of 2010 due to statutory changes that would have required it to establish a nationwide provider network – including outside of the three states in which it operates. Soon thereafter HPHC began to explore options for reentering the MA coordinated care market, and in 2012 submitted its notice of intent to CMS to participate in the MA-PD program.
> - In 2013, HPHC applied and was approved for two coordinated care plans for 2014 under Contract Nos. H1660 and H6750. H1660 covers the counties of Suffolk, Norfolk, Bristol, and Worcester in Massachusetts and York and Cumberland in Maine; H6750 covers the counties of Rockingham, Hillsborough, and Merrimack in New Hampshire.

H1660 and H6750. In February 2014, HPHC submitted Part C and Part D SAE applications for additional counties in all three states.[13]

In its application, HPHC attested "No" in response to the criterion: "The Medicare Advantage plan(s) currently offered by the Applicant, Applicant's parent organization, or subsidiary of the Applicant's parent organization has been operational since January 1, 2013 or earlier.[14]

On May 28, 2014,[15] CMS issued contract denial notices for H1660 and H6750 which indicated that:

> "You attested that your organization, currently offering a Medicare Advantage product, does not have at least 14 months of performance history with the Medicare Advantage program as of the application due date. Therefore you are not eligible to apply for a new Medicare Advantage product of service area expansion at this time."

HPHC filed a timely appeal pursuant to 42 C.F.R. §§ 422.660 and 423.650. By agreement of the parties, the two appeals captioned above are being adjudicated concurrently. After HPHC filed its initial brief, CMS filed a Motion for Summary Judgment and HPHC filed a subsequent Cross-Motion for Summary Judgment pursuant to 42 C.F.R. § 422.684(b). Both parties represented there is no dispute of material facts.[16]

III. ISSUE

Although CMS did not dispute the facts that HPHC presented, the parties do not agree regarding the application of the facts to the regulatory authority. The sole legal issue is whether HPHC has proven that CMS' denial of service area expansion applications for Contract Year 2015 on the grounds that the applicant lacked the requisite performance history was inconsistent with regulatory requirements.[17]

IV. PAST CONTRACT PERFORMANCE – LEGAL AUTHORITIES

A. Background

As part of its assessment of a plan's qualifications, CMS considers the applicant's performance under a current or prior contract during the 14 months preceding the submission of the pending application. CMS may deny an application based on the applicant's failure to comply with a Part C requirement during this period. CMS may rely on this basis even if the applicant demonstrates

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[13] CMS Reply Brief & Motion for Summary Judgment at 4 [hereinafter CMS Motion for Summary Judgment]. HPHC indicates that there are no MA coordinated care plan options in the New Hampshire counties HPHC Initial Brief at 3.

[14] HPHC Initial Brief, Exhibit 13 at 1 (showing the MA Attestations). *See also* HPHC Initial Brief, Exhibit 14 at 1 (showing the Part D Attestations).

[15] HPHC Exhibits 9 and 10.

[16] CMS Motion for Summary Judgment at 9, HPHC Motion for Summary Judgment at 1.

[17] CMS Motion for Summary Judgment at 4. Moreover, CMS concedes that HPHC 's applications otherwise demonstrated that it met all other Part C and Part D application requirements. *Id.* at 3.

through its submitted application that it otherwise meets all of the requirements for qualification as a contractor.

B. Rulemaking History - Federal Register

Prior to 2010, the regulations provided that CMS consider an applicant's past performance in a "previous year's contract"[18] or prior contract[19] when determining whether to approve an application for a new or expanded contract. In 2009, CMS published a Proposed Rule which introduced the 14-month look-back provision.[20] The proposed rule stated at 74 Fed. Reg. 54,634, 54,642 (Oct. 22, 2009):

> We also propose to clarify that the period that will be examined for past performance problems be limited to those identified by us during the 14 months *prior to the date* by which organizations must submit contract qualification applications to CMS (emphasis added).

The corresponding final rule at 75 Fed. Reg 19,678, 19,685 (Apr. 15, 2010) added:

> The purpose of the past performance review is to determine whether the sponsor has demonstrated, over a 14-month period, whether it has operated its Part C or D contract in a manner that suggests that it is generally meeting and capable of meeting program requirements and that new Medicare business would not jeopardize that status.
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> . . . We believe that the 14 month look-back provides an adequate amount of time for us to review an MA organization's or Part D sponsor's performance and the choice of 14 months as the look-back period was not arbitrary. As we noted previously, and in the proposed rule, *14 months covers the period spanning the start of the contract year to the time we receive applications for the following contact year*. To shorten that time period to, say, 12 months would leave a gap in our past performance review. Similarly, limiting the period to the 14-month timeframe gives sponsors and organizations the opportunity and incentive to promptly *establish a positive compliance track record* so that the next CMS past performance review will find them eligible for additional Part C or Part D business (emphasis added).

In 2011, CMS' past performance review was further refined when it added additional language at §§ 422.502(b)(2) and 422.503(b)(2) addressing situations in which applicants do not have 14 months of performance history. In the Final Rule at 76 Fed. Reg. 21,432–21,524 (Apr. 15, 2011),[21] CMS explained

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[18] 42 C.F.R. § 423.503(b) (2009).

[19] 42 C.F.R. § 422.502(b) (2009).

[20] The 14 month look-back provision was originally codified in a modified 42 C.F.R. § 422.502(b) and has been recodified to the current 42 C.F.R. § 422.502(b)(1) pursuant to the final rule at 76 Fed. Reg. 21,432, 21,524 (Apr. 15, 2011).

[21] *See also* corresponding Proposed Rule at 75 Fed. Reg. 71,190, 71241 (Nov. 22, 2010) which states: "At this time, we are proposing to further refine our intended approach to using past performance in making application

In the absence of 14 months of performance . . . this leaves a gap whereby CMS must either assume full compliance and exempt the entity from the past performance review, or deny additional applications from such entities until the applicant has accumulated 14 months' experience, during which it complied fully with the requirements of the Part C and/or Part D program.

Our interest in protecting Medicare beneficiaries and limiting program participants to the best performing organizations possible strongly suggests that *we take the latter approach.* Our justification for proposing this change was two-fold. First, we would ensure that new entrants to the Part C or Part D program could fully manage their current contracts and books of business before further expanding. Second, this change would require that entities rightfully focus their attention on launching their new Medicare contracts in a compliant and responsible manner, rather than focusing attention almost immediately on further expansions.

C. Regulatory Text

The text of the controlling regulation at 42 C.F.R. §422.502 discussed above reads, in pertinent part:

(b) *Use of information from a current or prior contract.*

(1) Except as provided in paragraphs (b)(2) through (b)(4) of this section, if an MA organization fails during the 14 months *preceding* the deadline established by CMS for the submission of contract qualification applications to comply with the requirements of the Part C program under any current or prior contract with CMS under title XVIII of the Act or fails to complete a corrective action plan during the 14 months preceding the deadline established by CMS for the submission of contract qualification applications, CMS may deny an application based on the applicant's failure to comply with the requirements of the Part C program under any current or prior contract with CMS even if the applicant currently meets all of the requirements of this part.

(2) In the absence of 14 months of performance history, CMS may deny an application based on a lack of information available to determine an applicant's capacity to comply with the requirements of the MA program.[22]

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determinations. Specifically, we are concerned about entities submitting applications to us where the entity has operated its contract(s) with us for less than 14 months at the time it submits a new application or service area expansion request. Practically speaking, an entity contracting with us for the first time would merely have 2 months experience before applications would be due for the following contract year. Two months is an inadequate amount of time for the entity to demonstrate its ability to comply with all Part C and/or Part D requirements."

[22] 42 C.F.R. § 422.502(b) (emphasis added).

D. 2015 Application Cycle – Subregulatory Authority

On January 15, 2014, CMS released its 2015 Application Cycle Past Performance Review Methodology Update. The Performance Review Methodology addressed the impact of the 14 month performance requirement on applicants during the 2014 application cycle:

> CMS clarified in its April 15, 2010 final Part C and D regulations that we limit out performance review each year to the 14-month period leading up the annual application submission deadline. . . . The specific 14-month performance period that will be assessed for the 2015 Application Review Cycle is January 1, 2013 through February 28, 2014. . . .
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> . . . In April 2011, CMS published new regulations stating that in the absence of 14 months' performance history we may deny an application based on a lack of information available to determine an applicant's capacity to comply with the requirements of the Part C or Part D programs. (§ 422.502(b)(2) and § 423.503(b)(2)) Therefore, *during the 2015 Application Cycle, organizations that commence their Part C and/or Part D operations in 2014 will not be permitted to expand their service areas or product types until they have accumulated at least 14 months of performance experience*, which can then be evaluated under this methodology.[23]

V. CONTENTIONS

A. CMS Contentions

CMS asserts that HPHC cannot prove by a preponderance of the evidence that the denial was inconsistent with the requirements that govern the Part C and Part D application processes. CMS denied the applications because HPHC did not hold its Medicare contract for the fourteen months preceding the February 2014 application deadline. CMS disagrees with HPHC's contention that its pre-2011 MA contracts should be considered under the 14-month look-back period. In part, CMS adopted 42 C.F.R. § 422.502(b)(1) to establish that the period of past performance review for MA contract applicants is the 14 months "preceding" the deadline As it is clear from the preamble discussion, CMS adopted § 422.502(b)(2) as an enhancement to § 422.502(b)(1), to specifically to address how it would treat those organizations whose Medicare contract performance was of a duration of less than the 14 months preceding the application deadline. Therefore, the reference in 42 C.F.R. § 422.502(b)(2) to "the absence of 14 months of performance history" is to the same performance period stated in § 422.502(b)(1); that is, the particular 14 months preceding the application submission deadline. There is nothing in the preamble to indicate that in adopting § 422.502(b)(2) CMS intended to create a completely new performance timeframe.

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[23] CMS Exhibit A at 6 (emphasis added) (internal citations omitted).

Reading 42 C.F.R. § 422.502(b)(2) as a stand-alone provision, isolated from § 422.502(b)(1), would potentially lead to "absurd" results. Under this approach, an organization with a new contract that held another MA contract at any time in the past, no matter how "stale" that past performance might be, could be permitted to take on new Medicare business almost immediately after starting the administration of its newest Medicare contract.[24] This would be problematic, particularly in light of the effort CMS has made establishing, through the adoption of § 422.502(b)(1), that only an MA organization's most recent contract performance is relevant within an assessment. Finally, CMS Past Performance Review methodology makes clear that the look-back period refers to the 14 month preceding the application and specifies that the "14-month performance period that will be assessed for the 2015 Application Review Cycle is January 1, 2013 through February 28, 2014."[25]

Likewise, CMS wishes to ensure that new entrants to the Part C or Part D program can fully manage their current contracts and books of business before expanding. Given HPHC's three-year-absence from the Medicare program, CMS states that it is in the Medicare program's best interest for HPHC to focus on what are essentially new Medicare operations before taking on additional Medicare business.

Moreover, CMS provided other policy justifications related to fairness for declining to use its discretion. For example, granting HPHC the opportunity for consideration of its pre-2011 performance could grant it an advantage relative to its competitors in the MA market. There is also a question of relevance (e.g., change in staff, systems, new regulatory and CMS program requirements) regarding HPHC's performance from at least three years ago to assess quality of its performance under an MA contract today.

B. HPHC Contentions

HPHC contends that CMS' denial is inconsistent with the factual record, regulations and guidance. First, HPHC possesses extensive experience with MA and Part D products and contracts from 1998 through 2010 (and it states there is no dispute about HPHC's positive performance history). HPHC considers 42 C.F.R. § 422.502(b)(2) to be inapplicable. The regulation provides that "[i]n the absence of 14 months of performance history, CMS may deny an application based on a lack of information available to determine an applicant's capacity to comply with the requirements of the MA program" is inapplicable. That subsection, which provides discretion to CMS, does not specify the 14-months of immediately preceding performance history.

The present situation is entirely unlike that for which 42 C.F.R. § 422.502(b)(2) was designed. HPHC asserts that this provision applies when the applicant has never participated in the MA and Part D programs and there is no track record that CMS could evaluate. The regulation was promulgated to ensure that "new entrants to the Part C or Part D program could fully manage their current contracts and books of business before further expanding."[26] CMS stated in the

[24] CMS Motion for Summary Judgment at 6.
[25] CMS Exhibit A at 6.
[26] HPHC Reply Brief at 2 (citing 76 Fed. Reg. 21,432, 21,524 (Apr. 15, 2011)).

2015 Application Cycle Past Performance Review Methodology Update that § 422.502(b)(2) applies to "organizations that commence their Part C and/or Part D operations in 2014."

Second, even if the regulation were to be construed to include the phrase "immediately preceding 14 months," it does not automatically make an applicant "not eligible" as the denial notice stated. Rather, the regulation text provides authority for CMS to exercise discretion to deny "based on a lack of information."[27] When an MA Organization has prior experience, CMS has the responsibility to make a reasoned judgment regarding the organization's capacity to comply with the requirements of the program. CMS's sub-regulatory position that it will not permit, under any circumstance, an organization that commenced Part C operations in 2014 to expand until it has accumulated 14 months of prior performance experience contradicts 42 C.F.R. § 422.502(b)(2).

HPHC's position would not bind the government to approve all applications for any entity with prior participation, no matter how long ago, as CMS suggests. HPHC participated in the Medicare Advantage program through contract year 2010, and re-entered for contract year 2014; an absence of just three contract years. Furthermore, in 2011 and 2012, it was still fulfilling obligations related to its 2010 contract (such as submission of reports, reconciliations, claims adjudication, and appeals). Also in 2011, it began preparing itself to renter the MA market. By 2013, it prepared and submitted its application to re-enter the program. These activities assured that HPHC remained knowledgeable of CMS requirements in order to begin operations in 2013 for the 2014 contract year.

HPHC's long history of successfully navigating and complying with significant changes to Medicare programs, using the same key staff, is strongly predictive of future compliance capacity. For new entrants, that immediately preceding history is all that is available; but for entities with a prior history, there is significant – and better – information available to determine their capacity to comply.[28] HPHC has also retained the same pharmacy benefit manager which provided prescription drug coverage for HPHC's prior Part D plans.

Denying applications of MA plans with established records of strong compliance and performance is inconsistent with Medicare's policy goal to provide beneficiaries the ability to choose the high-quality insurance product that best meets their needs. Notably, in the instance of H6750, CMS' determination may result in beneficiaries in Cheshire and Sullivan counties in New Hampshire having no available MA coordination of care products for 2015. CMS' denials impair Medicare beneficiaries across such counties from being able to appropriately weigh plans that have superior consumer satisfaction and quality when making critical healthcare decisions.

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[27] 42 C.F.R. § 422.502(b)(2).

[28] HPHC Motion for Summary Judgment at 4–5. HPHC outlined a number of individuals' extensive MA experience. Their collective experience is reflected in the lack of any issues identified by CMS during HPHC's rollout of its MA-PD Plan including marketing enrollment, premium collection, appeals and coverage determination. Some of the identified positions include:

Senior Vice President in Government Affairs and Programs (15 years of experience) oversight of HPHC's Deputy General Counsel (30 years), Senior Product Portfolio Manager (10 years), Medicare Compliance Officer (8 years), Director of Policy and Compliance for Appeals Grievances (12 years);Vice President and Controller in Financial Operations (10 years) Manager in Provider Accounting (10 years)Business Operations Manager (8 years); Vice President, (17 years) Director of Care Management (6 years); Product Manager in Pharmacy Operations (14 years).

VI. CONCLUSION

Applicants are required to prove, by a preponderance of the evidence, that CMS' denial of an application was inconsistent with applicable regulatory requirements.[29] Pursuant to 42 C.F.R. § 422.684 and the implementing Proposed Rule at 72 Fed. Reg. 68,700, 68,714 (Dec. 5, 2007), where no factual dispute exists, the Hearing Officer may grant a motion for summary judgment on the papers, without holding a hearing. Also, 42 C.F.R. § 422.688 states that in exercising his or her authority, the CMS Hearing Officer must comply with the Social Security Act, regulations, and general instructions issued by CMS.[30]

Both parties represent that there are no material factual disputes between CMS and HPHC. At its core, the issue in dispute is whether CMS properly denied the service area expansions on the basis that the applicant did not operate throughout the entire 14 months (January 1, 2013 through February 28, 2014) prior to the annual application submission deadline.[31]

The Hearing Officer finds that HPHC cannot prove by a preponderance of the evidence that the denial was inconsistent with the requirements governing the Parts C and D application process. As is clear from the preamble discussion, CMS adopted 42 C.F.R § 422.502(b)(2) to enhance § 422.502(b)(1) in order to specifically to address how it would treat those organizations whose Medicare contract performance was of a duration of less than the 14 months preceding the application deadline. Therefore the Hearing Officer agrees with CMS that the reference in § 422.502(b)(2) to "the absence of 14 months of performance history" can be most reasonably read to encompass the same performance period stated in § 422.502(b)(1); that is, the particular 14 months preceding the application submission deadline. Nothing in the regulation envisions consideration of routine, post-contract activities (e.g., reconciliations or claims adjudications) to count toward the 14-month look-back period. Moreover, there is nothing in the Preamble which indicates that CMS intended to create a completely new performance timeframe in § 422.502(b)(2), other than the 14 months preceding the application deadline.

Finally, general instructions, such as the 2015 Application Cycle Past Performance Review Methodology Update, are controlling in this proceeding pursuant to 42 C.F.R. § 422.688. These instructions expressly state that the look-back period refers to the 14 month preceding the application and specifies that the "14 month performance period that will be assessed for the 2015 Application Review Cycle is January 1, 2013 through February 28, 2014."

Finally, from a policy standpoint, CMS explains it wishes to ensure that new entrants to the Part C or Part D program can fully manage their current contracts and books of business before expanding. Notwithstanding HPHC's prior history with the Medicare program, given HPHC's recent absence from the Medicare program, CMS states that it is in the Medicare program's best interest for HPHC to focus on its essentially new Medicare operations before further expanding

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[29] 42 C.F.R. §§ 422.660 and 423.650.

[30] The preamble at 72 Fed. Reg. 68,700, 68,714 (Dec. 5, 2007) also notes that the Hearing Officer is bound by CMS regulations and general instructions in ruling on a motion for summary judgment.

[31] CMS Motion for Summary Judgment at 4. Moreover, CMS concedes that HPHC's applications otherwise demonstrated that it met all other Part C and Part D application requirements

its service area. CMS' position is reasonable and consistent with the controlling regulation text, preamble discussions, and CMS' general instructions.

The Hearing Officer finds that HPHC has not established that CMS' denial of service area expansion applications is inconsistent with regulatory requirements. CMS' Motion for Summary Judgment is granted.

Benjamin R. Cohen, Esq.
CMS Hearing Officer

July 17, 2014