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VIA ELECTRONIC MAIL & FACSIMILE (410-740-0818)

SEP 19 2013

Eric R. Wagner, President
MedStar Family Choice
5565 Sterrett Place, 5th Floor
Columbia, MD 21044

Re: MedStar Family Choice, Inc., Docket No. 2013 MA/PD App. 8 & App.11

Dear Mr. Wagner:

Enclosed is a copy of the Administrator's decision in the above case affirming the decision of the CMS Hearing Officer. This constitutes the final administrative decision of the Secretary of the Health and Human Services.

Sincerely yours,

Jacqueline R. Vaughn
Attorney Advisor

Enclosure

cc: Mark Hamelburg, Esq., MedStar Family Choice Representative (via email)
Danielle R. Moon, J.D., M.P.A., CMS (via email)
Cynthia G. Tudor, Ph.D., CMS (via email)

CENTERS FOR MEDICARE AND MEDICAID SERVICES

Decision of the Administrator

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In the Matter of:	Claim for:
MedStar Family Choice, Inc.	**Medicare Advantage Prescription Drug Plan** **Period Beginning: 2014** **Review of:** **Docket Nos. 2013-MA/PD App-08 & App. 11** **H9915**[1] **Dated: August 14, 2013**

This case is before the Administrator, Centers for Medicare & Medicaid Services (CMS), for review of the Hearing Officer's decision. The Plan timely requested administrative review under 42 C.F.R. §§422.692(a) and 423.666(a). The Administrator initiated review under 42 C.F.R. §§422.692(d) and 423.666(d). Further comments were received from the Plan requesting that the Administrator review and reverse the Hearing Officer's decision. CMS submitted comments stating that the CMS Hearing Officer's decision should be affirmed. Accordingly, this case is now before the Administrator for final administrative review.

ISSUE

The issue involves whether CMS' denial of the following applications for Contract year (CY) 2014 on the grounds that the applicant lacked 14 months performance history was consistent with 42 CFR 422.501, 422.502, 423.502 and 423.503:

(a) Service Area Expansion (SAE) application submitted by The Plan Family Choice, Inc. (The Plan or the Plan) to offer Medicare Advantage/Medicare

[1] The case involves a consolidation of two appeals: the "Denial of the Service Area Expansion Application for MA/PD Plan Organization Contract Year 2014"; and the "Denial of the Specialized MA Plan for Specialized Needs Individuals MA/PD Plan Organization Contract Year 2014 Contract No H9915."

Advantage Prescription Drug (MA-PD) plans in Baltimore City and Baltimore County, Maryland. (Hearing Office Docket No. APP8), and

(b) Initial application submitted by The Plan to offer a Specialized Medicare Advantage Plan for Special Needs Individuals (SNP) in the District of Columbia, and Baltimore City and Baltimore County, Maryland for Contract Year 2014. (Hearing Officer Docket No. APP11)

CMS HEARING OFFICER'S DECISION

The Hearing Officer found that CMS acted within its authority in denying application H9915 and granted CMS' Motion for Summary Judgment. The Hearing Officer found there was no dispute regarding the length of the Plan's tenure as a Medicare Contractor operating an MA-PD plan. The Plan confirmed to CMS and in the record that it has been operating only since January 1, 2013, less than the requisite 14 months. Thus, the Plan's applications were properly denied on the grounds that it lacked 14 months performance history as required by CMS instructions and regulations.

COMMENTS

The Plan requested review by the Administrator under 42 C.F.R. §422.692. The Plan submitted additional information in the form documentation that attests to the high quality of care and community impact of the Plan's health care delivery system. The Plan states that in seeking to expand their MA footprint to match their hospital and physician presence in the State of Maryland, they are seeking to optimize access to care for their patients in Maryland. The Plan stated that it had a wide provider network and resources and that it is part of The Plan Health (one of the largest nonprofit health care systems in District of Columbia (D.C.) and Maryland (MD), which serves one in five residents of D.C. and MD areas. The Plan also stated that it demonstrated commitment to serve beneficiaries with special needs and presently successfully serves over 30,000 Medicaid beneficiaries, respectively, in D.C. and MD. The Plan pointed to two independent entities (NCQA and a MD State hired quality review agency) that have consistently ranked the Plan's Family Choice Medicaid plan among the top in the region and nation. Any delay in the Plan's entry into the market would deprive affected Medicare beneficiaries of the opportunity to choose an established health plan with long established roots in the community. As such, the Plan requested that the Administrator exercise her discretionary powers to

approve the Plan's SAE and SNP applications. In the alternative, if both the SAE and SNP cannot be approved, the Plan requested that the SNP be approved for the existing contract D.C area.

With respect to App. 8, for a service expansion area, CMS strongly urged the Administrator to deny the Plan's request to overturn the Hearing Officer's decision. The Plan's application to expand after only two months of experience in the program was precisely the situation that the 14 months of past performance requirement was designed to address. Overturning the application denial would be detrimental to the program. CMS stated that Medicare beneficiaries in Baltimore City and Baltimore County have sufficient access to MAPD plans, so there is no compelling reason to make an exception to CMS' requirement in order to expand the plan offerings available in these areas.

CMS also stated that in just a few months, the Plan will have the opportunity to resubmit its expansion applications for a start-date of January 2015. By the time CMS reviews those applications they will have sufficient performance data to assess the Plan's qualifications, and barring any unexpected problems, CMS will be fully supportive of the Plan moving forward with their expansion plans at that time. Thus, CMS respectfully requested that the Administrator affirm the denial of the Plan's application.

DISCUSSION

The entire record furnished by the Hearing Officer has been examined, including all correspondence, position papers, exhibits, and subsequent submissions.

Under the regulations at 42 C.F.R. §§422.500 and 423.500 et seq., CMS has respectively established the general provisions for entities seeking to qualify as Medicare Advantage (MA) organizations under Part C, and/or Prescription Drug Plans (PDP) under Part D.[2] The regulation at 42 C.F.R. §422.4(c)(1) requires that MA organizations offering coordinated care plans (CCPs) must offer Part D benefits in the same service areas. Under 42 C.F.R. §422.4(c)(1)(iv) defines a specialized MA plan for special needs individuals (SNP) as including any type of coordinated care plan that meets CMS' SNP requirements and exclusively enrolls special needs

[2] CMS has revised and/or clarified some of the regulatory text governing the Part C and Part D programs. See, e.g., Proposed Rule, 74 Fed. Reg. 54634 (Oct. 22, 2009) and final Rule, 75 Fed. Reg. 19678 (April 15, 2010); 77 Fed. Reg. 22072, April 12, 2012 (final rule with comment period.)

individuals as defined by 42 C.F.R. §422.2 of this subpart. All MA plans wishing to offer a SNP are required to be approved by the National Commission of Quality Assurances (NCQA), effective January 1 2012.

Pursuant to 42 C.F.R. §§422.501 and 423.502, organizations seeking to qualify as an MA-PD plan have their applications reviewed by CMS to determine whether they meet the application requirements to enter into such a contract. The regulation concerning the Part C application requirements at 42 C.F.R. §422.501[3] states, in relevant part:

> (c) Completion of an application.
>
> > (1) In order to obtain a determination on whether it meets the requirement to become an MA organization and is qualified to provide a particular type of MA plan, an entity, or an individual authorized to act for the entity (the applicant) must complete a certified application in the form and manner required by CMS, including the following:
> > i. Documentation of appropriate State licensure or State certification that the entity is able to offer health insurance or health benefits coverage that meets State-specified standards applicable to MA plans, and is authorized by the State to accept prepaid capitation for providing, arranging, or paying for the comprehensive health care services to be offered under the MA contract.
> > ii. For regional plans, documentation of application for State licensure in any State in the region that the organization is not already licensed.
> > (2) The authorized individual must thoroughly describe how the entity and MA plan meet, or will meet, the requirements described in this part.

Similarly, under the regulations at 42 CFR 422.501(c)(2), potential MA-PD organizations submit applications to CMS, in which the applicant organization must document that it has a provider network in place that meets CMS requirements. Under the regulations at 42 CFR 522.501(c)(1) these applications also must be "completed in the form and manner required by CMS." The Part D regulatory application requirements track those set forth under the Part C regulatory application requirements, as appropriate.

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[3] *See* similar language for Part D at 42 C.F.R. §423.504(b)(2).

CMS established an online application process for both Part C and Part D plans referred to as the Health Plan Management System (HPMS). All new applicants and requests for a Service Area Expansion (SAE) are to be submitted through the HPMS by the strict deadlines established by CMS. CMS provided training and technical assistance to plans in completing their application. Plan applications were evaluated solely on the materials that were submitted into the HPMS system within the CMS established windows and deadlines. After the applicant files its initial application, CMS reviews the application and notifies the applicant of any existing deficiencies. The applicant is then given the opportunity to correct the deficiencies.

The regulations at 42 C.F.R. §422.502 specify the evaluation and determination procedures for applications to be determined qualified to act as an MA organization, and states in pertinent part:

> (a) *Basis for evaluation and determination.* (1) With the exception of evaluations conducted under paragraph (b) [Use of information from a current or prior contract], CMS evaluates an entities application for an MA contract solely on the basis of information contained in the application itself and any additional information that CMS obtains through on-site visits. (2) After evaluating all relevant information, CMS determines whether the application meets all the requirements in this part. (Emphasis added).[4]

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 and may deny an application based on the entity's failure to comply with this Part C/Part D requirement during this period. CMS may rely on this basis even if the applicant demonstrates, through its submitted application, that it otherwise meets all of the requirements for qualification as a Part C/Part D contractor. Specifically, the regulation at 42 CFR 422.502(b) states:

> *(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

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[4] The preamble to 75 Fed. Reg. 19678, 19683 (April 15, 2010), states that "we specifically proposed to make explicit that we will approve only those applications that demonstrate that they meet all (not substantially all) Part C and Part D requirements." CMS also states that expecting applications to meet "all" standards is practical and explains that "applicants receive enough information to successfully apply and are given two opportunities with instructions to cure deficiencies."

> 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.

The regulation with respect to the Part D applications also uses this same language at 42 CFR 423.503(b) and is herein incorporated by reference. With respect to promulgating 42 CFR 422.502(b) and 423.503(b), the Secretary explained that:

> Each year, as part of the application evaluation process, we conduct a comprehensive review of each Part C and D sponsor's past performance in the operation of its Medicare contract(s). Current regulations provide that organizations with current or prior contracts with CMS are subject to CMS denial of any new applications for additional or expanded Part C or D contracts if they fail during the preceding 14 months to comply with the requirements of the Part C or D programs, even if their applications otherwise demonstrate that they meet all of the Part C or D sponsor qualifications. In the absence of 14 months of performance, however, 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 programs.
>
> 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.
>
> Therefore, we proposed modifying §422.502(b) and §423.503(b) by adding additional language at §422.502(b)(2) and §423.503(b)(2) 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 program, respectively[5]

Thus, with respect to the need for 14 months of performance history for a new plan to expand or to submit a new application, Plans were advised of this proposed change as early as the November 2010 *Federal Register* and further discussion of the final clarification were set forth in the April 2011 *Federal Register*. This was also followed up with instructions and guidance to Applicants.[6] Following this clarification published in the *Federal Register* notice and comment rulemaking, CMS issued the "Performance Review Methodology for the 2013 Application Cycle" on December 2, 2011, which stated that:

> 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, beginning with the 2013 Application Cycle, organizations that commence their Part C and/or Part D operations in 2012 will not be permitted to expand their service areas or product types until they have

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[5] 76 Fed. Reg. 21432, 21524 (April 15, 2011) ("Centers for Medicare & Medicaid Services 42 CFR Parts 417, 422, and 423 Medicare Program; Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs for Contract Year 2012 and Other Changes") (final rule); *see also* 75 Fed. Reg. 71190 (November 22, 2010)("Centers for Medicare & Medicaid Services 42 CFR Parts 417, 422, and 423 Medicare Program; Proposed Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs for Contract Year 2012 and Other Proposed Changes")(proposed rule).

[6] See, e.g., December 2, 2011 Memorandum and Attachment "Performance Review Methodology for the 2013 Application Cycle" http://www.cms.gov/Medicare/Health-Plans/HealthPlansGenInfo/Downloads/32_PastPerformanceMethodology.pdf

> accumulated at least 14 months of performance experience, which can then be evaluated under this methodology.
>
> Importantly, these provisions only pertain to applying entities that currently operate Part C or Part D contract(s) but have done so for less than 14 months, and further, are unrelated (by virtue of being subsidiaries of the same parent) to any other contracting entity with at least 14 months' experience. So long as a contracting entity or another subsidiary of its parent organization has operated one or more Medicare contracts for the requisite period of time, applications for new contracts or service area expansions submitted by a current contracting entity will not be subject to denial for having less than 14 months experience. (Emphasis added.)

This was followed up with guidance issued January 17, 2013, setting forth the "2014 Application Cycle Past Performance Review Methodology Final"[7] which directly addressed further comments on this issue and stated that:

> Treatment of Organizations with less than 14 Months Performance History. The methodology document mentions the regulatory provision that gives CMS the authority to deny applications from entities with less than 14 months experience at the time an application is submitted (§422.502(b)(2) and §423.503(b)(2)). One organization that began its Medicare operations in January 2013 submitted comments that CMS should change its policy. CMS' position has not changed. The policy, published by CMS as a final rule in April 2011, was in place when organizations initially applied in February 2012 to operate in 2013, and plans had access to this regulation and should have considered this provision at the outset. Numerous organizations have told us they were aware of the provision and have made decisions accordingly. One organization starting Medicare operations in 2013 praised CMS' policy saying that it ensures plans newly entering the Medicare market will focus on the right things (i.e., taking care of beneficiaries) during their first year, instead of focusing on immediate expansion. In the preamble discussion accompanying the publication of this regulatory provision, CMS provided no indication that we would consider exceptions to this policy. However, sponsors have the opportunity to challenge CMS' application of this policy in their particular case by pursuing the

[7] http://cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/2014-Application-Cycle-PastPerformance-Methodology-Final.pdf

> regular administrative hearing process the Part C and D regulations afford all denied applicants (Subpart N of 42 C.F.R. Parts 422 and 423). (Emphasis added.)

After initial applications are submitted, CMS affords applicants an additional "courtesy" review and a period in which the applicant may cure its deficiencies. If CMS approves the application, it gives written notice to the applicant that it qualifies as an MA-PD plan. However, if an applicant fails to correct all of the deficiencies, CMS will issue the applicant a Notice of Intent to Deny under the regulations at 42 C.F.R. §422.502(c)(2).[8] If, after the 10-day cure period, CMS denies an MA-PD application, the applicant has a right to a hearing before a CMS Hearing Officer in accordance with 42 CFR 422.660 and/or 423.650. The regulations provide that at a hearing, the applicant has the burden of providing by a preponderance of the evidence that CMS' determination was inconsistent with the requirements of 422.501 and 422.502 for Part C and/or 422.502 and 423.503 for the Part D program.

In this case, MedStar Family Choice (MedStar or the Plan) is an MA-PD organization operating in the District of Columbia under Contract No. H9915. The Plan's contract became effective January 1, 2013.[9] Prior to this date, the Plan (or its parent organization) did not have a contract with CMS to offer any MA or MA-PD plans. In November 2012, the Plan submitted a Notice of Intent to Apply for a SAE for CY 2014 under its Part C/Part D contract. CMS then contacted the Plan to inform the organization that its application would be denied because it lacked 14 months past performance history with the Part C or Part D programs as required by regulation and CMS' 2014 Performance Review Methodology.[10] At the Plan's request, CMS met with the organization on January 8, 2013 and reiterated that its application would be denied.[11] On February 20, 2013, the Plan submitted an SAE application seeking to expand its Contract H9915 by offering MA-PD plans in two Baltimore City and Baltimore County, Maryland. The Plan also submitted an initial application to offer a Dual Eligible SNP (D-SNP) in the District of Columbia (the existing service area of Contract H9915), and in Baltimore City and Baltimore County, Maryland, the areas that are the subject of its SAE application. CMS responded to the SAE and D-SNP applications through separate notices.

On March 13, 2013, CMS sent the Plan a Deficiency Notice describing several deficiencies in its Part C SAE application. The notice provided instructions and a deadline for the Plan to make changes in its application to correct the deficiencies.

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[8] *See* similar language for Part D at 42 C.F.R. §423.503(c)(2).
[9] MedStar Initial Brief App. 8 at 1; CMS Brief App.8 at 4.
[10] CMS Brief for App. 8 at 4 and App. 11 at 4.
[11] *Id.*

On March 28, 2013, CMS sent the Plan a Deficiency Notice regarding its Part D SAE application. The notice stated that CMS had completed its review of the 2014 Part D application and that the existing contract with CMS was not in effect prior to January 1, 2012. Therefore, CMS found that the Plan was not eligible to apply for a new contract or service area expansion for 2014. Both notices concluded with the statement, "the outcome of the past performance analysis is not included in this round of application reviews. Any past performance-related difficulties will be provided to applicants at the end of April."

On April 26, 2013, CMS sent the Plan two separate Notices of Intent to Deny for its Part C and Part D SAE applications. While deficiencies were noted in the Part C Application, both Notices stated that CMS intended to deny the application because the Plan lacked the required 14 months of past performance history. Specifically, CMS stated that neither the Applicant, nor its parent organization, had an existing contract with CMS that was in effect as of January 1, 2012 and that the Applicant was not eligible to apply for a new contract or contract expansion for 2014. Finally on May 31, 2014, CMS sent the Plan final denial notices of its Part C and Part D SAE applications for Baltimore City and Baltimore County, Maryland stating that that neither the Plan, nor its parent organization, had an existing contract with CMS that was in effect prior to January 1, 2012 and, thus, the Plan was not eligible to apply for a new contract or a contract expansion for 2014.

On March 13, 2013, CMS sent the Plan an SNP application status notice, in the form of an email, regarding its D-SNP application. The notice stated that CMS had found no deficiencies in its D-SNP application. On May 31, 2013, the Plan received an electronic mail from CMS granting conditional approval of its SNP Application. The notice listed additional approvals that were required in order for the Plan to contract with CMS as a SNP sponsor. The notice also pointed out that any approval was conditional and that the SNP could only be offered in an MA approved service area. If there are any changes to the information supplied during the application process, or if was determined that any of the information upon which CMS based the approval was inaccurate, this approval could be withdrawn and a letter of intent to deny and/or denial notice issued. CMS also pointed out that: "If you have applied for a new MA-approved service area, approval of the new SNP or SNP SAE is contingent upon approval of the new MA service area. If your MA service area has not been approved due to unresolved deficiencies, your new SNP or SAE cannot be approved."[12] On June 24, 2013 CMS retracted the conditional approval of the SNP application and issued a denial based on its finding that neither the Plan, nor its parent organization, had an existing contract with CMS that was in effect prior to

[12] CMS Hearing Brief, Exhibit 2.

January 1, 2012 and, thus, the Plan was not eligible to apply for a new contract, contract expansion or a new Special Needs Plan for 2014.

The Plan argued that it is seeking to expand its service areas to match its parent health system's hospital and physician presence in the State of Maryland and, thus, as a result, approval of the application means that access to care for the patients in Maryland/District of Columbia would be drastically improved.[13] Moreover, the Plan has a significant reach on the community's health care population since its parent organization delivers care to one in every five residents of Maryland and the District of Columbia.[14] The Plan also pointed out that its Medicaid plan has been ranked by two independent quality rating agencies as a top regional and national plan. Legally the Plan objected to the denials as it claims that, if it would have known this restriction would be applied to it, it would have initially applied for a larger service area and types of MA/PD plan. Further it claims the application of this rule is discretionary as CMS "may" rather than "shall" deny an application where the Plan does not have at least 14 months of performance data to evaluate.

After a review of the record and applicable law and policy, the Administrator finds that the Hearing Officer properly upheld CMS' denial of the Plan's SAE and SNP applications for Part C and Part D on the grounds that neither the Plan, nor its parent organization, had the required 14 months performance history as required by CMS instructions and regulations. The record shows that it is undisputed that neither the Plan, nor the parent organization, had an existing contract with CMS that was in effect as of January 1, 2012. Further, CMS provided sufficient and repeated notices in the *Federal Register* (through notice and comment rulemaking) and in Memorandum Guidance for Applicants prior to the Plan's initial MA/PD application of this rule that CMS had adopted the authority to deny an application with less than

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[13] The latest MA enrollment data shows a significant number of MA/PD plans available in the Baltimore Maryland service area, although a much fewer number of SNP plans are available for that same area and the District of Columbia. However, the SNP plan cannot be approved for areas not approved under the SAE. http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MCRAdvPartDEnrolData/Monthly-MA-Enrollment-by-State-County-Contract.html?DLSort=1&DLPage=1&DLSortDir=descending

[14] However, the public records show that for the latest monthly enrollment by contract data, Medstar Family Choice, Inc. has enrolled 77 beneficiaries. http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MCRAdvPartDEnrolData/Monthly-Enrollment-by-Contract-Items/Enrollment-by-Contract-2013-08.html?DLPage=1&DLSort=1&DLSortDir=descending

14 months of performance data and the important reasons for such a policy.[15] All organizations in such a situation would only have two months of data upon which to evaluate an entity's performance, which CMS found to be inherently inadequate. In establishing its authority to deny applications for this reason, CMS notably did not set forth exception criteria, under which all such applicants, that are otherwise equally presenting only two months of data, could meaningfully and similarly demonstrate they were able to comply with the Part C and Part D requirements for the existing contract. CMS rationally balanced, *inter alia*, the need to protect Medicare beneficiaries and allow the most able of performing organizations to serve them (as demonstrated by their actual performance under the MA/PD contract), over any advantage to providing more immediate additional choice to those same beneficiaries. Organizations were given sufficient notice of such a policy to plan accordingly. In sum, the Administrator finds that the CMS denial of the Plan's SAE and SNP applications were appropriate and the Hearing Officer affirmation was proper and correct.

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[15] Even assuming *arguendo* that the Plan acted on a belief that the regulation provided CMS the discretion to approve additional types of MA/PD or SAE applications, without the requisite 14 months of performance data (instead of the authority to deny), it knowingly risked that CMS might not use such discretion in the later year application when it failed to include such areas and types in its initial application.

DECISION

The Administrator affirms the decision of the Hearing Officer in accordance with the foregoing opinion.

THIS CONSTITUTES THE FINAL ADMINISTRATIVE DECISION OF THE SECRETARY OF HEALTH AND HUMAN SERVICES

Date: 9/16/13

Marilyn Tavenner
Administrator
Centers for Medicare & Medicaid Services