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Office of the Attorney Advisor

AUG 2 5 2011

VIA FACSIMILE

Ms. Cindy Polich
United Healthcare Medicare & Retirement
MN006
9701 Data Park Drive
Minnetonka, MN 55343

Re: United Healthcare Insurance Company, Docket No. 2011-C/D-App-1-10

Dear Ms. Polich:

Enclosed is a copy of the Administrator's decision in the above case affirming the decision of the 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

CENTERS FOR MEDICARE AND MEDICAID SERVICES

Decision of the Administrator

In the Matter of:	**Claim for:**
United Healthcare Insurance Company	**Medicare Advantage Prescription Drug Plan Period Beginning: 2012**
Contracts Nos. H0710,H5417, H1944, H2001, H2406, H3812, H3912,H5652,H1509,S5820	**Review of: Docket No. 2011-C/D-App-1-10**
	Dated: July 21, 2011

This case is before the Administrator, Centers for Medicare & Medicaid Services (CMS), for review of the Hearing Officer's decision. The United Healthcare Insurance Company (Applicant) timely requested administrative review under 42 C.F.R. §§422.692(a) and 423.666(a). The Administrator initiated review under 42 CFR §§422.692 and 423.666. Additional comments were subsequently received from the Applicant requesting reversal of the Hearing Officer's decision. The CMS Centers for Medicare (CM) also submitted comments requesting affirmation of the Hearing Officer's decision. Accordingly, this case is now before the Administrator for final administrative review.

ISSUE

The issue involves whether CMS properly denied United Healthcare Insurance Company's applications for Medicare Advantage (Part C)/Prescription Drug (Part D) (MA-PD) service area expansions (SAE),[1] a Part D contract,[2] applications to add or expand special need plans (SNP) offerings,[3] and the initial applications for new MA-PD contracts, under which SNPs were to be offered.[4] CMS denied the foregoing applications based on the United Healthcare Insurance Company's failure

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[1] H0710, H1509, H1944, H 2001, H5417 and H5652

[2] S5820

[3] H2406, H5417, and H5652

[4] H3812, H3912

to meet the Part C and Part D requirements under its current and prior Medicare contracts.

HEARING OFFICER'S DECISION

The Hearing Officer granted CMS' Motion for Summary Judgment and found that CMS' denials of the Applicant's applications were proper. The Hearing Officer found that CMS denied all ten applications based on 42 CFR §§422.501, 422.502 and 423.503 because the applicants failed to comply with the terms of a current (i.e., 2011) or previous year's contracts with CMS. CMS applied the methodology set forth in the December 2010 memorandum issued prior to the beginning of the 2012 application cycle. CMS evaluated all of the Applicant's contracts on eleven performance categories and found that some of the Applicant's contracts received negative points in three of the eleven performance measures: 1) performance metrics (i.e., star ratings); 2) compliance letters; and 3) financial audits, as measured across the contracting organization level (the licensed risk bearing legal entity). The highest negative scores which were used involved two (2) negative points for performance measure, two (2) negative points for compliance letters and one (1) negative point for financial audits giving it a total of five (5) negative points for both its Part C and Part D plans. These scores were equal to, or exceeded, the threshold of negative performance points established by CMS in its methodology of 4 points for Part C plans and 5 points for Part D plans.

The Hearing Officer found that the regulation and preamble clarified that CMS would consider multiple current and prior contracts held by the organization in determining whether the organization's existing operations can be expanded. The Hearing Officer found that, while the Applicant argued contracts should be evaluated on an individual basis, the intent of the regulation was carried out in assessing the contracts at an organizational level. The Hearing Officer also found that CMS demonstrated that Special Needs Plans or SNPs did not require an adjustment in the methodology. Finally, CMS properly considered the financial audits from 2006-2007 in its evaluation of the current Applicant. CMS clearly stated the review period to be used and the 2006-2007 audits result fell within that period. Consequently, the Hearing Officer found that the Applicant failed to provide by a preponderance of the evidence that CMS' denial of its applications under the methodology was inconsistent with the requirements of 42 CFR §§422.501, 423.502 and 423.502 and 423.503.

COMMENTS

The Applicant requested review by the Administrator under 42 CFR §§422.692 and 423.666. The letter provided a brief overview of the procedural history and identified what it considered inaccuracies with the Hearing Office decision.

The Applicant contended that the CMS categorically rejected all the applications that sought expansion based on past contract performance. Each denial was based on CMS' finding that the Applicant failed to comply with the three requirements of the Medicare contract: it was an outlier with respect to compliance letters issued, it was an outlier based on performance metrics (Star ratings) of 2.5 stars or lower for some of its contracts) and it received negative findings as a result of "one-third audits." The Applicant stated that CMS relied upon its "Past Performance Methodology" to reject the applications. The basis for the rejection did not address the merits of the individual contracts, nor did it provide any evidence that these contracts were not (or would be) high performers.

The Applicant claimed that the Hearing Officer's decision, accepting CMS' assertions at face value, relied on certain erroneous facts and interpretation and did not contemplate whether the applications subject to this appeal would benefit the Medicare program and its beneficiaries. The Hearing Officer seemingly relied upon several factors to affirm CMS' determination to reject all ten applications. The Hearing Officer did not analyze, or review, the merits of the individual contracts, nor was there an analysis undertaken of the benefit to the Medicare program of approval of the applications.

Regarding the "one third audit" rating, the Applicant objected to the Hearing Officer's finding that it was appropriate for CMS to rely on 2006-2007 audit results because the reports were issued (and the poor performance was identified) in January 2011, which falls within CMS' past performance review period from January 1, 2010 through February 28, 2011 as set forth in the methodology. The Hearing Officer noted that CMS did not provide the status of the Applicant's 2008 audit findings which the Applicant pointed out, did not have any adverse findings and provide a better more recent gauge of auditing results. The Applicant objected to the Hearing Officer's failure to consider the more recent audit findings. The CMS and the Hearing Officer should have evaluated the 2008 audit results instead of the older results as they were identified by the contractor during the look back period and more accurately represent the current state of the Applicant's financial activities. The methodology also clearly states that those matters arise during the 14 month look back period but are not identified until after this period (i.e. after February 28, 2011) are included in the CMS assessment if this occurs before the methodology is finalized. If the more recent and relevant audits were considered,

CMS using its methodology would have not assigned negative performance points for this category possibly leading to the approval of some of the contracts.

Regarding the CMS data used, the Applicant pointed out that the Hearing Officer agreed that a large organization that has isolated instances of poor performance among many contracts could be prohibited from further expansion. However, the Hearing Officer concluded that this did not occur in the Applicant's case because poor performance related to, among other things, performance metric or star ratings which affected a significant number of the Applicant's plans. The Hearing Officer relied upon CMS' data finding that the Applicant had five Part C plans and six Part D plans with star ratings below 3.0. CMS had incorrectly characterized its performance and the Hearing Officer relied upon this erroneous data. The Applicant had pointed out that CMS' data was inconsistent and that CMS offers one document that indicates that only two of its many part D contracts had star ratings below 3.0 stars, yet the CMS brief states that there are six below 3.0 stars and only two Part D contracts have star ratings below 3.0 star rating. The Applicant explained that it was taking measures to improve the few contracts it has with star ratings lower than desired. These few contracts, representing a very small portion of the Applicant's members, were not part of the expansion request and were not subject to this appeal.

Regarding the special needs plans, the Hearing Officer stated that CMS considered having separate performance ratings for plans with special needs plan populations, but the data did not conclusively demonstrate that having SNP members in contracts materially pulled down the summary ratings for Parts C and D plans. Nevertheless, the Hearing Officer was cognizant of the preamble language that showed CMS was aware of a variety of products offered by CMS contractors and that it would adjust the methodology as appropriate. The Applicant argued that this language supports its view that the methodology extends beyond the intent of the regulations and is intended to allow some flexibility in the application of the methodology for those plan sponsors who have committed to service large segments of the vulnerable population and that no such consideration was given.

The Applicant also challenged CMS' methodology and intent. The Hearing Officer upheld the CMS' authority to consider multiple and current and prior contracts held by an organization in deeming whether the organization's existing operation can be expanded. The Hearing Officer also upheld CMS' methodology as consistent with CMS expressed intentions that negative performance should be assessed at the organization, or legal entity level, as opposed to just considering the merits of an individual application. However, the Applicant argued that it had demonstrated that the methodology is inconsistent with CMS' intent as CMS stated it would apply its methodology flexibly and conservatively, which was not the case for the contracts under appeal. The Hearing Officer failed to address the Applicant's argument that

its applications would not have been denied if CMS had reviewed on a contract by contract basis. The methodology and Hearing Officer also did not address why beneficiaries should not have the benefit of contracts that were operating effectively and efficiently with respect to the contracts applications under appeal. One of the contracts (H5652) received zero total negative performance points and one of the contracts (H2406) received one total negative performance points. The remaining eight contracts were assigned negative performance points, considerably lower than the thresholds the methodology requires to reject, which are otherwise sufficient applications. CMS applied the scoring for the otherwise performing contracts, for which no expansion contract was filed, to all of the Applicant's other contracts, including high performers. Even high performers were judged to not be expandable. A large single entity, with multiple contracts, is unfairly treated by this methodology as it gives competitive advantage to other organizations based not on their performance, but their legal structure.

In conclusion, the Applicant argued that CMS did not place adequate emphasis on the best interest of the Medicare program and its beneficiaries, which is inconsistent with the very mandate of the Medicare program to provide quality comprehensive services to elderly and disabled population. Determining the best interest of the Medicare program should be the primary goal of the application review process. The Applicant stated that it stood behind its goal of providing greater choice, enhanced access, administrative simplicity, and quality of services to Medicare beneficiaries. The Applicant submitted its expansion requests based on deliberate evaluation of serving the needs of the Medicare population. Approving the applications subject to the appeal will accomplish the shared goals of increased access and further expansion of quality plans.

The Applicant submitted further comments pointing out its prior submissions and that the administrative process has, to date, not addressed the merits of the individual contracts. There was no analysis of the benefit to the Medicare program of the approved contracts has been conducted. The Applicant was very selective in the ten contracts subject to this appeal to ensure they included high quality offerings, offerings that would enhance efficiency for beneficiaries and employers through expansions that are administrative in nature, and offerings with institutional special needs plans, which are regarded nationwide as providing a proven and successful model of care. The Applicant argued that the CMS methodology unfairly and disproportionately impacts those plan sponsors that provide items and services under a single legal entity to the greatest number of Medicare beneficiaries. The methodology also negatively impacts those entities that provide special needs. CMS failed to apply the methodology flexibly and conservatively to these contracts. A review of the record including the merits of the individual contracts shows that approval will benefit the programs beneficiaries and is consistent with the law.

The CM submitted comments requesting that the CMS Hearing Officer's decision be upheld. The CMS submitted the memorandum, *inter alia*, in further support of the important principle that it is necessary for CMS to review an applying organization's performance across all of that organization's Medicare contracts, not merely those contracts for which organizations seeks qualification to serve new areas or offer new products. CM also set forth its intent to respond to matters raised by the Applicant.

First, CMS has consistently stated, in operational guidance (such as the Health Plan Management System or HPMS memoranda), and rulemaking, that CMS reviews the applying organizations performance of all of its Medicare business. CMS explained that it takes this position as an organization demonstrating operational difficulties needs to focus on improving its existing operations before expanding its Medicare business. CMS explained that this method of exercising past performance review authority is the most effective method to protect beneficiaries, particularly those enrolled under poor performing contracts, by focusing the sponsor's full attention in taking corrective action. By contrast, the Applicant's policy would create the wrong set of incentives, as it would encourage sponsors with multiple contacts to focus their administrative and management efforts on maintaining the quality of only those contracts for which they intend to seek new business.

Second, the Applicant argued that CMS should not have relied upon the 2006-2007 audit results as one of the factors in denying the contracts based on poor performance. The Applicant claimed there was more recent audit data available that would be more appropriate for the CMS analysis. CMS stated that it would assign negative points where the Applicant has received a disclaimer or adverse audit report during the stated 14 month period of review set forth in the regulation. CMS stated that for the 2012 application cycle the past performance review period ran from January 1, 2010 through February 28, 2011. The methodology would consider performance that had occurred, or been identified, during the 14 month period and in the case of financial audits, CMS must rely on the audit reports to identify definitely any disclaimed or adverse results. CMS strictly applied the timeframes to the CMS review so that all applicants are treated fairly and consistently. For CMS to consider reports issued between April and June 2011, for audits conducted during 2008, would grant unfair advantage to the Applicant as CMS did not review the audit reports issued during that time for any other applicants. Moreover, CMS noted that this extended timeframe would not be advocated if it believed it might result in more adverse findings.

CMS explained that regarding the said audits conducted for 2008, that the relevant poor performance did not occur between January 1, 2010 and February 28, 2011, nor can the audit reports issued after April 2011 be said to constitute identification of

problems during the past review period January 1, 2010 through February 28, 2011. CMS explained how these rules help create a reliable source of audit related information.

Third, CMS corrected its star rating error in its brief, but asserted it was not material to the outcome of the matter. The Applicant received a rating of 2.5 stars or less on the Part D performance of six of its contracts during the past performance period (see Attestation of Elisabeth Goldstein) Thus, the correct value for this past performance measure is two. The Hearing Officer relied upon the correct star rating in making his decision.

Fourth, CMS asserted that special plans needs do not merit special consideration in the assessment of past performance. The record demonstrates that CMS gave full consideration to whether the star ratings of special needs plan contractors are lower than those of other plan sponsors, and if so, are they the result of the unique aspects of special needs plan administration. CMS made this determination after reviewing the ratings of all special needs plan.

Finally, CM stated that the CMS Hearing Officer properly found that CMS has developed, provided notice of, and supplied, a fair and comprehensive process for assessing contractor performance. CMS methodology was adopted for assessing past contract performance in order to ensure that program will be held fully accountable for the services they are obligated to provide for all of their members.

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 CFR §§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.[5] MA organizations offering coordinated care plans (CCPs) must offer Part D benefits in the same service areas. 42 CFR §422.4(c)(1). Organizations seeking to qualify as an MA-PD plan have their applications reviewed

[5] CMS has revised and/or clarified some of the regulatory text governing the Part C and Part D programs. *See* Proposed Rule, 74 Fed. Reg. 54634 (Oct. 22, 2009) and final Rule, 75 Fed. Reg. 19678 (April 15, 2010). The Rule was effective June 7, 2010 and applied from contract year 2011 and forward.

by CMS to determine whether they meet the application requirements to enter into such a contract.

The regulation concerning the Part D application requirements at 42 CFR §423.502(c)[6] states, in relevant part:

> (c) Completion of an application.
>
> (1) In order to obtain a determination on whether it meets the requirement to become a Part D plan sponsor... the entity (the applicant) must complete a certified application, in the form and manner required by CMS,... "
>
> (2) The authorized individual must describe thoroughly how the entity is qualified to meet all requirements described in this part. (Emphasis added).

For the 2012 and prior contract years, CMS established and required an online application process for both Part C and Part D plans called the Health Plan Management System (HPMS). All new applicants and requests to establish or expand service areas had to submit their applications 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 and information collected on site except as provided below.

The regulations at 42 C.F.R. §422.502 specify the evaluation and determination procedures for applications to be determined qualified to act as a Medicare Advantage-Part C plan and state in pertinent part:

> 422.502 *Evaluation and determination procedures.* (a) *Basis for evaluation and determination.* (1) With the exception of evaluations conducted under paragraph (b) of this section, CMS evaluates an application for an MA contract solely on the basis of information contained in the application itself and any additional information that CMS obtains through other means such as on-site visits.
>
> (2) After evaluating all relevant information, CMS determines whether the applicant's application meets all the requirements described in this part.
>
> (b) Use of information from a current or prior contract. 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

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[6] *See* similar language for Part C at 42 CFR §422.501. For the most part, the language in 42 CFR Part 422 and Part 423 are similar and/or identical

> 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.[7]

Similarly, the regulations at 42 CFR §423.503 specify the evaluation and determination procedures for applications to be determined qualified to act as a Part D sponsor, and states in pertinent part:

> § 423.503 *Evaluation and determination procedures for applications to be determined qualified to act as a sponsor.* (a) *Basis for evaluation and determination.* (1) With the exception of evaluations conducted under paragraph (b) of this section, CMS evaluates an entity's application 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 described in this part.
>
> (b) *Use of information from a current or prior contract.* (1) If a Part D plan sponsor fails during the 14 months preceding the deadline established by CMS for the submission of contract qualification applications (or in the case of a fallback entity, the previous 3-year contract) to comply with the requirements of the Part D 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 D 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

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[7] CMS made corresponding changes to 42 CFR 422.504(m) and 423.505(n), in which CMS stated that it would determine a sponsor out of compliance when it failed to meet a standard already articulated in the statute regulation or guidance, or in the absence of an articulated standard, if its performance represented an outlier relative to the performance of other organizations.

> determine an applicant's capacity to comply with the requirements of the Part D program

Paragraph (b)[8] originally provided that CMS may deny an applicant's failure to comply with the terms of "a prior contract" with CMS, even if the application currently meets all of the requirements. In the preamble of the October 22, 2009 rule[9], the Secretary proposed to modify these provisions at 42 CFR §§422.502(b) and 423.503(b). The Secretary stated that:

> As described in §422.502(b) and §423.503(b), we may deny an application based on the applicant's failure to comply with the terms of a prior contract with CMS even if the applicant currently meets all of the application requirements. However, we propose to modify §422.502(b) and §423.503(b) to state that we will review past performance across all of the contracts held by the applicant. The provision as currently drafted mentions a "prior contract" with CMS.

In explaining the reason for this modification, the Secretary stated that:

> Today, contracts are "evergreen" and some organizations hold multiple MA and/or PDP sponsor contracts; therefore the concept of "prior contract" is outdated, as the prior performance issues could have occurred in any other contract currently or formerly held by an applicant. Therefore, we propose to revise the language in §423.503(b) and §422.502(b) to refer to "any current or prior contract" held by the organization, instead of the current language referring to a "previous year's contract." We also propose to clarify that the period that will be

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[8] See 42 CFR §422.502(b) which stated: "*Use of information from a prior contracting period.* If an MA organization has failed to comply with the terms of a previous contract with CMS under title XVIII of the Act, or has failed to complete a corrective action plan during the term of the contract, CMS may deny an application based on the applicant's failure to comply with that prior contract with CMS even if the contract applicant meets all of the current requirements." 42 CFR §423.503(b) which stated that: "*Use of information from a prior contracting period.* If a Part D plan sponsor fails to comply with the terms of a previous year's contract (or in the case of a fallback entity, the previous 3-year contract) with CMS under title XVIII of the Act, or fails to complete a corrective action plan during the term of the contract, CMS may deny an application based on the applicant's failure to comply with that prior contract with CMS even if the applicant currently meets all of the requirements of this part."

[9] 74 Fed. Reg. 54634, 54641-54642.

> 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. Fourteen months covers the time period from the start of the previous contract year through the time that applications are received for the next contract year.
>
> Indicia of performance deficiencies that might lead us to conclude that an organization has failed to comply with a current or prior contract include, but are not limited to, poor performance ratings as displayed on the Medicare Options Compare and MPDPF web sites; receipt of requests for corrective action plans (CAPs) unrelated to an audit (as these types of CAPs generally involve direct beneficiary harm); and receipt of one or more other types of noncompliance notices from CMS (for example, notices of noncompliance or warning letters).
>
> ****
>
> We will review performance in accordance with these examples and other evidence of noncompliance, and will deny applications for initial contracts and service area expansions on the basis of noncompliant past performance. By specifically providing these examples and clarifying that we intend to exercise this authority, we believe that organizations will be motivated to enhance their compliance operations in order to avoid being out of compliance with program requirements, and this will significantly deter noncompliance leading to improved overall performance of organizations in the Part C and D programs.[10]

In response to comments the Secretary stated that:

> We also want to emphasis that we intend to be conservative in our determinations. *We expect to use our authority under this provision to exclude only those organizations demonstrating a pattern of poor performance.* Finally we acknowledge that not all types of noncompliance will be given equal weight and our methodology will assign weights to different measures based on factors such as beneficiary impact or program stability.[11]

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[10] 74 Fed. Reg. 54634 54641-54642.

[11] 75 Fed. Reg. 19678, 19685.

The Secretary also emphasized that:

> Our denial of an application based on an applicant's past contract performance is a reflection of our belief that an organization demonstrating significant operational difficulties should focus on improving its existing operations before expanding into new types of plan offerings or additional service areas. Such a determination has no impact, punitive or otherwise on a sponsors current Medicare rights and obligations. [12]

On December 12, 2010, CMS issued a "2012 Application Cycle Past Performance Review Methodology" addressing the past performance criteria of 42 CFR 422.502(b). CMS explained that:

> We are committed to ensuring that CMS contracts with only the strongest and best performing Medicare Advantage Organizations and Prescription Drug Plan Sponsors. The Past Performance Assessment Review enables us, in a systematic and rigorous way, to understand the performance levels of all contracting organizations and to identify organizations that should focus on their current book of business before further expanding. We strongly encourage organizations to use this document in conjunction with their on-going performance self-review activities to bolster their own monitoring efforts

CMS also pointed out, in the memorandum, that it had clarified in the April 15, 2010 final Part C and D regulations that CMS would limit the performance review each year to the 14-month period leading up to the annual application submission deadline and that as a practical matter, CMS counts the entire calendar month in which applications are due as the 14th month. CMS specified that the 14-month performance period that will be assessed for the 2012 Application Review Cycle was *January 1, 2010 through February 28, 2011.* CMS also stated that:

> For an instance of non-compliance to be considered in the review, the non-compliance or poor performance must have either occurred *or* been identified during the 14 month period. Thus, we may include in our analysis non-compliance that occurred in prior years but did not come to light or was not addressed until sometime during the review period. Likewise, if the problem occurred during the 14-month period but it was not identified until, for instance, the month following the end

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[12] 75 Fed Reg. 19678, 19685-19686

of the review period but before we finalize our results, we include the matter in our assessment.

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The methodology presented below is identical for both the Part C and Part D reviews. For program management purposes, we integrate the final separate C and D scores to compile an overall summary score for MA-PD organizations.

Performance Categories and Negative Performance Points
For the 2012 Application Cycle, we have established 11 distinct performance categories. We carefully analyze the performance of all contracts in each performance category and assign "negative points" to contracts with poor performance in that category. The number of potential negative points corresponds to the risk to the program and our beneficiaries from deficient performance in that particular area.
The 11 performance categories that are included in the review for the 2012 application cycle include:

1. **Compliance Letters** (i.e., Notices of Non-Compliance, Warning Letters, and Corrective Action Plans (CAPs))
2. **Performance Metrics** (i.e., the plan performance ratings, sometimes called "star ratings" developed each year and published on the Medicare.gov website)

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6. **One-Third Financial Audits** (i.e., organizations with adverse audit opinions or disclaimed audit reports stemming from a CMS One-Third Financial Audit)

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Relevant to this case the memorandum explained the three above factors stating that.

1. Compliance Letters

When CMS learns of a performance problem, we issue a compliance notice to the responsible organization. These notices serve to document the problem and, in some instances, request details on how the organization intends to address the problem. There are three key notice types: Notices of Non-Compliance (NONC), Warning Letters, and Ad Hoc Corrective Action Plan (CAP) Requests.

Notices of Non-Compliance are used to document small or isolated problems. Warning Letters are issued either when an organization has already received a NONC, yet the problem persists, or for a first offense for larger or more concerning problems. Unlike NONCs, these letters contain warning language about the potential consequences to the organization should the non-compliant performance continue. We also occasionally issue a Warning Letter with a request for a Business Plan when CMS determines that a plan of action is needed from the organization. The last type of letter, the CAP request, is reserved for persistent problems or very serious concerns that need in-depth and continued monitoring by CMS.

An outlier in this category is defined as an organization that is one of the worst performing organizations, based on a weighted distribution of the number and types of compliance letters received (or for conduct that occurred and for which letters will soon be issued) during the performance period across all organizations (including those that received no letters during the period, but excluding contracts otherwise not included in this analysis, such as PACE contracts). Specifically, a weighted score is calculated for each contract; the following table (Table 1) indicates the weights to be assigned for each type of letter or compliance event.
[Table not included]
After a Compliance Letter score has been calculated for each contract, we then rank the contracts in descending order from highest to lowest score (in the case of the Part D analysis, separately for MA-PD contracts and PDPs). Next, we identify the value (score) at the 90th percentile point and the 80th percentile point.

All contracts with a weighted score at or above the 90th percentile point receive 2 negative performance points in the Compliance Letter category. All contracts with a weighted score at or above the 80th percentile point, but less than the 90th percentile point, receive 1 negative performance point in this category. All other contracts receive 0 negative performance points for the Compliance Letter category.

The Health Plan Management System (HPMS) serves as CMS' definitive system of record for all such compliance notices. Each time a letter is issued the CMS issuing office enters key data elements into HPMS and uploads a copy of the letter. To obtain these data, we extract this information from HPMS. This ensures a complete and accurate data set. All letters issued during the performance period (or shortly after the performance period to the extent that the non-

compliance occurred during the performance period) are included in the extract and analysis.[]

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2. Performance Metrics

The most current "plan ratings" data as of the end of the 14-month performance period developed by CMS and posted on the Medicare.gov website are used for this analysis. As of the date of this memo, the most recent sponsor quality and performance metrics were calculated in accordance with the CY 2011 Technical Notes (separately available for Part C and Part D) made available to the public on on the CMS website at http://www.cms.gov/PrescriptionDrugCovGenIn/06_PerformanceData.asp#TopOfPage.

An outlier in this category is defined as any contract that received an overall summary score of 2.5 stars or below. The overall summary score summarizes a contract's performance across domains and underlying individual measures.

For Part D, there are currently four domains: Drug Plan Customer Service; Drug Plan Member Complaints and Medicare Audit Findings; Member Experience with Drug Plan; and Drug Pricing and Patient Safety. All told, there are 17 individual measures assigned among the four Part D domains. For Part C, there are five domains: Staying Healthy: Screenings, Tests and Vaccines; Managing Chronic (long-term) Conditions; Ratings of Health Plan Responsiveness and Care; Health Plan Members' Complaints and Appeals; and Health Plan's Telephone Customer Service. All together, there are 36 individual measures assigned among the five Part C domains.

A summary score is calculated separately for Part C measures and for Part D measures. Each summary score rating is based on an average of the individual measures, with consistent good performance recognized with a higher rating. While ratings of individual measures fall along a 5-star range with no half-star values, summary score ratings include half-stars to provide more differentiation among contracts.

A score of 2.5 stars or below was chosen as the outlier level because a score of "three stars" on any given individual measure is considered an indicator of adequate performance. Therefore a summary score falling below 3 stars indicates poor or "negative outlier" performance.

All outlier contracts in this category receive 2 negative performance points.

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6. One-Third Financial Audits

Sections 1857(d)(1) and 1860D-12(b)(3)(C) of the Social Security Act require the Secretary to provide for an annual audit of the financial records of at least one-third of all active MAOs and PDPs. All contracts that receive **adverse** audit opinions or **disclaimed** audit reports during the 14 month performance period receive 1 negative performance point. The auditor issues a ***disclaimed*** audit report when it could not form, and consequently refuses to present, an opinion on management's assertion (i.e., the auditor tried to audit an entity but could not complete the work to issue an opinion because of circumstances created by the audited organization). The auditor issues an ***adverse*** audit report when it determines that the financial data is materially misstated (i.e., the information contained is materially incorrect, unreliable, and inaccurate).

These types of audit reports signal a lack of internal controls over the sponsoring organization's operations and/or a serious failure by the sponsoring organization to devote the necessary resources to respond to the auditor's request for documentation. The scope of the one-third financial audits includes: 1) Solvency, 2) Related-Party Transactions, 3) Non Benefit Expense, 4) Part D Costs and Payments (TROOP, Direct and Indirect Remuneration), and 5) Direct Medical.

CMS explained further that:

Summary of Negative Point Values and Calculation of Contract-Level Scores

The results of the analyses described above are then compiled in separate Part C and Part D tracking spreadsheets. A contract is assigned the designated number of negative performance points in each category where it is deemed deficient according to the results of the analysis. Otherwise, the contract receives a score of 0 for the particular category. We sum the results across the performance categories to calculate a total negative performance score. Higher scores indicate evidence of performance problems across multiple and varied and/or high risk dimensions. Table 3 on the following page summarizes the negative performance points associated with each performance area.

Summarizing Results at the Contracting Organization (Legal Entity) Level.

While the analyses described above are conducted at the contract level, it is necessary to summarize the results at the legal entity level. Frequently a contracting organization (i.e., a licensed, risk-bearing legal entity) holds multiple contracts with CMS. In turn, some parent organizations own numerous legal entities, each of which hold one or more CMS contracts. We summarize the contract-level performance results at the contracting organization level by assigning to a contracting organization the highest point value assessed for each performance area among all of the contracts held by that organization. The assigned scores for each performance area are then added to produce a total score for that contracting organization. For instance, "ABC Health Plan" holds two Medicare contracts, HXXXX and SXXXX. In reviewing ABC's Part D past performance we find that HXXXX received 1 point for Compliance Letters and 2 points for Performance Metrics, and SXXXX received 1 point for Compliance Letters and 1 point for Formulary Exclusions. To calculate the performance of ABC Health Plan as a whole, we assign that contracting organization the highest number of points any of its contracts received per performance category. In this example, ABC Health Plan would be assigned 1 point for Compliance Letters, 2 points for Performance Metrics, and 1 point for Formulary Exclusions for a total past performance score of 4.

Contracting organizations with high negative performance scores (according to the cut-offs described below) are checked to see if they are applying for an initial contract or a service area expansion. Such applications are denied.

In determining those organizations that have significant performance problems, we established a contracting organization threshold of 4 negative performance points for Part C and 5 negative performance points for Part D. The difference is due to a larger number of applicable categories where points may be accumulated by Part D sponsors (e.g., formulary or LIS specific categories). It is sufficient to reach the designated threshold for either the Part C or Part D analysis to be considered an overall poor performer.[13]

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[13] CMS also explained an even handed approach to avoid gaming of the system by relying on related party principles. ("Additionally, we identify applying contracting organizations with no prior contracting history with CMS

These cut-offs were established to identify organizations that were outliers in at least one serious performance category (e.g. a current sanction) or in multiple performance categories.

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Negative Performance Point Thresholds

In determining those organizations that have significant performance problems, we established a contracting organization threshold of 4 negative performance points for Part C and 5 negative performance points for Part D. The difference is due to a larger number of applicable categories where points may be accumulated by Part D sponsors (e.g., formulary or LIS specific categories). It is sufficient to reach the designated threshold for either the Part C or Part D analysis to be considered an overall poor performer.

These cut-offs were established to identify organizations that were outliers in at least one serious performance category (e.g. a current sanction) or in multiple performance categories. While even 1 negative performance point indicates a contract's "outlier" status in an important performance area, we established 4 or 5 points as the minimum total score for identifying those organizations with performance problems significant enough for us to take definitive action, such as denying expansion applications. *This allows us to concentrate on those organizations that are either performance outliers in multiple categories or otherwise represent a high risk to the program.* That said, we reserve the flexibility to increase the threshold values as necessary to account for shifts in the underlying performance categories and their associated point values to ensure that the analysis continues to identify true outliers.

(i.e., a legal entity brand new to the Medicare program). We determine whether that entity is held by a parent of other Part C or D contracting organizations. In these instances, it is reasonable in the absence of any actual contract performance by the subsidiary applicant, to impute to the applicant the performance of its sibling organizations as part of CMS' application evaluation. This approach prevents parent organizations whose subsidiaries are poor Part C or D performers from evading CMS' past performance review authority by creating new legal entities to submit Part C or D applications. Should one or more of the sibling organizations have a high negative performance score, the application from the new legal entity will be denied.)

> While we use the individual C and D scores for purposes of approving or denying C and D applications, respectively, for program management purposes, we integrate the final separate C and D scores to compile an overall summary score for MA-PD organizations.

In the instant case, the Applicant, in February 2010, filed for Medicare Advantage (Part C)/Prescription Drug (Part D) (MA-PD) service area expansions (SAE) applications[14] and Part D contract application,[15] applications to add or expand special need plans (SNP),[16] and initial applications for new MA-PD contracts, under which it planned to offer SNPs.[17] On April 28, 2011, the Applicant received Notices of Intent to Deny applications for the ten MA plans and PDs that are a part of this appeal.

The Notices of the Intent to Deny stated that the Applicant failed to comply with the terms of the current or previous year's contract with CMS and, accordingly, pursuant to 42 CFR 422.502(b), that CMS would issue final notices of denials regardless of the presence or absence of deficiencies in the submitted application material. The Applicant was given the opportunity to withdraw the Application, or appeal a formal denial notice to the Hearing Officer. The Notices of Intent to Deny further stated that no material can be submitted to cure the issue based on past performance. The Notices of Intent to Deny found that the Applicant was an outlier in formal compliance actions with *several hundred letters* issued covering the following topics: failure to meet call center standards, failure to meet marketing activity standards, failure to meet Medicare Part D program website requirements, failure to effectuate decision made by the independent review entity, EOB privacy issues, inappropriate broker behavior, formulary transition policy issue failure to submit best available evidence, failure to abide by formulary update policy issues regarding prescription drugs that were within protected classes, failure to meet administration and management requirements, incorrect rider language on ID cards, low income premium subsidy issues, out of area disenrollment, service area reduction notice issued in error, incorrect termination notice issued in error and mapping issues.[18]

In addition, the Notices of the Intent to Deny found that the Company had a number of plans that were part of a one-third financial audit and received negative findings.

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[14] H0710, H1509, H1944, H 2001, H5417 and H5652
[15] S5820
[16] H2406, H5417, and H5652
[17] H3812, H3912
[18] See, e,g, Applicant's Exhibit 1. Contract H5652, MA Application. Notice of Intent to Deny, Part D Application –Notice of Intent to Deny.

The audits cover a variety of issues including but not limited to solvency, related party transactions, non-benefit expenses, Part D cost and payments, and direct medical. Finally, the Notices of intent to Deny found that the company had received a below average star rating (2.5 stars or lower out of 5 stars) in the areas of health plan and drug quality for contracts affiliated with the legal entities that submitted the applications and service area requests. The Notices listed the below average ratings in the following areas; drug plan customer service, drug plan member complaints and Medicare audit findings, drug pricing and patient safety, staying healthy, screenings tests and vaccines, managing chronic conditions, ratings of health plan responsiveness and care, health plan members complaints appeals and choosing to leave the health plan, and health plan's telephone customer service. CMS issued Denial Notices incorporating the foregoing findings on May 27, 2011 for the applications at issue.[19]

During the application process, the Applicant also submitted an email as a follow-up regarding its discussion on, *inter alia*, its concerns about Special Needs memberships and the adverse impact on the star ratings. The Applicant proposed that Special Needs plans should be considered unique from a quality rating perspective. The Applicant provided certain comparisons based on percentage of special needs membership of its own plans.

On appeal, in support of the SNP premise, the Applicant also provided a declaration of employee, who also addressed the audit findings and the performance of the individual contracts which CMS had denied. The Applicant provided an analysis for each of the contracts at issue under varied criteria: some were discussed as to their overall member satisfaction, readmission rates, etc., others based on the unique circumstances or offerings as to the individual contracts and the various areas in which they would conduct business (e.g., counties in Florida, Pennsylvania, Kentucky, Ohio, Oregon, Connecticut, Virginia, New Hampshire, Maine, Massachusetts). In response to the Applicant's appeal, CMS provided a summary of the scoring performed on the Applicant's contracts, globally; the declarations, with explanations, of CMS staff that were responsible for the application of the methodology to the particular Applicant with respect to the annual audits, compliance letters, and star ratings; and a summary of the Applicant's past performance as compared to all contracting entities.

The record shows that the Applicant received negative points in three of the eleven performance measures; 1) performance metrics (star ratings)= two; 2) financial audits=one; 3) compliance letters=two, which resulted in a past performance rating

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[19] *See* e.g. Applicant Exhibit 2

of five or Part C and Part D respectively.[20] While not disputing the specific ratings as determined based on the methodology prescribed by the December 12, 2010 memorandum,[21] the Applicant nevertheless argued that the applications should be approved. The Applicant argued that the contracts should be rated individually, as opposed to at the organizational level, and as the individual contracts past performances are not problematic, the contracts should be approved. In addition, the Applicant argued that an organizational level examination penalizes large entities, such as the Applicant, based on a few poor performing contracts, which would not have occurred if it were legally structured as separate entities. Moreover, the Applicant stated that it is penalized as it provides services to Special Needs patients, which it claims has an adverse affect on its entity wide ratings. The Applicant also argued that the post-2006-2007 audit should have formed the basis for the financial audit ratings and that based on that audit, it would not have likely accumulated the final disqualifying past performance score. Finally the Applicant stated that CMS policy does not balance the best interest of the Medicare beneficiaries in denying these contracts.

While the Applicant argued that the Hearing Officer's decision is flawed, as it did not address the respective contracts' past performance, individually, such an argument can only succeed if CMS' policy to look at the organization's performance is rejected. The Administrator finds that the policy to evaluate past performance, based on an entity-wide contract evaluation, is a reasonable and well balanced policy, rationally related to the criteria and methods used, and properly promulgated by regulation as further explained by CMS guidance materials. As CMS stated, the purpose of this policy is to ensure that CMS contracts with only the strongest and best performing Medicare Advantage Organizations and Prescription Drug Plan Sponsors. The Past Performance Assessment Review enables CMS, in a systematic and objective way to understand the performance levels of all contracting organizations and to identify organizations that should focus on their current book of business before further expanding. The Secretary specifically stated that this policy was a "reflection of our belief that an organization demonstrating significant operational difficulties should focus on improving its existing operations before expanding into new types of plan offerings or additional services areas." Such a end goal is in the best interest of the Medicare program and its beneficiaries.

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[20] CMS pointed out that the average past performance score for all contracting entities under Part C and Part D was 1.32. The record shows certain errors in both parties' briefs, which were submitted under tight timeframes, which do not impact the determination of the final past performance score.

[21] That is, the Applicant does not point to mathematical or compilation or weighting errors in arriving at the final past performance rating, although it strongly disagrees with the overall methodology and certain of the data used to arrive at that rating.

The past performance factors used by CMS are relevant to ensuring the financial integrity and quality of care provided by the entity legally responsible for the contract. The Administrator further finds that the particular performance measures for which the Applicant received negative scores are rationally related to furthering the underlying objective of this application criterion. The underlying merits of each individual contract can only be measured in light of the overall operational, financial and performance health of the legal entity which is responsible for that contract. Regardless of whether the legal entity has one contract or multiple contracts with CMS, this same principle is equally applicable. Moreover, as CMS noted, adopting the Applicant's approach would encourage entities to focus resources on favored contracts, with a lost opportunity that has possible adverse impact on the beneficiaries, to incentivize improvement in problem contracts that are already offered. Therefore, the Hearing Officer did not error in reviewing the past performance rating only in the contractual context of the legal entity as a whole, rather than on a contract by contract basis.

With respect to the validity of the methodology as applied to the performance (star) ratings in this case, the Administrator also finds that the record does not demonstrate that the Applicant's provision of special needs offerings would have systematically and adversely affected its performance ratings in this case for either Part C or D contracts.[22] CMS data supports that competent SNP administrators are capable of earning good ratings. The record shows that the Applicant's rating, was not only an outlier among peers, but was evidenced as an issue throughout the Applicant's operation.

CMS also pointed out that the Applicant incorrectly suggested that there is a later, more contemporaneous, audit that could have been used in lieu of the 2006-2007 audits and that this data may have changed its financial audit rating. CMS provided declarations that the 2009 audits have not been contracted. In addition, the regulation provides that the past performance review period ran from January 1, 2010 through February 28, 2011. The methodology would consider performance that had occurred, or been identified during, the 14 month period and in the case of financial

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[22] CMS Exhibit 4, Paragraph 12, 13. Looking at all contracts, CMS was not able to identify a correlation between Special Needs Plans and poor rating due to the nature of the members. In addition, the Applicant suggested certain preventative measures may not be appropriate for certain special needs population thereby lowering a plan's rating. However, CMS noted that a core set of HEDIS measures are collected by all Special Needs Plans, which includes colorectral cancer screening, spirometry testing to confirm COPD, glaucoma screening, and blood pressure controls.

audits, CMS must rely on the issued audit reports to identify definitely any disclaimed or adverse results. Consequently, CMS would not have considered reports for audits conducted after 2007 and issued between April and June 2011. Moreover, the audit reports that were used are reasonably interpreted by CMS as evidence that there may be a lack of internal controls with respect to the identified contracts and a failure to designate necessary resources to respond to the auditor's requests for documentation and that the Applicant was failing to comply with Part C and D program reports. Rather than an anomalous finding, the record further supports that the Applicant's performance across the board was demonstrated to be poorer than its peers. The negative findings with respect to the compliance letters also do not appear to be an anomalous result, where the CMS issuance of compliance notices was across significant numbers of the Applicant's contracts, in significant numbers and the Applicant's compliance letter score was significantly higher than other entities.

In sum, the Administrator finds that, after a review of the record, the Applicant failed to demonstrate, by a preponderance of the evidence, that CMS' past performance scores and subsequent denial of the applications was inconsistent with its authority or the regulations at 42 CFR Parts 422 and 423.

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: 8/23/11

Marilyn Tavenner
Principal Deputy Administrator and Chief Operating Officer
Centers for Medicare & Medicaid Services