CENTERS FOR MEDICARE AND MEDICAID SERVICES

Hearing Officer Decision

In the Matter of

United Healthcare Insurance Company	*	
	*	Docket No. 2011 C/D App 1-10
	*	
Service Area Expansions and	*	
Initial Denials	*	
	*	
Contract Nos. H0710, H1509, H1944, H2001,	*	
H2406, H3812, H3912, H5417, H5652 and S5820	*	

Jurisdiction

This appeal is provided pursuant to 42 C.F.R. §§ 422.660 and 423.650. The Centers for Medicare and Medicaid Services (CMS) Hearing Officer designated by the CMS Administrator to hear this case is the undersigned, Paul Lichtenstein.

Issue

Whether CMS' denial of the applications for qualification for service area expansion (SAEs) of its Part C and D operations, as well as its applications to add or expand special need plan (SNP) offerings to its contracts, and denial of initial applications for new MA-PD contracts, under which it planned to offer SNPs, was consistent with the requirements of 42 C.F.R. §§422.501 and 422.502 and/or 423.502 and 423.503.[1]

Statutory and Regulatory Background

The Social Security Act (SSA or the Act) authorizes CMS to enter into contracts with entities seeking to offer Medicare Advantage (MA) benefits (Part C) and Medicare outpatient prescription benefits (Part D) to Medicare beneficiaries.[2] Pursuant to 42 C.F.R. §§422.500 and 423.500 et seq.,[3] CMS has established the general provisions for entities seeking to qualify as Medicare Advantage-

[1] CMS denied all of the applications based on the Applicant's failure to meet Part C and D requirements under current or prior Medicare contracts. *See* 42 C.F.R. §§ 422.502(b) or 423.503(b).

[2] *See* SSA §§1857 and 1860D-12.

[3] CMS has revised and/or clarified some of the regulations governing the Part C and Part D programs. *See* Proposed Rule, 74 Fed. Reg. 54634 (October 22, 2009) (2010 Proposed Rule) and Final Rule, 75 Fed. Reg. 19678 (April 15, 2010) (2010 Final Rule). The Summary of the 2010 Final Rule states ―This final rule makes revisions to the regulations governing the Medicare Advantage (MA) program (Part C) and prescription drug benefit program (Part D) based on our continued experience in the administration of the Part C and D programs. The revisions strengthen various program participation and exit requirements; strengthen beneficiary protections; ensure that plan offerings to beneficiaries include meaningful differences; improve plan payment rules and processes; improve data collection for oversight and quality assessment, implement new policies and clarify existing program policy. The Final Rule is effective June 7, 2010 and applies from contract year 2011 forward.

Prescription Drug (MA-PD) plans. MA organizations offering coordinated care plans (CCPs) must offer Part D benefits in the same service areas.[4]

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. *See* 42 C.F.R. §§422.501 and 423.502.

The current regulation concerning the Part C application requirements at 42 C.F.R. §422.501 states, in relevant part:

> (c) Completion of an Application.
>
> (1) In order to obtain a determination on whether it meets the requirements 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 fully complete all parts of a certified application, in the form and manner required by CMS...
>
> (2)The authorized individual must thoroughly describe how the entity and MA plan meet, or will meet, all the requirements described in this part.

CMS has established 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 expand service areas had to submit their applications through the HPMS by deadlines established by CMS. CMS provided training and technical assistance to plans in completing their applications and plan applications were evaluated solely on the materials they submitted into the HPMS by the deadlines established by CMS.

After an applicant files its initial application, CMS reviews the application, notifies the applicant of any deficiencies and gives the applicant an opportunity to correct those deficiencies.

The regulation at 42 C.F.R. §§ 422.502 and 423.503 specifies the evaluation and determination criteria qualifying a plan applicant to act as a Part C sponsor. It states, in relevant part:

> (a) Basis of 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.

[4] *See* 42 C.F.R. §422.4(c)(1).

> (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 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 <u>any current or prior contract</u> with CMS <u>even if the applicant currently meets all of the requirements</u> of this part**. [5]

42 C.F.R. § 422.502(b).[6] (Emphasis added.)

Additionally, the 2010 Final Rule added a new provision specifying that CMS may determine sponsor non-compliance with the Part C requirements in accordance with 42 C.F.R. §§422.504(m)(1) and (2) and 423.505(n)(1) and (2). The regulation at §422.504(m) states in relevant part:

> (1) CMS may determine that an MA organization is out of compliance with a Part C requirement when the organization **fails to meet performance standards articulated in the Part C statutes, regulations, or guidance**.
> (2) **If CMS has not already articulated a measure** for determining noncompliance, CMS may determine that a MA organization is out of compliance **when its performance** in fulfilling part C requirements **represents an outlier** relative to the performance of other MA organizations.

(Emphasis added).[7]

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[5] CMS modified this portion of the regulation in the 2010 Final Rule at 19684-6. The preamble states the following.

> [W]e proposed to modify these provisions at § 422.502(b) and § 423.503(b) to clarify that we will review past performance across any and all of the contracts held by the applicant, by specifically revising the language 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 clarified that the period that will be examined for past performance problems will 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.

[6] *See* similar provision for Part D at 42 C.F.R. §423.503(b).

[7] The preamble to the 2010 Final Rule at 19686 states the following.

> [W]e added paragraphs Sec. 422.504(m)(1) and (2) and Sec. 423.505(n)(1) and (2) to make explicit our existing authority to find organizations or sponsors out of compliance with MA and Part D requirements when the organization's or sponsor's performance fails to meet performance standards articulated in statutes, regulations, and guidance or when an organization's or sponsor's performance represents an outlier relative to the performance of other

(Emphasis added).[8]

If the applicant fails to correct all of the deficiencies, CMS issues the applicant a "Notice of Intent to Deny" (NOID) under the regulation at 42 C.F.R. §§ 422.502(c)(2).[9]

If CMS denies an MA-PD application, the applicant has a right to a hearing before a CMS Hearing Officer under 42 C.F.R. §§422.660 or 423.650. The regulations state that at hearing, the applicant has the burden of proving by a preponderance of the evidence that CMS' determination was inconsistent with the requirements of §§422.501 for Part C and §§ 422.502 and 423.503 for Part D.

Subregulatory Guidance

CMS issued its 2012 Application Cycle Past Performance Review Methodology on December 12, 2010 (Methodology) through its HPMS.[10] Revelant provisions of the Methodology are stated below.

> This methodology below describes in detail the approach CMS uses to evaluate the performance of all Medicare C and D contractors, evaluations that may also identify organizations with performance so impaired that CMS would prohibit the organization from further expanding its Medicare operations.
>
> ***Review Period***
>
> CMS clarified in its April 15, 2010 final Part C and D regulations that we limit our performance review each year to the 14-month period leading up to the annual application submission deadline. (As a practical matter, we count the entire calendar month in which applications are due as the 14th month.) The specific 14-month performance period that will be assessed for the 2012 Application Review Cycle is January 1, 2010 through February 28, 2011.
>
> 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 of the review period but before we finalize our results, we include the matter in our assessment.
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organizations or sponsors. In this final rule, we adopt the provisions as proposed.

[8] The preamble to the 2010 Final Rule at 19683 states: "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."

[9] *See* similar provision for Part D at 42 C.F.R. §423.503(c)(2).

[10] CMS Website, http://www.cms.gov/PrescriptionDrugCovContra/Downloads/PastPerformanceMethodology_12.10.10Final.pdf

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)
3. **Multiple Ad Hoc Corrective Action Plans (CAPs)** (i.e., findings of egregious violations that were discovered outside of the audit process, such as through beneficiary complaints)
4. **Ad Hoc CAPs with Beneficiary Impact** (i.e., CAPs where the compliance violation hindered health or drug access or imposed a financial burden on plan members)
5. **Financial Watch List** (i.e., organizations with financial solvency problems)
6. **One-Third Financial Audits** (i.e., organizations with adverse audit opinions or disclaimed audit reports stemming from a CMS One-Third Financial Audit)[11]
7. **Performance Audits** (i.e., significant findings, in number or scope, as described in a performance audit report)
8. **Exclusions** (i.e., exclusion from: receiving auto-enrollees, appearing in Medicare & You, having certain formulary update opportunities, or participating in the Online Enrollment Center)
9. **Enforcement Actions** (i.e., intermediate sanctions and civil money penalties imposed or in place during the performance period)
10. **Terminations** (i.e., requests by an organization to rescind a contract with CMS after the annual non-renewal deadline or after the annual marketing and enrollment period has begun, mutual terminations to be effective mid-year, or terminations initiated by CMS)
11. **Outstanding Compliance Concerns Not Otherwise Captured** (i.e., compliance and enforcement actions largely developed but not yet formally issued by CMS)

In calculating scores under the Methodology, it states the following:

[11] Section 1857(d)(1) and 1860D-12(b)(3)(C) of the Act requires the Secretary to provide for an annual audit of the financial records of a least one third of all active MAOs and PDPs. All contracts that receive adverse audit opinions or disclaimed audit reports receive on negative performance point under the Methodology. The auditor issues a disclaimed audit report when it could not form and and consequently refuses to present an opinion on management's assertions. The auditor issues an adverse audit report when it determines that the financial data is materially misstated. *See* Methodology at 7.

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.

Additionally, we identify applying contracting organizations with no prior contracting history with CMS (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.

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.

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.

(Emphasis added.)

Factual and Procedural Background

United Healthcare Insurance Company (United) is a large provider of MA-PD services. United MA-PD plans cover approximately 694,248 Medicare members and holds 40 MA-PD contracts with CMS.[12] During the Contract Year (CY) 20011, United submitted ten applications to CMS for approval.

On April 28, 2011, CMS sent NOIDs to the United applications.[13] Specifically, CMS denied United's application for qualification for service area expansions of its Part C and Part D plan operations under contracts H0710, H1509, H1944, H5417, and H5652 and its Part D operations under S5820, as well as its applications to add or expand special needs plan offerings to its contracts, H2406, H5417, and H5652. CMS also denied United's applications for new MA-PD contracts, H3812 and H3912, under which it planned to offer SNPs. The NOIDs stated that CMS has determined, pursuant to 42 C.F.R. §§ 422.502(b) and/or 423.503(c)(2), that United failed to comply with the terms of a current (i.e., 2011) or previous year's contract with CMS. The NOID stated that CMS would be issuing a final notice of denial of the applications regardless of the presence or absence of deficiencies in the submitted application materials and that no material could be submitted to cure this issue.

CMS assessed United's past performance using the published Methodology. CMS assigned United Part C and D past performance scores by assessing the performance of all of the organization's Medicare contracts for the period of January 2010 through February 2011across each of eleven performance measures, consistent with the Methodology. United contracts received negative points in three of the eleven performance measures: performance metrics (i.e., star ratings), compliance letters, and financial audits.[14] The highest number of negative points for each measure earned by a UHIC contract (star ratings=2, financial audits=1, compliance letters=2) were summed by CMS to calculate the past performance ratings of "5" for both Part C and D plans.

United filed timely appeal requests. On June 14, 2011, United submitted a brief in support of its position that CMS' determinations were inconsistent with the application requirements in 42 C.F.R. §§422.501 and 422.502 and/or 423.502 and 423.503. On June 20, 2011, CMS submitted a brief in reply to United's brief and in support of its denial of all of United's applications. On June 23, 2011, United submitted a reply brief. By letter dated June 29, 2011, United requested that the case be decided on the record.

Applicant's Contentions

United contends that the rules governing the Medicare program require that requests for expansion of MA and PDP plans be submitted on a contract-by-contract basis and that CMS reviews and grants such requests based on enumerated standards, subject to appeal on a contract-by-contract basis. United indicates that contrary to these requirements, CMS has denied all of its

[12] *See* Declaration of David Walsh, Senior Director of Regulatory Affairs for UnitedHealthcare Medicare and Retirement, a subsidiary of United Health Group, the parent organization of United, United Brief, Exhibit 6, No. 6.
[13] *See* United Brief, Exhibit 1.
[14] *Id.*

requests, on a legal entity basis, based on the Methodology which ignores the differences among plans included within each of these contracts and also ignores differences among contracts by applying its findings at the entity level. This wholesale denial is at odds with CMS' stated process for contract-level review and provides disincentives for MA organizations to offer SNPs. The Methodology also results in inequitable treatment among various plan sponsors depending on the number of contracts held by the sponsor and the complexity of its plans.

United indicates that the 10 applications in this case include high performing MA and PDP contract offerings that are diverse both in product composition and geographic area. This appeal includes an MA contract that has exceeded 95% overall member satisfaction for five straight years and has a hospital readmission rate of approximately half the national average (H5652), a contract that has been awarded a performance rating of four out of a possible five stars (H2001), and a contract that will offer members more choice in a location where little choice exists (H1944).[15] One contract subject to this appeal provides services in five counties that would have been approved two years ago but for an administrative error occurring when the counties were inadvertently excluded from the original national service area that CMS approved in 2009 (H1509).[16] The sole PDP contract part of this appeal represents United's effort to include New York within a service offering so employers can provide coverage to all employees through a complete national service area (S5820).[17] United also looked to expand its institutional special needs plans, which have been nationally recognized as a model of quality care for this vulnerable population, into additional counties in Connecticut, Florida, Kentucky, and Ohio (H0710, H5417, and H2406). Finally, UHIC seeks to offer new contracts that will deliver integrated care to individuals in a network of assisted living facilities in Oregon and Pennsylvania (H3812 and H3912).

United points out that CMS has promulgated detailed requirements relating to the application process and the evaluation and determination procedures for entities seeking to apply to be sponsors of MA plans or PDPs.[18] In general, CMS is required to evaluate an application for a new MA or PDP contract or contract expansion "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."[19] After CMS evaluates <u>all relevant information</u>, it determines whether the applicant's application meets all requirements in CMS regulations.[20] However, in a recent rule, CMS changed the regulations to state that it "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 CMS regulatory requirements."[21]

CMS cites 42 C.F.R. § 422.502(b) as authority to categorically deny the applications that are being appealed. In the preamble to the 2010 Final Rule, CMS states,

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[15] United Brief, Exhibit 6, §§ 13, 15 -16.
[16] *Id.* §14.
[17] *Id.* §17.
[18] 42 C.F.R. §§ 422.501, 423.502. Similar requirements exist in the Medicare Part D regulations. 42 C.F.R. §§ 423.502, 423.503.
[19] 42 C.F.R. § 422.502(a)(1).
[20] 42 C.F.R. § 422.502(a)(2) (emphasis added).
[21] 42 C.F.R. § 422.502(b) (emphasis added); 2010 Final Rule at 19684. The same standard exists in the Medicare Part D regulations. 42 C.F.R. § 423.503(b).

> We expect to make past performance methodology available through publication in our manuals. We believe that the manuals provide us and sponsors with the best available avenue for providing such detailed information and making updates to it as we continue to gain more experience with conducting past performance analysis.[22]

United points out that the Methodology was neither promulgated by regulation nor submitted as part of a comment request from stakeholders. Furthermore, instead of publishing it in the manuals as the regulation anticipated, CMS unilaterally issued a memorandum without stakeholder comment outlining an elaborate review structure on December 12, 2010.

Under the Methodology, CMS has established 11 performance categories; assigns "negative point values" to all categories and many sub-factors of the categories that are reviewed; and that it may reject requests for expansions from MA contracts with four or more negative points, and PDP contracts with five or more negative points. United points out that under the Methodology, CMS assigns total negative point values on a contract basis (ignoring plan differences as well as multiple contracts in a single entity), and ignores the overall individual contract's performance. Instead, results are applied to the legal entity level and CMS assigns the highest number of negative points associated with the worst contract performers for each performance area among all of the contracts held by that legal entity to determine whether a request for expansion will be denied, based on past performance. Given United's size and the complexity of its plan offerings, even if United reaches the threshold number of negative performance points pursuant to the Methodology, this does not legally indicate that it has "failed to meet the requirements" of Medicare Parts C and D, which is the standard required to deny applications based on past performance set forth in CMS regulations.[23]

United notes that in the past, CMS evaluated applications for an MA contracts solely on the basis of information contained in the application itself related to that contract. However, CMS reached beyond the usual process with the promulgation of a recent regulation that permits the agency to look outside of the contract application if an MA plan or PDP fails to comply with Parts C and D program requirements.[24] CMS bases its authority to establish this Methodology on its newly created authority to deny applications even if all regulatory requirements are met, based on past performance.[25] In the preamble to the 2010 Final Rule, CMS states,

> We also want to emphasize 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.[26]

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[22] 2010 Final Rule at 19685.
[23] *See* 42 C.F.R. §§ 422.502(b), 423.503(b).
[24] 42 C.F.R. §§ 422.502(b), 423.503(b).
[25] The Methodology, (attached hereto as an Appendix) p. 1.
[26] 2010 Final Rule at 19685.

United contends that CMS has not been conservative with its new authority – it created a Methodology that does not capture widespread poor performance and, instead, looks at the few "worst" performing contracts within a large legal entity and precludes some of the best performers from expanding into new geographic service areas by extrapolating the "worst" performers to taint a large entity with diverse contracts. This unfairly impacts large organizations (which may have high performing plans) in favor of a wholesale arbitrary denial, an outcome that is at odds with CMS's stated purpose of the Methodology. While this approach may seem rational when reviewing a contract sponsored by a legal entity that has few contracts, United contends that applying the Methodology at the legal entity level disproportionately impacts large entities.

United points out that the four contracts that have a 2.5 star ratings have significant portions of SNP and Medicaid enrollees, covering a total of approximately 26,689 enrollees.[27] In effect, the star ratings of contracts covering 3.8% of its Medicare beneficiaries is imputed to all other contracts (36) that either have at least 3 stars (and many of which are ranked even higher) or are not rated.

United also asserts that the Methodology itself inequitably and disproportionately impacts United and other plan sponsors that provide SNPs to Medicare's most vulnerable beneficiaries. CMS denial is based upon a methodology that focused on a small number of contracts that are not seeking to expand and are not subject to this appeal. United also notes that a careful review of these contracts reveals that one (H2111) had 100% of its members in an SNP and all four of these contracts have significant portions of members in SNPs (at the end of 2010, contract H1717 was 43% SNP, contract H3887 was 24% SNP, and contract H7187 was 30% SNP).[28]

United points out that SNPs provide MA services to the following subsets of vulnerable Medicare beneficiaries.[29] The Methodology does not take into account the fundamental differences in quality measures between SNPs and MA plans. The star rating system relies heavily on measures related to preventive health screening and treatment of risk factors that may not be appropriate for individuals in the SNP population.[30] United indicates that the Methodology will have the unintended consequences of discouraging large entities from renewing contracts with SNPs serving Medicare's most vulnerable populations.

United also presented a detailed review of the contracts that are the basis of this appeal in order to demonstrate that they individually merit approval for expansion.[31] United asserts that the data provided by CMS illustrates how many of its contracts under appeal are outperforming the industry based on the low or non-existent negative points that have been assigned. United notes that CMS's brief indicates the problems relate "to only a small number of its dozens of contracts."[32] Nevertheless, CMS concludes that, "when an entity holds multiple contracts, it is appropriate to factor identified non-compliance into the entity's overall score, no matter which

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[27] Ex. 6, §§ 6, 7.
[28] Ex. 6, § 8.
[29] *See* CMS Website, *Special Needs Plans Assessment Program Overview, available at* http://www.cms.gov/specialneedsplans/.
[30] *See* United Brief at 14-15.
[31] *See* United Brief at 16–27.
[32] *See* CMS Brief at 12.

contract may be the source of non-compliance."[33] Although it is clear that CMS followed its published Methodology, CMS has not supported: (1) that the Methodology is in accordance with CMS's review process and the regulations that evaluate applications on a contract-by-contract basis, and (2) how this furthers the key requirements of the Medicare program – serving the needs of the elderly and disabled population.

Finally, United points out that much of the data CMS uses in the Methodology does not relate to circumstances present in the current contracts or even in the entity. For example, the one-third financial audits the Methodology analyzes are based on contract years 2006 and 2007. United explained that this the issues was caused by adverse or disclaimed findings in a minority of contracts and has been addressed. In the latest round of financial audits conducted on United (for contract year 2008), there were no adverse or disclaimed findings. [34]

United explains that its applications represent thoughtful, selective expansions that will enhance the Medicare program. Accordingly, CMS' denial of these applications should be overturned.

CMS' Contentions

CMS indicates that United has the burden of proving by a preponderance of the evidence that CMS' determination was inconsistent with Medicare Advantage and Part D requirements as defined in 42 C.F.R. §422.501, §422.502, §423.502, and §423.503. 42 C.F.R. §422.660(b)(1) and §423.650(b)(1). CMS contends that United fails to meet the preponderance standard and CMS' determination was fully supported by both the facts of United's performance issues and CMS' regulatory authority to deny on that basis.

CMS states that it denied United's applications solely on the basis of its determination that United failed to comply with Part C and D requirements under its current MA and PDP sponsor contracts, pursuant to its authority at 42 C.F.R §§422.502(b) and 423.503(b). CMS notes that it clarified the past performance authority through its 2010 Final Rule.[35] There, CMS amended §422.502(b) and §423.503(b) to state that in conducting its analysis of a contracting organization's past performance, it would look back over the 14-month period immediately preceding the deadline for the submission of contract qualification applications. In the same rule, it also added paragraphs 42 C.F.R. §422.504(m) and §423.505(n) which it stated that CMS would determine a sponsor to be out of compliance when it failed to meet a standard already articulated in statute, regulation, or guidance or, in the absence of an articulated standard, its performance represented an outlier relative to the performance of other organizations.

CMS indicated in the preamble that it expected to develop a methodology for conducting the analysis of organizations' past Medicare contract performance and make it available through publication in its manuals. Because of the additional time needed to draft and publish manual sections, CMS published its Methodology through the HPMS, the electronic system of records that CMS maintains for the administration of the Part C and Part D programs on December 12, 2010. CMS states that there is no substantive difference between guidance released through

[33] *Id.*
[34] While CMS indicates that it has not yet contracted for the 2009 audits, CMS Brief at 10, United asserts that there is no rational for ignoring the 2008 audit and relying on older audits.
[35] 2010 Final Rule at 19684.

HPMS and its manual and therefore, it was permissible for CMS to meet the preamble commitment, in a more timely manner, by issuing the Methodology through HPMS.

CMS indicates that it assigned United's Part C and D past performance scores by assessing the performance of all of the organization's Medicare contracts for the period of January 2010 through February 2011. It did so by evaluating United across each of the eleven performance measures in the published methodology. United contracts received negative points in three of the eleven performance measures: performance metrics (i.e., star ratings), compliance letters, and financial audits.[36] The highest number of negative points for each measure earned by a United contract (star ratings=2, financial audits=1, compliance letters=2) and all together United had a score of "5" on both the Part C and D sides. In contrast, the average past performance score for all contracting entities under Part C was 1.22, as it was also for Part D contractors.[37]

CMS notes that United contends that CMS should restrict its analysis of past contract performance to only the performance associated with the contracts for which an organization has submitted an application (and specifically in this case, for which United has requested an appeal from its CY 2012 application denials). CMS states that this would be inconsistent with the purpose of 42 C.F.R §422.502(b) and §423.503(b) and would limit its ability to restrict organizations with previous or existing contracts that have not complied with Medicare program requirements.

CMS states that the purpose of the past performance analysis, as part of the contract application process, is to ensure that organizations that have demonstrated difficulties in administering their current Medicare lines of business are not permitted to expand their operations before they take appropriate action to correct identified deficiencies. The effective application of this authority by definition requires a review and assessment of the legal entity, not simply one contract out of many that an organization may hold.

The regulatory and preamble language itself makes clear that CMS must consider the performance of the "MA organization" or "Part D plan sponsor" as a whole. The language recognizes that CMS contracts with an entity and explicitly states that CMS will review performance of the applicant in aggregate, across its various contract offerings.

CMS further indicates that United's proposed limitation fails to consider that CMS must assess applications not only for service area expansions, but also for entirely new Medicare contracts. Were CMS to adopt United's methodology, it would not be able to conduct any past performance review, as part of our consideration of applications for new contracts, as there can be no past performance associated with a contract that CMS has yet to award.

CMS, for further context, points out that a determination not to approve an application for contract qualification is distinct from a determination to terminate or non-renew a contract, or impose intermediate sanctions. Accordingly, the findings that CMS must make with respect to each action are different.

[36] CMS Brief, Exhibit 1.
[37] CMS Brief, Exhibit 2, Item 15.

To justify a contract termination, CMS generally determines that a sponsor has substantially failed to meet one or more Part C or D program requirements.[38] A similar analysis applies to CMS' imposition of intermediate sanctions (e.g., suspension of the organization's marketing and enrollment activities).[39] These higher thresholds are appropriate when one considers the severe consequences that a sponsor suffers when it loses some or all of its right to conduct Medicare business. This high standard in part provides assurances to contracting organizations that once they have made the investments necessary to operate their Medicare business, it will not be taken away on the basis of minor instances of non-compliance. CMS also has an interest in the infrequent occurrence of contract terminations as they create disruption for beneficiaries who must elect new plan coverage or have it elected for them.

The past performance portion of the application process, by contrast, presents the opportunity for CMS to consider whether an organization should be permitted to absorb additional Medicare business before beneficiaries begin to rely on newly approved plans and organizations make investments in reliance on the new contract. To deny an application, CMS only needs to determine that a lower level of non-compliance with Part C or D requirements exist.

CMS notes that United contends that under the Methodology, any large organization, holding multiple Medicare contracts, would be disadvantaged relative to other applicants when CMS conducts its past performance reviews. United indicated that it holds over 40 Medicare Advantage contracts serving approximately 700,000 beneficiaries and that its poor performance on a small number of contracts serving fewer than 5% of its total Medicare enrollment is being given too much weight in CMS' analysis.[40] CMS' expectation in response to such scores would be for United to focus its resources on improving these ratings, rather than expanding its service area. CMS contends that it is in the best interests of the Part C and D programs to restrict expansion until there is improvement in organizations with poor performers.

CMS indicates that in its Methodology, organizations accumulate negative points in a performance measure only when their performance represents an extreme outlier relative to other contracting organizations. While United objects to performance measure scores being "rolled up" to the contracting entity, the main objective of the past performance review authority is to assess an entity's fitness to take on new business. When an entity holds multiple contracts, it is appropriate to factor identified non-compliance into the entity's overall score, no matter which contract may be the source of the non-compliance.

CMS also asserts an analysis of the performance history of all of that entity's contracts is entirely consistent with the goals and requirements of 42 C.F.R. §422.502(b) and §423.503(b) and is designed to ensure that an organization could not dismiss and fail to correct poor performance on the premise that it only affects a small percentage of their membership while asking CMS to allow it to expand through the application process.

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[38] 42 C.F.R. §422.509(a), §423.510(a).

[39] 42 C.F.R. §422.752(a) and (b), §423.752(a) and (b).

[40] In presenting its assertion that the Methodology is unfair, United states, United Brief at 8, that CMS assigns negative point values to each of a sponsor's separate contracts, but then ignores the overall score for that contract by taking the highest scores for each performance category from all of an entity's contracts and applying them to the entity. CMS notes, however, in this case, that United holds three separate contracts (H1717, H3887, and H7187) which each received a total of 4 Part C negative performance points, sufficient to meet the threshold for denial of United's applications.

CMS indicates its Part C and D plan rating results for 2011, the most recently issued, provide no support for the argument that MA organizations offering SNPs face special challenges in achieving good star ratings. The results for all Part D contracts, when broken down into three categories by percentage of SNP enrollment per contract (SNP enrollment less than 50%, SNP enrollment greater than 50%, and SNP enrollment 100% of total contract enrollment) show that approximately 15% to 18% in each category receive less than three stars.[41] The Part C results are slightly more mixed but still show that contracts with SNP enrollment receiving less than three stars are decidedly in the minority relative to their peers. Among the same enrollment percentage categories described for Part D, the percentage of Part C contracts with low star ratings ranged from approximately 15% to 29%. The rate of less than three star performers drops when SNP enrollment increases from 50% or more to exactly 100%. That is, contracts with only SNP members tend to have strong performance, equal to contracts with fewer than 50% SNP members. As a result, one may conclude based on these data that having SNP members in a contract does not pull down summary plan rating results for either the Part C or Part D ratings.

With respect to the One-third Financial Audits, CMS explains that in January 2010, CMS-contracted auditors issued United a total of seven reports which resulted in adverse or disclaimed opinions on management's assertions pertaining to financial audits for contract years 2006 and 2007. United received reports of adverse opinions for operations during contract year 2006 for contract H0620, and for contract years 2006 and 2007 for contracts H2111 and H2228.[42] It also received reports which resulted in disclaimed opinions for 2006 and 2007 for contact H5507.[43] These types of audit reports signal the auditor's determination that there may be a lack of internal controls over United's operations with respect to the identified contracts and/or a failure to devote the necessary resources to respond to an auditor's request for documentation.

Each report representing a decision by an auditor to issue a report with adverse or disclaimed findings stands on its own as evidence of an organization's failure to comply with Part C and D program reports. The significance of these reports is amplified when viewed in the context of the performance of all audited Part C and D sponsors. For the 2006 contract year, CMS' contractors issued opinions following 89 engagements, and of that number only 14 resulted in disclaimers and 7 in adverse opinions.[44] For 2007, reports were issued for a total of 200 engagements, of which 24 resulted in disclaimers and 9 in adverse opinions.[45] United's audit performance is demonstrably poorer than its peers in the Part C and D program. In 2006, United had 3 adverse opinions and 1 disclaimer, and in 2007, two adverse opinions and 1 disclaimer.[46] Also, if the implementation of Part D presented any significant obstacles to sponsors achieving acceptable audit results as suggested by United,[47] it is not demonstrated by this data as all sponsors were required to implement Part D at the same time and comply with the same requirements, yet only a handful had poor audit results.

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[41] CMS Brief. Exhibit 4, No.12.
[42] CMS Brief, Exhibit 5, Nos. 4 and 6.
[43] *Id*., Nos. 5 and 7.
[44] *Id*., No. 9.
[45] *Id*., No. 11.
[46] *Id*., Nos. 4,5,6 and 7.
[47] United Brief at 18.

United states that the adverse and disclaimed opinions referenced above have "been removed."[48] According to CMS' Office of Financial Management, the component responsible for administering the one-third audit program, and the Program Compliance and Oversight Group, the component responsible for monitoring organizations' correction of audit findings, this is not so.[49] Also, CMS questioned how United can state that "the Financial Activity Audits for 2009 have not resulted in any adverse or disclaimed findings," when CMS has not yet even contracted with auditors to perform the contract year 2009 audits.[50]

CMS assigned negative points to United for its performance with respect to the number and type of letters that CMS issued documenting its non-compliance with Part C or D requirements.[51] CMS takes account not only of the number, but also the significance of each compliance notice.[52] CMS assigns one negative past performance point to a contract for which a weighted compliance letter score fell at or above the 80th percentile among all contracts and two points for those contracts with scores at or above the 90th percentile. For Part C, the 80th percentile was a weighted score of 10, while the 90th percentile was 14. For Part D, the 80th percentile for MA-PD contracts was 14, while the 90th percentile was 19.[53] The Part D weighted score for 24 United contracts reached the 90th percentile or above, earning each contract two negative points for its Part D performance.[54] The Part C weighted score for 22 United contracts reached the 90th percentile or above, earning each of those contracts two negative points for their Part C performance.[55] As the highest negative point value for compliance letters achieved by any United contract was "two," CMS added two points to United's Part C and D past performance scores.[56]

The high rate at which United's Part C and D performance required CMS to issue compliance notices is not limited to a single or even a handful of United's contracts. With 43 of United's 53 Part D sponsor contracts (MA-PD and stand-alone PDP), and 35 of its 51 MA contracts rated as at least 80% outliers with respect to compliance notices, CMS believes this is a clear indication of weaknesses in United's performance across all lines of its Medicare business.[57] Performance of the contact-level comparison suggested by United only confirms CMS' assessment of United's compliance letter performance. The average weighted Part D compliance letter score for all MA-PD contracts was 8.19, while the average among those contracts held by United was 17.47. The average for all PDP sponsor contracts was 8.56, while United's average was 25.5.[58] Finally, for Part C, the average score among all MA contracts was 5.59, while United contracts averaged 12.8.[59]

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[48] *Id.*
[49] CMS Brief, Exhibit 5, No. 8; CMS Brief, Exhibit 6, No. 4.
[50] United Initial Brief at 18, CMS Brief, Exhibit 5, No. 12.
[51] CMS Brief, Exhibits 7 and 8.
[52] Methodology at 3 - 5.
[53] CMS Brief, Exhibit 2, No. 9.
[54] *Id.*, No. 9.
[55] *Id.*, No. 10.
[56] *Id.*, No. 14.
[57] Id., No. 10.
[58] *Id.*, No. 11.
[59] *Id.*

CMS points out that United discusses ways in which it believes that approval of the applications that are the subject of this appeal would be in the best interests of the Medicare program and its beneficiaries.[60] CMS asserts that this information does not pertain to any Part C or D application requirement under §422.502 and §423.503 or the application materials CMS issued pursuant to such authority, and CMS would not have been authorized to consider them during the CY 2012 application process. Moreover, the information has no bearing on United's past Medicare contact performance, the only basis for denying the applications, and therefore should not be considered under the Hearing Officer's authority.

Decision

The Hearing Officer notes that the issue in this case is whether CMS' denial of United' applications was consistent with the requirements in 42 C.F.R. §§ 422.501 and 422.502 and/or 423.502 and 423.503.

The record in this case is clear. CMS denied all ten of United's applications pursuant to 42 C.F.R. §§ 422.502(b) or 423.503(b) because United failed to comply with the terms of a current (i.e., 2011) or previous year's contracts with CMS. It is undisputed that CMS evaluated United's performance utilizing the Methodology it issued in December 2010 through its HPMS prior to the beginning of the 2012 Application Cycle. Under the Methodology, CMS evaluated all of the United's contracts on eleven performance categories. CMS found that some of United's contracts received negative points in three of the eleven performance measures: performance metrics (i.e., star ratings), compliance letters, and financial audits.[61] CMS summarized the contract-level performance results (that is, for each of United's contracts) to the contracting organization level (that is, the licensed, risk bearing legal entity, in this case United) that holds the contracts with CMS. The highest negative scores among United's contracts (2 negative points for performance measures, 2 negative points for compliance letters and 1 negative point for financial audits) were assigned to United, giving it a total score of 5 negative points for both its Part C and D plans. These scores equaled or exceeded the threshold of negative performance points establish by CMS in its Methodology of 4 points for Part C plans and 5 points for Part D plans.

The Hearing Officer notes that United questions whether CMS' Methodology, which assesses past performance at the legal entity level, as opposed to the past performance at the individual applicant level, was proper and consistent with the rest of the regulation that requires CMS to evaluate each application based on what is submitted in the application.[62]

The Hearing Officer notes that the current controlling regulation pertaining to application evaluation and determination procedures at 42 C.F.R. §§ 422.502 and 423.503, states the following.

> (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

[60] United Brief at 20 - 27.
[61] CMS Brief, Exhibit 1.
[62] *See* United contentions referring to 42 C.F.R. 422.502(a) and 423.503(a), supra.

> 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 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.**

42 C.F.R. § 422.502(b).[63] (Emphasis added.)

Moreover, in the Preamble to the 2010 Proposed Rule, CMS further explained the controlling (modified) regulation.

> 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. 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.''

(emphasis added).[64]

The Hearing Officer further notes that in the Preamble to the 2010 Final Rule, CMS also stated:

[63] *See* similar provision for Part D at 42 C.F.R. §423.503(b).
[64] 2010 Proposed Rule at 54641-2.

> 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.

(emphasis added).[65]

The Hearing Officer finds that to the extent that an MA organization may have had any question regarding CMS' authority to review past performance, the new regulatory text and preamble clarify that CMS would consider multiple current and prior contracts held by the organization in determining whether the organization's existing operations can be expanded.

Furthermore, the Hearing Officer notes that CMS issued its Methodology to organizations on December 12, 2010 through its HPMS, the electronic system of records that CMS maintains for the administration of the Part C and D programs.[66] In the cover memorandum to the Methodology, CMS states the following.

> Sections 42 C.F.R §422.502(b) and §423.503(b) of the regulations governing the Medicare Advantage and Prescription Drug programs authorize CMS to deny an organization's application either to offer Medicare benefits under a new contract or in an expanded service area during the subsequent contract year if a review of an organization's past performance finds that the organization has been out of compliance with any requirement.

In the Methodology, CMS evaluates and calculates negative performance both at the contract level and then summarizes the results at the contracting organization (legal entity) level. The Methodology states the following.

> **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.**

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[65] 2010 Final Rule at 19685-6.

[66] The Hearing Officer notes that United raised concerns that the Methodology was not issued in CMS' Medicare Managed Care and Prescription Drug Manuals as proposed in the Preamble to the 2010 Final Rule. The Hearing Officer notes that CMS routinely issues guidance concerning the administration of the Part C and D programs through the HPMS and that there is no substantive difference in releasing this guidance through the HPMS as opposed to the manuals. Also, while the preamble to the 2010 Final Rule at 19684-5, states that CMS "expected" to make the past performance available through publication in the manual, the December 2010 letter itself satisfied the associated commenters concern that CMS clearly articulate its methodology.

* * *

> 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.

The Hearing Officer notes that United has pointed out a number of concerns with the CMS' Methodology. United contends that the 10 individual applications at issue in this case were from contracts that would not have been denied based on their own performance records; that the Methodology, itself, unfairly and disproportionately impacts large plan sponsors that may only have a few areas of poor performance; and unfairly and disproportionately impacts organization that offer SNPs that serve Medicare's most vulnerable beneficiaries. The Hearing Officer finds that the Methodology CMS established to determine negative performance among any prior or current contract of a MA organization is consistent with the expressed intention of the regulation to assess negative performance at the organization or legal entity level as opposed to just considering the merits of an individual applicant.[67] The Hearing Officer also notes that the Methodology is consistent with CMS' intentions, expressed in the preambles of the 2010 Proposed and Final Rules, that an organization demonstrating significant operational difficulties should focus on improving its existing operations before expanding. With respect to SNPs, the Hearing Officer notes that CMS, in the Preamble to the 2010 Final Rule, indicated that it was "cognizant of the variety of products offered by Medicare contractors, and when an element of our past performance evaluation is affected by the unique feature of a particular plan type, we will adjust our methodology as appropriate"[68] The Hearing Officer notes that CMS considered the issue of performance rating by plans with SNP populations.[69] The data did not conclusively indicate that having SNP members in a contract materially pulled down summary plan ratings for either Part C or Part D ratings.[70]

Finally, the Hearing Officer notes that United objected to the use of the one-third financial audits from fiscal years 2006 and 2007 in its evaluation of its current applicant. United asserted that it did not receive adverse results in the 2008 audits, and questioned why this more recent year was not utilized in the analysis. The Hearing Officer notes that the review period was addressed in the Methodology. It states:

> CMS clarified in its April 15, 2010 final Part C and D regulations that we limit our performance review each year to the 14-month period leading up to the annual application submission deadline. (As a practical matter, we count the entire calendar month in which applications are due as the 14th month.) The specific 14-month

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[67] The Hearing Officer notes that under the Methodology, it is possible for a large organization, with isolated instances of poor performance among its many contracts, to be prohibited from further expansion, however, that did not happen in this case. The Hearing Officer notes that for two measures, the poor performance affected a significant number of United's plans. With regard to performance metrics (star ratings), United had 5 Part C plans with rating below 3.0 and 6 Part D plans with ratings below 3.0, CMS Brief, Exhibit 4 at No. 10, and for compliance letters, United had 22 Part C plans reach the 90th percentile and 24 Part D plans reach the 90th percentile, CMS Brief, Exhibit 2 at No. 10.

[68] 2010 Final Rule at 19685.

[69] *See* CMS Brief at 8.

[70] *Id.*

> performance period that will be assessed for the 2012 Application Review Cycle is January 1, 2010 through February 28, 2011. 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 of the review period but before we finalize our results, we include the matter in our assessment.

Methodolgy at 3.

While the Hearing Officer notes that the status of the 2008 one-third audit results is not addressed in the record, the Hearing Officer finds that it was appropriate to rely on the 2006 and 2007 audit results because the reports were issued (that is, the poor performance was identified) in January 2010,[71] which falls within the prior 14 month period.

Conclusion

The Hearing Officer finds that United has failed to prove by a preponderance of the evidence that CMS' denial of its applications under the Methodology was inconsistent with the requirements of 42 C.F.R. §§422.501 and 422.502 and 423.502 and 503.

Paul Lichtenstein
CMS Hearing Officer
Date: July 21, 2011

[71] *See* CMS Exhibit 5 at Nos. 4 and 6.