IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF IOWA

UNITY HEALTHCARE, Plaintiff(s), vs. ERIC D. HARGAN, Acting Secretary of Health and Human Services,[1] Defendant(s).	3:14-cv-00121-HCA (Davenport Division)
LAKES REGIONAL HEALTHCARE, Plaintiff(s), vs. ERIC D. HARGAN, Acting Secretary of the Department of Health and Human Services, Defendant(s).	5:14-cv-04097-HCA (Northern District of Iowa, Western Division) MEMORANDUM OPINION AND ORDER FOR JUDGMENT

Plaintiffs Unity Healthcare and Lakes Regional Healthcare, both Iowa hospitals, challenge decisions of the Secretary of the Department of Health and Human Services (the "Secretary") denying them payment of a specific Medicare payment known as the volume-decrease adjustment or "VDA."[2] The facts are undisputed and the plaintiffs do not challenge the statutes, regulations or interpretive guides under which the Secretary made the decision. At issue is whether the Secretary's decision was arbitrary and capricious or not supported by substantial evidence.

[1] Secretary Hargan is substituted for his predecessor in accordance with Federal Rule of Civil Procedure 25(d).

[2] As discussed further *infra* at 8-9, Unity's requested VDA was substantially reduced and Lakes' request denied.

Although these cases remain separate, because the PRRB and the Secretary dealt with them jointly, the factual background is similar and legal issues the same, the Court will issue one ruling which will be filed in each case.

I. STATUTORY AND REGULATORY BACKGROUND

The Medicare Program (the "Program") was established to provide health insurance to the aged and disabled. 42 U.S.C. § 1395 *et seq*. The Secretary has delegated authority to administer the Program to the Centers for Medicare and Medicaid Services ("CMS").[3] Under the Program qualifying health care providers are reimbursed for the costs of treating Medicare patients. 42 U.S.C. § 1395g. The payment and audit functions of CMS have been contracted to organizations known as fiscal intermediaries (FIs) and Medicare Administrative Contractors (MACs), both of which determine payment amounts due providers under the applicable law and interpretive guidelines CMS has published. 42 U.S.C. § 1395h, 42 C.F.R. §§ 413.20(b) and .24(b).

Under the Social Security Amendments of 1983, Pub. L. No. 98-21 tit. VI, 97 Stat. 65, 149-72, hospitals are reimbursed for inpatient operating costs and capital-related costs on the basis of predetermined rates for each patient discharge, the Inpatient Prospective Payment System (IPPS). 42 U.S.C. § 1395ww(d). IPPS payments are based on a diagnosis-related group ("DRG") assigned to each patient. *Id.* § 1395ww(d)(2). DRG amounts "approximate the average cost of caring for a patient with a given diagnosis in a cost-effective hospital" with adjustments for geography and other factors, and not the actual cost of caring for a patient. (Pl. Brief [19-1]).

Providers (hospitals) submit annual cost reports to the MAC at the close of their accounting year, showing costs incurred for the fiscal year and the proportion of the costs allocable to the Program. 42 C.F.R. §§ 413.20, 413.24(f). The MAC audits the cost report and issues a Notice of

[3] Formerly the Health Care Financing Administration (HCFA). (Def. Brief [25] at 1).

Program Reimbursement (NPR), the total Medicare reimbursement due the hospital for that fiscal year. 42 C.F.R. § 405.1803. A hospital may appeal the MAC's reimbursement determination to the Provider Reimbursement Review Board ("PRRB"). 42 U.S.C. § 1395oo(a); 42 C.F.R. § 405.1835. The PRRB is an administrative review entity appointed by the Secretary to adjudicate disputes between hospitals and the MACs, 42 U.S.C. § 1395oo(a), conduct hearings and issue written decisions. 42 C.F.R. § 405.1871. A decision by the PRRB is final unless reversed, affirmed or modified by the Secretary. 42 U.S.C. § 1395oo(f)(1); 42 C.F.R. § 405.1875(b). The Secretary has delegated PRRB review authority to the Administrator of CMS ("Administrator"). 42 C.F.R. § 405.1834. A final decision by PRRB or by the Administrator is subject to judicial review. 42 U.S.C. § 1395oo(f); 42 C.F.R. § 405.1877.

Both plaintiff hospitals qualify as "Sole Community Hospitals" (SCHs) as defined in 42 C.F.R. § 412.92. SCHs may be entitled to an adjustment of their Medicare reimbursement payments if they incur a decrease in inpatient discharges of more than five percent from one cost reporting year to the next, the VDA.

> In the case of a sole community hospital that experiences, in a cost reporting period compared to the previous cost reporting period, a decrease of more than 5 percent in its total number of inpatient cases due to circumstances beyond its control, the Secretary shall provide for such adjustment to the payment amounts under this subsection (other than under paragraph (9)) as may be necessary to fully compensate the hospital for the fixed costs it incurs in the period in providing inpatient hospital services, including the reasonable cost of maintaining necessary core staff and services.

42 U.S.C. § 1395ww(d)(5)(D)(ii). To qualify for the VDA, a hospital must timely submit its request for payment with information which "[d]emonstrate[es] the size of the decrease in discharges and the resulting effect on per discharge costs" and "show[ing] that the decrease is due to circumstances beyond the hospital's control." 42 C.F.R. § 412.92(e)(2). It is undisputed that both plaintiff hospitals experienced qualifying decreases.

The FI or MAC then determines the appropriate adjustment amount, if any, which is due the hospital:

> The intermediary determines a lump sum adjustment amount not to exceed the difference between the hospital's Medicare inpatient operating costs and the hospital's total DRG revenue for inpatient operating costs based on DRG-adjusted prospective payment rates for inpatient operating costs . . . .
>
> (i) In determining the adjustment amount, the intermediary considers—
>
> > (A) The individual hospital's needs and circumstances, including the reasonable cost of maintaining necessary core staff and services in view of minimum staffing requirements imposed by State agencies;
> > (B) The hospital's fixed (and semi-fixed) costs, other than those costs paid on a reasonable cost basis under part 413 of this chapter; and
> > (C) The length of time the hospital has experienced a decrease in utilization.

42 C.F.R. § 412.92(e)(3). CMS has provided interpretive guidance in the Provider Reimbursement Manual, CMS Pub. No. 15-1 (PRM 15-1). The applicable guidance instructs the MACs in calculating VDAs:

> B. Amount of Payment Adjustment. - Additional payment is made to an eligible SCH for the fixed costs it incurs in the period in providing inpatient hospital services including the reasonable cost of maintaining necessary core staff and services, not to exceed the difference between the hospital's Medicare inpatient operating cost and the hospital's total DRG revenue.
>
> Fixed costs are those costs over which management has no control. Most truly fixed costs, such as rent, interest, and depreciation, are capital-related costs and are paid on a reasonable cost basis, regardless of volume. Variable costs, on the other hand, are those costs for items and services that vary directly with utilization such as food and laundry costs.
>
> In a hospital setting, however, many costs are neither perfectly fixed nor perfectly variable, but are semifixed. Semifixed costs are those costs for items and services that are essential for the hospital to maintain operation but also vary somewhat with volume. For purposes of this adjustment, many semifixed costs, such as personnel-related costs, may be considered as fixed on a case-by-case basis.
>
> In evaluating semifixed costs, the intermediary considers the length of time the hospital has experienced a decrease in utilization. For a short period of time, most

> semifixed costs are considered fixed. As the period of decreased utilization continues, we expect that a cost-effective hospital would take action to reduce unnecessary expenses. Therefore, if a hospital did not take such action, some of the semifixed costs may not be included in determining the amount of the payment adjustment.
>
> The adjustment amount includes the reasonable cost of maintaining necessary core staff and services. The intermediary reviews the determination of core staff and services based on an individual hospital's needs and circumstances; e.g., minimum staffing requirements imposed by State agencies.

PRM 15-1 § 2810.1(B). In processing an adjustment request the following further directions are provided:

> D. Determination on Requests.--The intermediary reviews a hospital's request for additional payment for completeness and accuracy. If any of the required documentation is missing, incomplete, or inaccurate, the intermediary requests the needed information. The intermediary makes a determination on the request and notifies the hospital of the decision within 180 days of the date the intermediary receives all required information.
>
> The payment adjustment is calculated under the same assumption used to evaluate core staff, i.e., the hospital is assumed to have budgeted based on prior year utilization and to have had insufficient time in the year in which the volume decrease occurred to make significant reductions in cost. Therefore, the adjustment allows an increase in cost up to the prior year's total Program Inpatient Operating Cost (excluding pass-through costs), increased by the PPS update factor.

Id. § 2810.1(D). The manual then gives examples of how to make the adjustment request:

> EXAMPLE A: Hospital C has justified an adjustment to its DRG payment for its FYE September 30, 1987. The adjustment is calculated as follows:

Hospital C
PPS Payment Adjustment
Fiscal Year Ended 09/30/87

[1]FY 1986 Program Operating Cost		$2,900,000
PPS Update Factor	x	1.0115
FY 1987 Maximum Allowable Cost		$2,933,350
Hospital C FY 1987 Program Inpatient Operating Cost		$2,800,000
[2]FY 1987 DRG Payment	-	$2,500,000
FY 1987 Payment Adjustment		$ 300,000

[1]From Worksheet D-1, Part II, Line 54
[2]From Worksheet E, Part A, Lines 1A and 1B

Since Hospital C's FY 1987 Program Inpatient Operating Cost was less than that of FY 1986 increased by the PPS update factor, its adjustment is the entire difference between FY 1987 Program Inpatient Operating Cost and FY 1987 DRG payments.

EXAMPLE B: Hospital D has justified an adjustment to its DRG payment for its FYE December 31, 1988. The adjustment is calculated as follows:

Hospital D
PPS Payment Adjustment
Fiscal Year Ended 12/31/88

FY 1987 Program Operating Cost		$1,400,000
PPS Update Factor	x	1.0247
FY 1988 Maximum Allowable Cost		$1,434,580
Hospital D FY 1988 Program Inpatient Operating Cost		$1,500,000
FY 1988 DRG Payment	-	$1,020,000
FY 1988 Payment Adjustment		$ 414,580

> Hospital D's FY 1988 Program Inpatient Operating Cost exceeded that of FY 1987 increased by the PPS update factor, so the adjustment is the difference between FY 1987 cost adjusted by the update factor and FY 1988 DRG payments.

Id.

II. FACTUAL AND PROCEDURAL BACKGROUND

A. Unity Healthcare

Unity Healthcare ("Unity") operates a 48-bed general acute-care facility in Muscatine, Iowa. Unity is certified to provide inpatient hospital services under the Program and has qualified for and been reimbursed by CMS as an SCH. Its designated intermediary (MAC) is Wisconsin Physician Services. (Tr. [10] at 48). [4]

Between fiscal year (FY) 2005 and FY 2006 Unity experienced a 16.89% decline in inpatient discharges. (Tr. [10] at 48). The MAC has stipulated the decline was due to circumstances beyond Unity's control. (*Id.*) Unity received its NPR for FY 2006 on December 7, 2007 and submitted a request for VDA of $741,308. (*Id.*) Unity calculated its request as follows:

FY 2005 Program Operating Cost	1	$6,714,575
PPS Update Factor	2	x 1.037
FY 2005[5] Maximum Allowable Cost	3	$6,963,014
FY 2006 Program Inpatient Operating Cost	4	$5,698,829
FY 2006 DRG Payment	5	- 4,957,521
FY 2006 Payment Adjustment	6	$ 741,308

(Tr. [10-2] at 722).

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[4] All transcript citations are from the Southern District docket in 3:14-cv-00121-HCA. For ease of reference the Court has referred to the transcripts as "Tr." and the docket number.

[5] The Court, based on the examples given in the PRM, believes that this reference should actually be FY 2006 Maximum Allowable Cost (*see* p.5-6 *supra*), but that issue does not impact the analysis or conclusion in this opinion.

The MAC adjusted the reported costs by reclassifying certain costs as "variable," specifically, Unity's costs for (i) billable medical supplies, (ii) billable drugs and intravenous solutions, (iii) professional services and supplies obtained from outside providers for physical therapy, reference laboratory, blood bank, and radiology; and (iv) dietary and linen services and supplies. (Tr. at [10-1] at 394, 719). The total variable costs were subtracted from the FY 2006 Program Inpatient Operating Cost as follows:

FY 2006 Program Inpatient Operating Cost	$5,698,829
Less Variable Costs for FY 2006	- 664,994
Net FY 2006 Fixed/Semifixed Costs	$5,033,835

The MAC then took the net costs and substituted it into the line 4 amount from Unity's calculations as follows:

Net FY 2006 Fixed/Semifixed Costs	$5,033,835
Less FY 2006 DRG Payment	- 4,957,521
Net VDA Payment	$ 76,314

(Tr. [10-2] at 716). Unity disagreed with the MAC's calculations resulting in a lesser VDA and appealed the MAC's decision to the PRRB.

B. Lakes Regional Healthcare

Lakes Regional Healthcare ("Lakes") operates a 49-bed general acute-care facility in Spirit Lake, Iowa. Lakes is also certified to provide inpatient hospital services under the Program and has qualified for and been reimbursed by CMS as an SCH. It has the same designated intermediary (MAC) as Unity -- Wisconsin Physician Services. (Tr. [13-1] at 49).

Between fiscal year (FY) 2005 and FY 2006 Lakes experienced a 10.42% decline in inpatient discharges. (Tr. [13-1] at 49). The MAC has stipulated the decline was due to circumstances beyond Lakes' control. (*Id.*) Lakes received its NPR for FY 2006 on February 12, 2008 and submitted a request for VDA of $1,184,574. (*Id.*) Lakes calculated its request as follows:

FY 2005 Program Operating Cost	1	$5,317,296
PPS Update Factor	2	x 1.037
FY 2005[6] Maximum Allowable Cost	3	$5,514,036
FY 2006 Program Inpatient Operating Cost	4	$4,923,186
FY 2006 DRG Payment	5	- 3,738,612
FY 2006 Payment Adjustment	6	$ 1,184,574

(Tr. [13-2] at 530).

The MAC adjusted the reported costs by reclassifying certain costs as "variable," specifically, Unity's costs for (i) billable medical supplies associated with anesthesia, laboratory, oncology and emergency departments and respiratory therapy services, (ii) billable drugs and intravenous solutions, (iii) professional services and supplies obtained from outside providers for physical therapy, speech therapy, blood bank, and radiology; and (iv) dietary and linen services and supplies. (Tr. at [13-1] at 232). The total variable costs was subtracted from the FY 2006 Program Inpatient Operating Cost as follows:

FY 2006 Program Inpatient Operating Cost	$4,923,186
Less Variable Costs for FY 2006	- 1,360,118
Net FY 2006 Fixed/Semifixed Costs	$3,563,068

The MAC then took the net costs and substituted it into the line 4 amount from Lake's calculations as follows:

Net FY 2006 Fixed/Semifixed Costs	$3,563,068
Less FY 2006 DRG Payment	- 3,738,612
Net VDA Payment	$ - 175,544

(Tr. [13-2] at 374). On this basis, the MAC denied Lakes a VDA. (*Id.* at 371-73). Lakes appealed the MAC's decision to the PRRB.

[6] The Court, based on the examples given in the PRM, believes that this reference should actually be FY 2006 Maximum Allowable Cost (*see* p.5-6 *supra*), but that issue does not impact the analysis or conclusion in this opinion.

C. PRRB Proceedings

The PRRB held hearings on these cases on February 2 and 3, 2012, and incorporated the transcript from the Lakes case into the Unity case. Both hospitals argued that the MAC's exclusion of "variable costs" was contrary to statute and regulation and, if the exclusion was permissible, the costs eliminated were fixed or semifixed and should not have been excluded. (Tr. [10-1] at 345-362; [13-2] at 681-698).

During the Unity hearing on February 2, 2012, Dean Steiner, a Medicare auditor at the MAC, testified that in late 2008 his manager gave him the task of looking at VDAs because "we were seeing some very high dollar amounts in reviewing that process." (Tr. [10] at 261). Steiner understood that in the past the MAC had not previously removed variable costs in processing VDA requests. (*Id.* at 273). There had been no change in the regulations nor any change in the manual. (*Id.*) Mr. Steiner understood the purpose of the statute and regulation was "to ensure that the Provider is fully compensated for their fixed and semi-fixed costs so that they could continue operating as a hospital . . . no matter how many patients walk through the door." (*Id.* at 262). After looking at the statute and regulations, Mr. Steiner testified that he had determined the MAC had not been handling variable costs properly and that the only costs the MAC was to consider were fixed and semi-fixed costs. (*Id.* at 263, 274). He testified the MAC asked CMS for guidance but they never received a response. (*Id.*)

Because neither Unity nor Lakes had identified variable costs in their submissions, Mr. Steiner and the MAC reviewed the trial balances submitted with the hospitals' cost reports and "identified those accounts or sub-accounts that in our judgment would vary with utilization." (Tr. [10] at 264). To the extent an account may have included rental equipment or salaries, Steiner did not include those accounts, taking what he testified was a "very conservative approach in

identifying what [he] thought were variable costs." (*Id.* at 265). After coming up with total variable costs, they used a factoring schedule and grouped the adjustments by cost center, then reran the cost report to compute a revised Medicare operating cost. (*Id.*) Mr. Steiner testified some providers may submit variable costs with their requests; some would submit variable costs when the MAC requested; and some would not provide any variable cost estimates. (*Id.* at 266). The PRM manual defined variable costs as "those that vary based on utilization." (*Id.* at 271). He testified that physical therapy services were considered variable since they were usually paid on a per service or percentage of charge basis; medical supplies and drugs because they were charged to particular patients. (*Id.*) His assumption that drugs varied with patient volume was only a "commonsense assumption" and not based on any studies or any reference book. (*Id.* at 270). He agreed that hospital management had no control over physician orders of various things as blood or drugs. (*Id.* at 275).

On July 10, 2014, the PRRB issued its decision in both cases. (Tr. [10] at 44-63; [13-1] at 44-64). It found the MAC was authorized to eliminate variable costs to determine total fixed operating costs, but that the MAC had improperly calculated the adjustment amount and the hospitals were entitled to the VDA amounts they had requested. (*Id.* [10] at 63; [13-1] at 64). Specifically, the PRRB found that the net payment adjustment requested by the hospitals was the ceiling for payment and that since the fixed costs of each (after exclusion of the variable costs) exceeded that "ceiling," both hospitals were entitled to the ceiling amount. (*Id.* [10] at 62; [13-1] at 63).

The Administrator notified the parties the PRRB decisions would be reviewed. (Tr. at [10] at 28; [13-1] at 28). The parties and the Director of the CMS Division of Acute Care submitted comments to the Administrator, who after review modified the PRRB decisions, affirming in part

and reversing in part. (Tr. [10] at 2-11; [13-1] at 2-11). In the September 4, 2014, decisions the Administrator affirmed the PRRB finding that the MAC correctly identified and removed variable costs, but reversed the PRRB's finding on the methodology for calculating the VDA amount, stating the MAC's methodology was proper. (*Id.* [10] at 8-9; [13-1] at 8-9). The hospitals' complaints seeking judicial review were filed October 30, 2014.

III. STANDARD OF REVIEW

This Court's review of Medicare reimbursement decisions is limited to reviewing the administrative record under the Administrative Procedures Act. 42 U.S.C. § 1395oo(f)(1); 5 U.S.C. § 706. The Court only may "hold unlawful and set aside agency action, findings and conclusions" which it finds to be "arbitrary, capricious, an abuse of discretion or otherwise not in accordance with law" or "unsupported by substantial evidence." 5 U.S.C. § 706(2)(A), (E). The agency's interpretation of statutes and regulations is entitled to "substantial deference." *Siebrasse v. USDA*, 418 F.3d 847, 851 (8th Cir. 2005). "However, an interpretation which is 'plainly erroneous or inconsistent with the regulation' must be reversed." *Columbus Cmty. Hosp., Inc. v. Califano*, 614 F.2d 181, 185 (8th Cir. 1980)(quoting *Bowles v. Seminole Rock & Sand Co.*, 325 U.S. 410, 414, (1945); *Appelwick v. Hoffman*, 540 F.2d 404, 406 (8th Cir. 1976)).

> [T]he APA requires an agency to provide more substantial justification when "its new policy rests upon factual findings that contradict those which underlay its prior policy; or when its prior policy has engendered serious reliance interests that must be taken into account. It would be arbitrary and capricious to ignore such matters."

Perez v. Mortgage Bankers Ass'n, __ U.S. __, 135 S. Ct. 1199, 1209 (2015)(quoting *F.C.C. v. Fox Television Stations, Inc.*, 556 U.S. 502, 515 (2009)(citation omitted)).

IV. LEGAL ANALYSIS

A. Arbitrary/Capricious/Contrary to Applicable Law

The hospitals' challenge to the Secretary/Administrator's decision is three-fold: (1) the Secretary ignored the plain language of the VDA statute and regulation; (2) the decision directly contradicts the Secretary's own interpretive guidelines on the VDA regulation; and (3) the Secretary's decision is illogical. The Secretary responds that exclusion of variable costs is supported by the plain language of the statute, regulation and guidelines, and the methodology applied accomplishes the purposes of the statute. Interestingly, both sides argue the language of the statute, regulation and PRM is plain, plaintiff arguing the Secretary did not follow them, the Secretary arguing he did.

The issue raised is a matter of first impression in this district. The parties have brought to the Court's attention only one other federal court case dealing with the issues at hand: Magistrate Judge Mahoney's Report and Recommendation in *St. Anthony Regional Hospital v. Hargan*, No. 5:16-cv-3117-LTS (N.D. Iowa Dec. 29, 2017).

The statute states the VDA is intended to compensate "medicare dependent, small rural hospital(s)" for fixed costs they incur when they have a qualifying decrease in inpatient cases. The statute does not reference "semi-fixed" or "variable" costs. 42 U.S.C. § 1395ww(d)(5)(G)(iii). The implementing regulation expands reimbursable costs to include "semi-fixed" costs. 42 C.F.R. § 412.92(e)(3). "Variable costs" are not referenced in either. Both the statute and regulation, however, reference "necessary core staff and services" as being included in "fixed costs."

> (i) In determining the adjustment amount, the intermediary considers—
>
> > (A) The individual hospital's needs and circumstances, including the reasonable cost of maintaining necessary core staff and services in view of minimum staffing requirements imposed by State agencies;

> (B) The hospital's fixed (and semi-fixed) costs, other than those costs paid on a reasonable cost basis under part 413 of this chapter; and . . .

42 C.F.R. § 412.92(e)(3). "Variable costs" are separately discussed in the history accompanying publication of the original interim rule:

> Variable costs, on the other hand, are those costs for items and services that vary directly with utilization. However, in a hospital setting many costs are neither perfectly fixed nor perfectly variable, but are semifixed. Semifixed costs are those costs for items and services that are essential for the hospital to maintain operation but will also vary with volume. For the purposes of this adjustment, many semifixed costs, such as personnel related costs, may be considered as fixed on a case by case basis. An adjustment will not be made for truly variable costs, such as food and laundry services.

48 FR 39752, 39781 (Sept. 1, 1983). PRM 15-1 § 2810.1(B) tracks the language from the Federal Register, with the addition of "food and laundry costs" as examples of costs which vary with utilization.

When Congress made the switch to the IPPS system, the Health Care Financing Administration (HCFA)[7] promulgated new rules to implement the switch "from a cost-based, retrospective reimbursement system to a diagnosis specific prospective payment system." 48 FR 39752, 39752. HCFA noted as reasons for the change:

> Numerous studies have highlighted the dynamic growth in health care spending in the United States, particularly the rapid increase in Medicare program hospital costs. These cost issues have been, for many years, a focal point of discussion and action on the part of all levels of government and various sections of the health care industry. Of concern to us is that these increasing Medicare expenditures constrain the ability of the Federal government to fund other needed programs.
> . . .
>
> A third factor is Medicare's current cost reimbursement system, which by its very nature tends to aggravate this cost problem. The economic incentives of this system contribute to cost increases by rewarding hospitals and physicians who increase utilization and thus their allowable reimbursable costs. There is little incentive for

[7] Now CMS.

> hospitals and physicians to operate more efficiently as all allowable costs are fully reimbursed.
> . . .
>
> As a means of restraining hospital expenditure growth, prospective payment places hospitals at risk in terms of the management of their operations and the use of their resources. Thus, we believe that this system will begin to address some of the serious problems inherent in the present cost reimbursement payment methodology and, therefore, will allow us to better manage the Medicare program and preserve the integrity of the trust funds.

48 FR 39752, 39804-05. Given the above expressed legislative goal of restraining the growth of hospital expenditures and passing some of the burden (and risk) of cost management on to the hospitals, the Secretary's interpretation of the statute and the regulation as requiring qualifying hospitals be compensated only for fixed (or semifixed) costs is not inconsistent with the plain language of the statute or with the legislative intent.

The hospitals next argue the Secretary's decision contradicts the PRM and he has failed to give a "reasoned basis for failing to comply with [his] own express, longstanding interpretive rules governing calculation of the VDA payment." (Pl. Brief [19-1] at 18). They argue the MAC's explanation "that it was handling more requests and requests for larger amounts" coupled with a 2004 letter from CMS instructing the MAC to include variable costs in the VDA calculation (with respect to the request of another provider) and the instructions in the PRM itself demonstrates the arbitrary and capricious nature of the Secretary's decision to exclude variable costs in the 2006 calculations. (*Id.* at 19-20).

Taking the last argument first, the instructions in the PRM are ambiguous. The PRM examples do not explain what makes up the amount in line 4 of the examples -- FY Program Inpatient Operating Cost – the hospitals assume it is the total cost for the fiscal year. Line 4 could just as readily be, as the Secretary has now determined, the net costs for the fiscal year after variable costs are subtracted. The hospitals do not cite the Court to anything in the PRM which

suggests the Line 4 amounts can only be or must be a hospital's total FY inpatient costs, both fixed and variable. In any event, the PRM is not a "notice-and-comment" rule covered by the APA, instead, it falls into the category of "interpretative rules, general statements of policy or rules of agency organization, procedure or practice." *Perez*, __ U.S. at __ , 135 S. Ct. at 1203-04; 5 U.S.C. § 553(b)(A). As such, it '"do[es] not have the force and effect of law and [is] not accorded that weight in the adjudicatory process.'" *Perez*, __ U.S. at __, 135 S. Ct. at 1204 (quoting *Shalala v. Guernsey Mem'l Hosp.*, 514 U.S. 87, 99 (1995)). An agency may change its interpretation "if the revised interpretation is consistent with the underlying regulations." *Perez*, __ U.S. at __, 135 S. Ct. at 1209 (quoting Petitioner's Brief in 13-1052 at 44). The Secretary's determination is consistent with language accompanying the 1987 amendments to the regulations:

> We believe that this language makes it clear that a hospital that has continued to receive payments under the prospective payment system that are greater than its inpatient operating costs, even though there has been a decline in occupancy, is not entitled to receive a payment adjustment. Hospitals that receive payments that are greater than the hospitals' Medicare inpatient operating costs have been “fully compensated” for those costs by the prospective payment system. Consequently, we believe that no further adjustment should be granted to these hospitals.

52 Fed. Reg. 33034, 33049, Section D. *Payments to Sole Community Hospitals* (September 1, 1987).

As for the 2004 letter from CMS instructing the MAC to include variable costs in a VDA for another provider, such a direction is entirely consistent with the directive in 42 C.F.R. § 412.108(d)(3)(i) that "[i]n determining the adjustment amount, the [MAC] consider[] . . . [t]he *individual* hospital's needs and circumstances. . . ." *See* 52 Fed. Reg. 33034, 33049 ("We determine on a case-by-case basis whether an adjustment will be granted and the amount of that adjustment."). Clearly, the VDA determinations are made on an individualized basis and in the 2004 case, the provider itself "excluded costs relating to food, drugs and supplies" when it

submitted its SCH payment adjustment application. (Tr. [10-2] at 724). It is not determinable from the 2004 determination letter what variable costs CMS determined would be appropriate to include with respect to the provider involved.

The MAC's explanation for exclusion of variable costs came via the testimony of Mr. Steiner, who testified that in late 2008 his manager directed him to look at the VDAs "because "we were seeing some very high dollar amounts in reviewing that process." (Tr. [10] at 261). Mr. Steiner understood that in the past the MAC had not removed variable costs in processing VDA requests. (*Id.* at 273). After looking at the statute and regulations, Mr. Steiner testified that he had determined the MAC had not been handling variable costs properly and that the only costs the MAC was to consider were fixed and semi-fixed costs. (*Id.* at 263, 274).

At hearing, counsel for the hospitals argued that because hospitals cannot control what tests and medications physicians might order which the hospitals must then provide, those "uncontrollable" costs qualify as "fixed" costs, in line with guidance in the PRM that "Fixed costs are those costs over which management has no control." Again, the PRM does not have the force and effect of law and the Court finds the language in the PRM defining "fixed costs" to be overly simplistic, given the complicated cost accounting involved. Counsel also pointed to provisions in the Iowa Administrative Code requiring hospitals to provide proper dietary services and to Medicare's formulary requirements as supporting a finding medications and food should be considered fixed costs. Mr. Steiner testified that when he reviewed the hospitals' trial balances submitted with their cost reports, he went through and identified accounts or sub-accounts that would vary with utilization, such as medications and supplies charged to patients, outside laboratory tests, radiology and therapy services, but excluded sub-accounts for professional fees and equipment rentals as fixed costs. (Tr. [10] at 264-265). This is consistent with the statute which

"also requires that the adjustment amount include the reasonable cost of maintaining necessary core staff and services. HCFA will review the determination of core staff and services based on an individual hospital's needs and circumstances; e.g., minimum staffing requirements imposed by State agencies." 48 FR 39752-01, 39781-82.

The hospitals argued fewer patients does not necessarily translate into less patient utilization if the patients are sicker. As the Secretary pointed out, however, there is nothing in the record to suggest the hospitals had "sicker" patients during the relevant time period.

The Court finds the following: The regulations did not change nor did the facts underlying their promulgation -- the Secretary discovered the Department had made a mistake in how it had been calculating VDA payments under the existing regulations. The government was paying out increasing sums to hospitals, payments which covered the hospitals' fixed and variable inpatient costs, a scenario not contemplated by the statute or the intent of the IPPS system: "[to] restrain[] hospital expenditure growth, prospective payment places hospitals at risk in terms of the management of their operations and the use of their resources." 48 FR 39752, 39804-05. The IPPS was not intended to make qualifying hospitals whole, only to "full compensate the hospital for the *fixed costs* it incurs . . . including the reasonable cost of maintaining necessary core staff and services." 42 U.S.C. § 1395ww(d)(5)(D)(ii), (d)(5)(G)(iii). The Secretary took steps to correct the Department's error but did not change the regulations, only the interpretation of the existing regulations. *See* 42 U.S.C. § 1395ww(d)(5)(I)(Secretary authorized "to provide by regulation for such other exceptions and adjustments to such payment amounts under this subsection as the Secretary deems appropriate"). The steps taken, to exclude variable costs from VDA calculations, are consistent with the statutory and regulatory language and the purpose of the IPPS system. *Cf. Guernsey*, 514 U.S. at 94-95 (Secretary's decision that regulation did not require reimbursement

according to GAAP was a "reasonable regulatory interpretation" to which deference was owed); *Bob Jones University v. United States*, 461 U.S. 574, 596 (1983)("In an area as complex as the tax system, the agency Congress vests with administrative responsibility must be able to exercise its authority to meet changing conditions and new problems."). The Secretary's decision was not arbitrary, capricious or contrary to applicable law.

B. Substantial Evidence

Alternatively, plaintiffs argue the Secretary's decision was not supported by substantial evidence and that the record demonstrated the disputed costs were "at a minimum, semifixed" or "were necessary and essential to maintain core services." (Pl. Brief [19-1] at 19, 26). Defendant responds that both the PRRB and the Secretary agreed with the MAC the costs were variable in accordance with traditional accounting principles. (Def. Brief [25] at 10).

In support of their argument, plaintiffs point to testimony by Mr. Steiner that his statement "[i]f you have fewer patients, it's most likely you're going to have fewer drugs" was a "commonsense assumption" and not based on empirical studies. (Tr. [10] at 270). Mr. Steiner testified that the PRM defined "variable costs as those that vary based on utilization" and in response to a query whether drugs could be considered "semi-fixed costs" testified that drugs chargeable to a particular patient was utilization and that "[a]s there are fewer drugs prescribed by physicians, fewer drugs provided by the hospital, the cost would go down. There's less utilization of chargeable drugs." (*Id.* at 271). Plaintiffs did not, however, present any evidence regarding the costs excluded by Mr. Steiner, only argument and inferences from cross-examination of witnesses on general cost topics. Plaintiffs did not present any empirical studies to contradict Mr. Steiner's "commonsense" assumptions. Plaintiffs did not bring in any witnesses to explain why the costs excluded were in fact necessary and essential to the hospitals' core services. In fact, outside of the

various cost statements included in the record, the Court cannot make any determination about the validity or invalidity of Mr. Steiner's assumptions.

On the record before the Court, plaintiffs have not carried their burden of proof on their claim the Secretary's decision is not supported by substantial evidence.

C. Newly Discovered Authority

While this matter has been pending, CMS posted notice of a proposed rule change on April 28, 2017, which plaintiff Lakes Regional has brought to the Court's attention.[8] The proposed rule change directly addresses the VDA calculation methodology discussed above, albeit prospectively only for cost reporting periods beginning on or after October 1, 2017. Federal Register, Vol. 82, No. 081, Part II, 82 FR 19796, 19935. Acknowledging the prospective nature of the rule change, Lakes Regional argues it "clearly demonstrate[s] that the Secretary's decision in the instant case was arbitrary, capricious, and contrary to the intent of the VDA statute and the purpose of the VDA payments. . . ." (Pl. Supp. Brief [33-1] at 4). Defendant argues the proposed rule does not apply and if it does, explains why it does not help plaintiffs. Defendant has provided the Final Rule dated August 14, 2017 for the Court's consideration. 82 Fed. Reg. 37990, 2017 WL 3453563 (Aug. 14, 2017). (Def. Resp. [37-1], Ex. A)("Ex. A").

The Court does not reach the issue how the Proposed Rule or Final Rule apply to plaintiffs' VDA calculations as it agrees neither have any effect in the present case. With respect to the Proposed Rule, under Eighth Circuit law, "proposed regulations . . . have no legal effect." *United States v. Springer*, 354 F.3d 772, 776 (8th Cir. 2004)(quoting *Sweet v. Sheahan*, 235 F.3d 80, 87, 2d Cir. 2000)). As for the Final Rule, by its terms it applies to "cost reporting periods beginning

[8] Plaintiff Unity HealthCare has also supplemented their briefing with reference to the amended regulation. (Pl. Supp. Brief [33-1]).

on or after October 1, 2017." (Ex. A at 14)("We also do not agree that we should apply our proposed methodology retroactively." (*Id.* at 13)). Plaintiff does not specifically seek retroactive application of the Final Rule but argues it is evidence the Secretary's application of the VDA methodology in the present case was arbitrary, capricious, and an abuse of discretion. (Pl. Brief [33-1] at 4). "The mere fact that regulations were modified, without more, is simply not enough to demonstrate that the prior regulations were invalid." *LaRouche v. Fed. Election Comm'n,* 28 F.3d 137, 141 (D.C. Cir. 1994). *See also Nat'l Cable & Telcomms. Ass'n v. Brand X Internet Servs.*, 545 U.S. 967, 981-82 (2005)("An initial agency interpretation is not instantly carved in stone. On the contrary, the agency . . . must consider varying interpretations and the wisdom of its policy on a continuing basis . . .," quoting *Chevron, USA v. Nat'l Resources Defense Council, Inc.*, 467 U.S. 837, 863-64 (2008)); *Smiley v. Citibank*, 517 U.S. 735, 741-42 (1996)("change is not invalidating"). The fact that the Secretary has made modifications to VDA methodology to be applied to future cases has no effect on the Court's findings in the present case.

The Court also has reviewed Magistrate Judge Mahoney's Report and Recommendation in *St. Anthony Regional Hospital v. Hargan*, No. 5:16-cv-3117-LTS (N.D. Iowa Dec. 29, 2017). The arguments considered in that Report and Recommendation correspond with those made in this case. The Court agrees with Judge Mahoney's analysis.

V. CONCLUSIONS OF LAW AND ORDER FOR JUDGMENT

The Court finds the Secretary's decision regarding VDA payments to plaintiff hospitals was not arbitrary, capricious or contrary to law and was supported by substantial evidence. The Secretary's decision is **affirmed** and plaintiffs' Complaint is dismissed.

IT IS SO ORDERED.

Dated this 30th day of January, 2018.

Helen C. Adams
Chief U.S. Magistrate Judge