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I. BAD DEBT

A. *Summer Hill Nursing Home v. Johnson,* 603 F.Supp.2d 35 (D.D.C., Mar. 25, 2009)(Provider Properly Established that Bad Debts were Uncollectible)

Summer Hill Nursing Home, a 120-bed skilled nursing facility, submitted a cost report to its FI claiming bad debts relating to uncollectible deductible and co-insurance amounts for dual-eligible patients. Summer Hill's FI denied the claim, however, because Summer Hill wrote off the dual eligible bad debt prior to billing New Jersey Medicaid for the deductible and co-insurance amounts. Sometime after receiving notice of the FI's disallowance, Summer Hill billed New Jersey Medicaid for the bad debts and received remittance advices refusing to pay the debts, on the grounds that the Medicare payment already exceeded the Medicaid allowable payment ceiling. Summer Hill then appealed the FI's disallowance to the PRRB, which reversed the disallowance on the grounds that CMS's policy, that the provider must submit evidence that they have billed state Medicaid programs for uncollectible deductible and co-insurance obligations and receive a refusal to pay before being reimbursed by Medicare, had no foundation in law. The Secretary, however, reversed the PRRB's decision, finding that the bad debts were not "worthless when written off" because the provider did not bill the State and receive a remittance advice to meet the reasonable collection effort requirements of the regulations and manual provisions. Summer Hill appealed this decision to the district court, which granted Summer Hill's motion for summary judgment, finding that the Secretary's denial of reimbursement was arbitrary and capricious.

In its decision, the Court acknowledged that the parties spent the bulk of their briefs arguing over the validity of the Secretary's must bill policy, but explained that it would not reach the issue because the Secretary failed to explain how the policy was violated here. The Secretary had acknowledged, on the record, that upon receipt of the remittance advices from New Jersey Medicaid refusing to pay the debts, it was in compliance with the "spirit, if not the letter," of the must bill policy. The Secretary failed to explain why Summer Hill's receipt of remittance advices was insufficient to establish that the debts were uncollectible when claimed. The Secretary's counsel also relied on Joint Signature Memorandum 370 ("JSM 370"), which states that the provider must make certain that no other source would be legally responsible for payment prior to claiming bad debt from Medicare. The Court noted that there was no evidence that the agency relied on JSM 370 in making its decision, and it could not accept counsel's post-hoc rationalization as a substitute for the Secretary's lack of explanation. Further, JSM 370 failed to provide rationale for why remittance advanced received after a claim is filed but prior to the Secretary's decision must be disregarded since they establish that the debts were actually uncollectible when claimed.

In a separate action, *Summer Hill Nursing Home LLC v. Sebelius*, 2010 WL 9960 (D.D.C. Jan. 4, 2010), Summer Hill moved for costs and attorneys' fees pursuant to the Equal Access to Justice Act ("EAJA"), 28 U.S.C. 2412, which makes attorneys' fees mandatory if the government's position is not substantially justified and discretionary if the Court finds the government acted in bad faith. The district court granted costs, but denied attorney fees. The Secretary's failure to explain why the belated submission of remittance advices was insufficient to satisfy the billing policy did not enable the Court to conclude there was no substantial

justification for the Secretary's decision; nor could the Court, on that basis, conclude that the Secretary acted in bad faith.

B. *Abington Crest Nursing and Rehabilitation Center, et al. v. Sebelius,* 575 F.3d 717 (D.C.Cir. Aug. 4, 2009) (Bad Debt Reimbursement Not Applicable to Services Paid Under Fee Schedule Methodology)

In *Abington Crest*, a group of skilled nursing facilities ("Plaintiffs") challenged their fiscal intermediary's disallowance of bad debt claims for uncollectible deductibles and coinsurance payments.

Prior to 1997, Medicare reimbursed skilled nursing facilities ("SNF") based on their reasonable costs; in 1997, the Balanced Budget Act changed the payment scheme for SNF services in two ways: (1) it changed the reimbursement methodology for SNF services covered under Part A from a reasonable cost system to a prospective payment system and (2) it changed the reimbursement methodology for SNF therapy services from reimbursement-based on reasonable costs to reimbursement-based on a pre-existing Medicare Part B fee schedule applicable to physicians. In their cost reports for fiscal year 1999, the Plaintiffs claimed uncollectible deductibles and coinsurance payments as bad debts; the intermediary, however, disallowed the claims on the ground that Medicare's bad debt reimbursement policy applies only to reasonable cost payment system, and not to the fee schedule system.

The Plaintiffs appealed the intermediary's decision to the PRRB and prevailed; the PRRB found that although Congress had changed the payment system for SNFs from a reasonable cost basis to a fee schedule basis, it had not changed the bad debt policy. The Administrator, however, disagreed, and reversed the PRRB's decision, ruling that the Plaintiffs' bad debts were not reimbursable under the fee schedule system. In particular, the Administrator found that Medicare's longstanding policy has been not to pay for bad debts for services paid under a reasonable charge (as opposed to reasonable cost) or fee schedule methodology.

The Plaintiffs then filed suit in the district court, which granted the Secretary's motion for summary judgment, and concluded that the Secretary's interpretation of the applicable Medicare law and regulations, to deny the reimbursement of bad debts arising from Part B services provided by the Plaintiffs, was a reasonable construction of the regulations.

On appeal, the D.C. Circuit affirmed the district court's grant of summary judgment to the Secretary. In response to the Plaintiffs' argument that the Secretary's denial of their bad debt claims violates Medicare's statutory anti-cross-subsidization principle at 42 U.S.C. § 1395x(v)(1)(A), the D.C. Circuit first pointed out that the statutory ban against cross-subsidization does not directly address bad debt, nor does it indicate whether bad debt must be reimbursed under a fee schedule system. Since the anti-cross-subsidization principle is contained in a subsection of the statute that deals with "reasonable costs," the Court concluded that the Secretary permissibly read the ban to apply only to reimbursement systems based on reasonable costs and thus to justify bad debt reimbursement only under such systems. The Secretary successfully explained that the application of the bad debt reimbursement to Part A PPS is appropriate because the prospective rates are determined based on hospitals' average costs during the base period; bad debts incurred during the base period are not included in the calculation. The Part B physician fee schedule, on the other hand,

is based on health care providers' charges, and historically, those charges include the cost of doing business, including expenses such as bad debt. The Secretary also explained that application of bad debt reimbursement to ambulatory surgical centers ("ASC") was consistent with its bad debt policy because even though ASCs are paid on a fee schedule, the payment rates for ASCs are based on costs rather than charges. If the Plaintiffs wanted to assert that the Medicare Part B physician fee schedule has nothing to do with the costs of SNFs in providing care, then their "quarrel is with Congress and not the Secretary."

The Plaintiffs also argued that the Secretary's denial of reimbursement for bad debts disregarded the plain terms of the regulation, which states, in part "[t]o assure that such covered service costs are not borne by others, the costs attributable to the deductible and coinsurance amounts that remain unpaid are added to the Medicare share of allowable costs." The D.C. Circuit disagreed, finding that, though the regulation addressed bad debt, it does not answer the question of whether bad debt applied to payment systems based on fee schedules. It was therefore "perfectly sensible" for the Secretary to read the regulatory anti-cross-subsidization principle in the same manner as its statutory counterpart and conclude that it applied only to reasonable cost reimbursement systems. In short, the Secretary's interpretation of the regulation was neither plainly erroneous nor inconsistent with the regulation, and therefore commanded deference.

C. *Baptist Healthcare System dba Baptist Regional Medical Center v. Sebelius* 646 F.Supp.2d 28 (D.D.C. August 18, 2009)(Providers Not Required to Conduct Asset Test to Determine Indigence for Bad Debt Purposes)

Baptist Regional Medical Center ("Baptist") challenged its fiscal intermediary's disallowance of bad debt on the basis that the hospital did not conduct an asset test as part of its indigence determination. The PRRB ruled that the Provider Reimbursement Manual ("PRM") did not create a mandatory asset test for indigence, and on those grounds, Baptist's bad debts should be reimbursed. The Administrator, however, disagreed, finding that the PRM does create a mandatory asset test. In particular, the Administrator found that the words "should" is synonymous with the word "must" in the context of the PRM provision. Baptist appealed the Administrator's decision to the D.C. District Court, and the Court granted Baptist's motion for summary judgment.

For the cost reporting periods at issue, September 1, 1998 through August 31, 2001, Baptist required patients with debts greater than $800 to complete a financial disclosure form that included inquiries for both income and assets; for patients with debts less than $800, Baptist only asked about income. In addition, Baptist determined that some patients were indigent through an upfront screening process, whereby they completed a financial aid worksheet prior to admission. Baptist would also consider whether a patient resided in a certain "catchment area" or high poverty county as a factor to determine indigence.

With respect to reimbursement for bad debts generally, 42 C.F.R. Section 413.89(e) lays out specific criteria that must be met in order for the bad debt to be considered reimbursable, and the Secretary further clarified this regulation in interpretive manuals, guidelines, letters and other publications. Most notably, Section 310 of the PRM explains that the provider must make reasonable collection efforts before a bad debt can be considered an allowable cost. In cases where the provider determines that a patient is "indigent," however, the debt associated with that patient may be deemed uncollectible without applying the specific procedures in PRM Section 310. Section

312 of the PRM offers guidance on how a provider may determine that a patient is indigent: (A) the patient's indigence must be determined by the provider, (B) the provider should take into account a patient's total resources, including but not limited to an analysis of assets, liabilities and income and expenses, (C) the provider must determine that no source other than the patient would be legally responsible for the patient's medical bill, and (D) the patient's file should contain documentation of the method by which indigence was determined.

The district court analyzed the language of PRM Section 312 and concluded that a provider is not required to conduct an asset test to determine whether a Medicare beneficiary is indigent. The Court cited several cases distinguishing between the terms "should" and "must" and concluded that the Secretary had the discretion to change the language of the PRM to use the word "must" but had not chosen to do so here. If the Secretary wanted to preclude courts from reaching this same decision in future decisions, it should amend Section 312.

D. *Detroit Receiving Hospital, et al v. Leavitt*, 575 F.3d 609 (6th Cir. July 30, 2009) (CMS May Limit QMB Bad Debt Reimbursement)

In *Detroit Receiving Hospital*, a group of public and private hospitals ("Hospitals") challenged a regulation that reduced the amount of allowable bad debt that providers are able to claim as the regulation is applied to bad debts associated with Qualified Medicare Beneficiaries ("QMBs"). In particular, the Hospitals argued that because they are compelled to accept partial reimbursement for Medicare bad debt associated with QMBs, the provision violated the Medicare Act's ban of "cross subsidization." As Hospitals sought to invalidate the regulation as applied to QMB bad debt, the PRRB found that it lacked the authority to grant the relief requested and thus granted Hospitals' request for expedited judicial review.

The Hospitals thus brought suit challenging the regulation in district court. The court, however, found that the Secretary's resolution of the tension between the statute reducing the allowable amount for Medicare bad debt and the Medicare Act's ban on cross-subsidization was reasonable given the "well-established rule of statutory construction that 'where a specific provision conflicts with a general one, the specific governs." Since the prohibition of cross-subsidization is a general provision, while the Medicare bad debt reduction provision is specific, the district court held that the regulation "reasonably gives effect to the more specific provision of the statute." The court also emphasized that the ban on cross-subsidization does not guarantee recovery of all of the costs associated with the provision of Medicare services in every instance.

On appeal, the Sixth Circuit affirmed the district court's holding. In particular, the Sixth Circuit determined that the statutory scheme is clear on its face and provides no exceptions to the bad debt reimbursement reduction for QMB bad debt. In fact, the Sixth Circuit pointed out that bad debt reimbursement is reduced without regard to whether the patient is a QMB, and the cross-subsidization ban is not inconsistent with that provision. Thus, the Secretary's promulgation of a regulation that mirrors the statute cannot violate the cross-subsidization ban. Further, even if the statutory provisions were in tension, the bad debt reimbursement reduction provision, as the more specific policy embodied in a later federal statute, would govern.

E. *Vitality Rehab, Inc. v. Sebelius*, 641 F.Supp.2d 984 (C.D. Cal., Aug. 3, 2009)(Secretary Reasonably Concluded that Bad Debt was Not Reimbursable under Fee Schedule Payment Methodology)

Prior to 1999, Medicare reimbursed providers of Part B services for the reasonable costs of covered services, but on January 1, 1999, through the Balanced Budget Act of 1997, Congress changed the payment methodology such that part B providers were reimbursed according to a fixed physician fee schedule. Under the reasonable cost methodology, providers were reimbursed for bad debts. The statute on reasonable costs provides that the Secretary shall prescribe regulations regarding reasonable costs which shall take into account both direct and indirect costs such that the costs for Medicare-covered individuals are not be borne by uncovered individuals, and costs for uncovered individuals are not be borne by Medicare (the "anti-cross-subsidization principle"). 42 U.S.C. § 1395x(v)(1)(A).

Vitality Rehab, Inc., an outpatient rehabilitation facility that participated in Medicare as a part B provider, filed a cost report for its fiscal year 1999, including a claim for reimbursement of bad debts for patients who were dually eligible for Medicare and Medicaid. The FI denied the claim, explaining that it was not allowable after January 1, 1999 under the fee schedule payment methodology. Vitality appealed to the PRRB, who reversed the FI, but the Administrator reviewed the PRRB's decision and upheld the FI's disallowance. Vitality appealed to the district court, which ultimately found that the Secretary's denial was reasonable, supported by substantial evidence, and consistent with the Medicare statute and regulations.

The Court first found that the bad debt regulations, found at 42 C.F.R. § 413.80 et seq., did not unambiguously address whether bad debts arising from an entity's provision of Part B services paid under a fee schedule were reimbursable. Further, the overall statutory and regulatory scheme, especially the fact that the relevant regulations appeared in subsections with the word "cost" in the heading, created ambiguity as to whether a cost-based reimbursement system was a prerequisite to also reimburse for bad debts. Second, the Court found the Secretary's explanation, that the bad debt provisions were originally implemented to effectuate Congress' reasonable cost anti-cross-subsidization provision and therefore were not controlling under a fee schedule payment methodology, provided a reasonable basis to support the Secretary's decision to deny reimbursement of bad debt. The Court further explained that another reasonable basis for the Secretary's decision was that it was improper to separately reimburse bad debts for services paid on a fee schedule because a fee schedule includes a built-in profit margin that already accounts for all costs, including bad debts. Vitality also argued that when Congress changed the payment methodology for Part B therapy services, Congress did not limit the right of therapy service providers to receive payment for bad debt, as it explicitly did for other types of Medicare providers. The Court, however, explained that Congressional silence alone would not control statutory interpretation, and further, because the bad debt reimbursement policy is an exclusive feature of the reasonable cost system, Congress need not address the issue through specific legislation for Part B therapy service providers. Vitality also tried to argue that the Secretary's Notice of Proposed Rulemaking in 2003, which made clear that bad debts were not allowable for entities paid under reasonable charge or fee-schedule methodology, showed that the regulation required reimbursement under the changed payment system, otherwise the rule would have been unnecessary. The Court pointed out, however, that in the proposed rule

itself, the Secretary explained that the rule was a confirmation of bad debt policy for services paid under reasonable-charge or fee-schedule methodologies. The Court also rejected Vitality's argument that the training materials it received acknowledged Congress' intent that bad debts be paid under a prospective payment system. The Court noted that the materials did not discuss the applicability of bad debt reimbursement for claims paid under fee schedule, and further, the materials specifically stated that Congress had not intended to address the bad debt reimbursement issue. Finally, Vitality pointed to a stipulation it signed with its FI that provided that Medicare would still reimburse Vitality 100% of all co-insurance which becomes bad debt. The Court, however, explained that the Secretary was not bound by the stipulation.

II. WAGE INDEX/RURAL FLOOR

A. *Anna Jacques Hospital, et al. v. Sebelius*, 583 F.3d 1 (D.C.Cir. Sept. 11, 2009) (When Calculating Wage Index, the Secretary May Exclude Data from Critical Access Hospitals that Qualified as Subsection (d) Hospitals During the Survey Year)

Congress requires the Secretary, at least every 12 months, to update the wage index on the basis of a survey of wages and wage-related costs of subsection (d) hospitals in the United States. Accordingly, the Secretary calculates each year's wage index by using data from the survey conducted three years earlier, removing data from the survey that fails to meet certain criteria for reasonableness, and soliciting comments from the public. Prior to 2003, the Secretary included wage data for facilities that were subsection (d) hospitals during the survey year, regardless of whether they were classified as such by the time she calculated the wage index. In 2003, however, the Secretary proposed a policy whereby she would exclude wage data for hospitals that were subsection (d) hospitals during the survey but became critical access hospitals before the year for which the wage index was actually calculated; this policy was first applied when calculating the fiscal year 2005 wage index. That year, a group of subsection (d) hospitals in Massachusetts (the "Hospitals") filed suit in the district court seeking injunctive relief requiring the Secretary to recalculate the fiscal year 2005 wage to include data from all facilities that qualified as subsection (d) hospitals in 2001, the survey year, even if they no longer qualified as such after the survey year. The district court granted the Hospitals' motion for summary judgment, finding that the Secretary's interpretation violated the statutory requirement that the wage index reflect the labor costs of all subsection (d) hospitals whose cost reports are used to conduct the annual survey, regardless of their status at the time the index is calculated. The court ordered the Secretary to recalculate the FY 2005 wage index for Massachusetts using the data from all facilities that qualified as subsection (d) in 2001. The Hospitals separately challenged the Secretary's calculation of the FY 2006 wage index for Massachusetts on the same grounds, and the district court granted summary judgment in that case as well.

The Secretary appealed both decisions to the D.C. Court of Appeals, and the Court ultimately reversed the district court decision. The appeal turned on three issues: (1) whether the Secretary's interpretation of the statutory provision requiring annual calculation of the wage index was permissible under *Chevron*, (2) whether she acted arbitrarily in failing to adequately explain her approach in calculating the wage index, and (3) whether she acted arbitrarily by treating data from similarly situated hospitals differently. On the first point, the Court concluded that the Secretary's interpretation was reasonable; the statute requires that her calculation of the

wage index be made "on the basis of" the survey, but it is silent on whether she must use all of the survey data. In fact, the Court pointed out, the Secretary has explicit discretion to remove some data as long as the survey data constitute the principal component of the wage index calculation. On the second point, the Hospitals argued that the Secretary acted arbitrarily by failing to provide a reasoned explanation for ceasing to use data for facilities that qualified as subsection (d) hospitals at the time of survey. The Court concluded that the agency was free to change its mind so long as it supplies a reasoned analysis, and it had done so here. In particular, the Secretary had explained that it was appropriate to remove critical access hospital data from the survey because they had a "substantial negative impact" on the wage indexes for subsection (d) hospitals due to their substantially different labor costs. Finally, the Hospitals argued that the Secretary's decision to exclude only the data from critical access hospitals, and not any other types of hospitals that lost their subsection (d) status, was arbitrary. The Court found that the Hospitals failed to support their argument that critical access hospitals are similarly situated to other hospitals that have lost their subsection (d) status. The Hospitals' mere allegation that the other types of hospitals that lost their subsection (d) status had significantly differently labor costs than subsection (d) hospitals, absent any showing that they were outliers like critical access hospitals, was an "asserted but unanalyzed argument."

B. *Cape Cod Hospital, et al., v. Leavitt,* 677 F.Supp.2d 18 (D.D.C. Dec. 21, 2009) (Secretary's Calculation of the Rural Floor Budget Neutrality Adjustment was Reasonable)

Under the Medicare Act, the amount of reimbursement to a hospital for a given service is dependant on the hospital's average standardized amount per discharge and the area wage index applicable to the hospital. The standardized amount is divided into two parts: a labor-related share and a non-labor-related share. The Secretary adjusts the labor-related portion of the standardized amount for differences in hospital wage levels in different geographic areas. In order to calculate the relative wage-level adjustment, the Secretary calculates and assigns an area wage index value to each hospital reflecting the wage levels in the hospital's geographic location. CMS updates the wage indexes annually. The Balanced Budget Act of 1997 includes a provision that required the wage index for hospitals in urban areas to be no less than the wage index for hospitals located in rural areas in the same state (the "rural floor"). The rural floor adjustment is to be applied in a budget-neutral fashion, meaning the payments in a given fiscal year are not be greater or less than those that would have been made in that year if the rural floor provision had not applied. In *Cape* Cod, a group of hospitals ("Plaintiffs") alleged that the Secretary's calculation of the rural floor budget neutrality adjustment contradicted the statute.

For Fiscal Year ("FY") 2007, CMS issued a proposed rule establishing the wage index on April 25, 2006, setting forth specific instructions for those wishing to deliver comments. In May 2006, there was an e-mail exchange regarding the calculation of rural floor budget neutrality between the Plaintiffs' consultant and a CMS employee; Plaintiffs also submitted a letter, dated June 9, 2006, which was acknowledged as received by CMS but which was not included in the rulemaking record. The final rule for FY 2007 did not adopt any changes to the rural floor adjustment methodology, nor did it address the consultant's observations about the rural floor adjustment. On May 3, 2007, CMS issued a proposed rule for FY 2008, in which it reevaluated the rural floor adjustment methodology and the May 2006 e-mail exchange. The e-mail exchange was included in the FY 2008 administrative record. Under the new methodology for

FY 2008, the budget neutrality adjustment factor would be applied to the wage index rather than the standardized amount, as it had done in the past. CMS also proposed a one-time adjustment to the standardized amount, in effect neutralizing the 2007 rural floor adjustment. The Plaintiffs submitted a request for additional information, but CMS declined to provide the information. In August 2007, the Secretary published the rule as final. In the rule, CMS noted that the calculation of the rural floor budget neutrality adjustment for prior years was flawed because it created an inappropriate duplicating effect that was permanently built in to the standardized amount for application of the rural floor.

Plaintiffs challenged both the FY 2007 and 2008 final rules before the PRRB, and the PRRB eventually granted EJR. The district court granted summary judgment for the Secretary, and denied summary judgment for the Plaintiffs. First, the Court addressed the Secretary's motion to strike the partial administrative record filed by the Plaintiffs, which included the May 2006 e-mail exchange and the June 9, 2006 comment letter. The Court agreed with the Secretary that the Plaintiffs were unable to show if and how CMS considered the e-mail exchange in the context of the FY 2007 rulemaking, and thus determined that it was properly excluded from the FY 2007 administrative record. The Court found that the June 9, 2006 formal comment letter, however, was improperly excluded. While the consultant did not follow the rule's suggestion to call a specific CMS number regarding hand delivery of a comment, he did follow the mandatory procedure of calling CMS and hand-delivering the comment letter, which CMS accepted.

The Court then addressed the Plaintiffs' challenges to CMS's rulemaking. First, the Court found that the Secretary's interpretation of the statutory provision requiring calculation of a budget-neutral rural floor adjustment did not exceed her authority. The Court found that the statute instructed the Secretary to adjust the wage index in a manner which assured budget neutrality, but did not instruct the Secretary on how to accomplish this task. Because the statute requires the Secretary to ensure budget neutrality in the fiscal year for which the adjustment is applicable, and does not speak to prior years, the Court determined that the Secretary's conclusion in the FY 2008 final rule not to revisit past errors was a reasonable one. Further, the Secretary's decision to change her methodology in FY 2008 could not be viewed as a concession that prior calculations were incorrect, because the Secretary was entitled to depart from prior policy when such departure is fully explained.

Next, the Court determined that the Secretary violated procedural rulemaking requirements with respect to FY 2007, but not to FY 2008. The Court found that for both years, the Secretary adequately explained the nature of her calculations. For FY 2007, however, by ignoring the June 9, 2006 comment letter, the Secretary failed to address Plaintiffs' comments. For 2008, however, the Court found that the Secretary directly responded to comments by changing the methodology used to calculate the rural floor budget neutrality adjustment and by explaining that the agency would calculate the adjustment by comparing "simulated payments using "FY 2006 discharge data and FY 2008 wage indexes without the rural floor to simulated payments using the same data with a rural floor." Even though the Court found that the Secretary failed to adequately respond to the comments in FY 2007 rulemaking, however, it ruled that the injury was harmless because the Secretary reversed the FY 2007 adjustment in the FY 2008 final rule. The Court failed to appreciate the Plaintiffs' argument that the error that CMS acknowledged in the FY 2008 rule was built in to the standardized amount in prior years

and that reversing the FY 2007 adjustment alone did not account for the effect of this error. The Plaintiffs have appealed this decision to the D.C. Circuit Court of Appeals.

C. *Southeast Alabama Medical Center, et al. v. Sebelius*, 572 F.3d 912 (D.C.Cir., July 17, 2009)(Secretary's Methodology for Compiling Occupational Mix Data is Reasonable)

In *Southeast Alabama Medical Center*, a group of hospitals (the "Hospitals") alleged that the Secretary exceeded his authority in compiling occupational mix data for purposes of developing wage indices.

Under 42 U.S.C. § 1395ww(d)(3)(E), the Secretary must establish a factor to adjust the proportion of hospital costs attributable to wages and wage-related costs (the "Factor"). To account for geographic differences in wages, this adjustment must reflect the hospital's wage level in its particular geographic area relative to the national average hospital wage level (the "Proportion"). To determine the proper adjustment amounts, the Secretary is required to survey hospital wages by occupational category, excluding any data related to wages and wage-related costs incurred in furnishing skilled nursing services.

The Hospitals specifically alleged that the Secretary acted arbitrarily and capriciously in adopting regulations implementing the survey of occupational mix data. At the administrative level, both the PRRB and CMS Administrator disagreed. The case reached the District of Columbia District Court on cross motions for summary judgment; the district court ultimately granted the Secretary's motion, finding most of the Hospitals' arguments to be unsupported by a plain reading of the relevant statute and regulations.

The D.C. Circuit affirmed the judgment of the district court, reversing solely with respect to HHS's decision to include postage costs in the Proportion. First, the D.C. Circuit concluded that, based on common definitions of the term "wage," it was not unreasonable for the Secretary to determine that payments made for employees' health insurance, worker's compensation insurance, pension plans and other fringe benefits should be included in determining wages. Secondly, while it may have been reasonable for the Secretary to restrict the Proportion to cost items that vary on a local basis, it was not unreasonable for the agency to decline to do so. With respect to payments made to independent contractors for nonmedical services, the D.C. Circuit looked to the statute and concluded that it merely requires the inclusion of "costs which are attributable to wages and wage-related costs." 42 U.S.C. §1395ww(d)(3)(E). The agency did not act unreasonably in interpreting that phrase to include nonmedical costs. Finally, the Hospitals challenged the agency's decision to include postage costs in calculating the Proportion; HHS had considered excluding postage from the Proportion in 2003 but had declined to do so. It was not until the FY 2006 rulemaking that the agency determined it was appropriate to exclude postage costs from the Proportion since postage costs are set at nationally uniform rates and are not affected by local purchasing power. On this point, the D.C. Circuit concluded that the agency failed to explain why postage should be included in the Proportion, and remanded to the district court to allow the agency to provide an adequate explanation.

The Hospitals also contended that the agency's decision to include certain contract labor cost items in the Proportion but not the Factor conflicts with the Medicare statute and the Administrative

Procedure Act. The D.C. Circuit rejected this argument, pointing out that the statutory requirements for the calculation of the Proportion and the Factor are different; while it would have been preferable for the agency to use the same cost items in both, the limited deviations it permitted were not unreasonable.

The D.C. Circuit also rejected the argument that the agency violated the Medicare statute by failing to adjust the Factor to account for occupational mix. 42 U.S.C. § 1395ww(d)(3)(E) provided that the survey on which the Factor is based "shall measure" occupational mix to the extent determined feasible by the Secretary. In 2000, Congress replaced this discretionary language and required the Secretary to measure data on occupational mix at least once every three years, an uncodified provision of the legislation instructed the Secretary to "first complete" the task no later than September 30, 2003 for application beginning on October 1, 2004 (i.e. FY 2005). Thus, for the fiscal years relevant to this case (2003 and 2004), the Secretary had a pass with respect to occupational mix; he just had to measure the data in time for application in FY 2005.

Finally, the Hospitals alleged that HHS impermissibly failed to account for interstate employment in calculating the Factor. The D.C. Circuit concluded that this argument failed on its merits; the statute requires only that the Factor should reflect the relative hospital wage level in the geographic area of the hospital compared to the national average wage level. The statute does not define geographic area; nor does it require HHS to take into account the movement of workers across areas. In fact, the Secretary's longstanding policy of using Metropolitan Statistical Areas to define those geographic areas has been deemed reasonable; thus, it is likewise reasonable for the agency to decline to incorporate migratory and commuting patterns in its definition.

D. *St. Michael's Medical Center v. Sebelius*, 648 F. Supp.2d 18 (D.D.C., Aug. 26, 2009)(Secretary Reasonably Excluded Data from Reclassified Hospitals in Calculating Wage Index)

For purposes of the wage index, the Secretary classifies a hospital as being located in either an urban or rural area using Metropolitan Statistical Areas ("MSAs"). If it meets certain criteria, Congress allows a hospital to seek geographic reclassification from its geographically-based wage area to a nearby wage area for payment purposes. Congress implemented a statutory provision to prevent the wage index of a rural area from decreasing when a hospital originating from that area reclassifies to an urban area; but no such statutory provision exists to prevent the wage index of an urban area from decreasing when a hospital originating from that area reclassifies to a rural (or different urban) area. CMS adopted a rule in 2001, however, that indicated that it would include the wage data for reclassified urban hospitals in both the area to which it was relocated and the area in which it was physically located. That rule went into effect beginning with FY 2002.

22 urban hospitals ("Plaintiffs") challenged the Secretary's practice of calculating the wage index for urban areas without including the data from hospitals that had been reclassified into higher-wage areas for FY 2000 and 2001. For their cost reports for FY 2000 and 2001, their FIs omitted data from the reclassified hospital(s) in calculating the wage index. The Plaintiffs appealed this omission to the PRRB, and the PRRB determined that EJR was appropriate because the Board was without the authority to decide the legal question; specifically, the PRRB

could not provide the relief that the plaintiffs were seeking (i.e. correction of their own wage data). Plaintiffs thus filed their complaint in district court, which ultimately determined that the Secretary's interpretation was neither unreasonable nor arbitrary, and therefore, the policy of omitting data from reclassified hospitals was a permissible construction of the statute.

The Court initially acknowledged that the administrative record lacked certain factual information required to determine the amount of reimbursement due if the Providers prevailed, but nonetheless determined that it was in a position to resolve the legal dispute. Plaintiffs argued that the Secretary's exclusion of the data was a violation of 42 U.S.C. § 1395ww(d)(3)(E), which requires the Secretary to use a "factor (established by the Secretary) reflecting the relative hospital wage level in the geographic area of the hospital…" in calculating the wage index. Plaintiffs insisted that this provision unambiguously required the Secretary to include the data of reclassified hospitals. The Court disagreed, finding that the statute, while unambiguously requiring the Secretary to establish a factor that reflects the relative hospital wage level in the geographic area of the hospital, leaves substantial discretion to the Secretary in determining what constitutes "relative wage level" and the relevant "geographic area. Further, the Court determined that the statutory framework, which establishes the "hold harmless" provision for rural hospitals and sets the "rural floor" below which no wage index may fall, reinforced the conclusion that the statute did not unambiguously require the Secretary to include reclassified hospitals in the area where they are physically located.

The Court then determined that the Secretary's policy of excluding the data was a permissible construction of the statute. Plaintiff's argued that, because the agency implemented the "hold harmless" provision for FY 2002, the prior practice of excluding reclassified hospitals' data was based on an impermissible construction of the statute. The Court again disagreed, finding that the agency was permitted to change its practice and was even required to do so when it determined that inclusion of the data was a preferable approach. Further, here, when the agency reevaluated its interpretation, it clearly explained its rationale in doing so. Plaintiffs asserted that the interpretation applied beginning in FY 2002 was reasonable, but failed to explain why the prior interpretation was unreasonable or arbitrary.

In conclusion, the Court addressed the Plaintiffs' claim that the Secretary's policy violated their right to equal protection. Evaluating the claim under the rational basis standard, the Court concluded that Plaintiffs contended there was no reason to treat urban and rural hospitals differently, or to reimburse similarly situated hospitals at different levels before and after FY 2002, but failed to challenge the Secretary's justification for distinguishing the hospitals or not applying the change in the calculation of wage indexes retroactively.

III. CAPITAL COSTS

Medicare reimburses providers for the loss from a sale of a depreciable asset. 42 C.F.R. § 413.134(f)(2)(i). The Statutory Merger Provision, 42 C.F.R. § 413.134(k)(2), provides for a possible adjustment where assets are disposed through a statutory merger. This provision provides that, if the merged corporation was a healthcare provider before the merger, it is subject to the provisions of paragraph (f). Paragraph (f), the Bona Fide Sales Provision, lists methods of disposition of depreciable assets, including, specifically, "bona fide sale." In May 2000, CMS amended the Provider Reimbursement Manual ("PRM") with regard to the Bona Fide Sales

Provision to read as follows: "a bona fide sale contemplates an arm's length transaction between a willing and well-informed buyer and seller, neither being under coercion, for reasonable consideration. An arm's length transaction is a transaction negotiated by unrelated parties, each acting in its own self-interest" ("2000 PRM Amendment"). CMS also issued Program Memorandum A-00-76, dated October 19, 2000 ("2000 PM "), to explain that "no gain or loss may be recognized for Medicare payment purposes unless the transfer of the assets resulted from a bona fide sale as required by regulation 413.134 (f) and as defined in the PRM at 104.24." Providers have disputed CMS's interpretation and application of the guidance relating to losses on mergers, as illustrated in the cases below.

A. *Albert Einstein Medical Center, Inc. v. Sebelius*, 566 F.3d 368 (3d Circ., May 22, 2009) (Merger Does Not Qualify as Bona Fide Sale)

Germantown Hospital and Medical Center ("Old Germantown"), a non-profit corporation operating a struggling acute care hospital, elected to pursue affiliation with Albert Einstein Medical Center, Inc ("Einstein") in an attempt to continue to serve the health care needs of the community. Einstein incorporated a new entity, Germantown Hospital and Community Health Services ("New Germantown"), and Old Germantown merged into this entity. New Germantown had a board of 40 members, 6 of whom had been on the old Germantown board; in addition, seven members of Old Germantown's board became members of Einstein's board, and two members of Old Germantown's board served on Einstein's executive committee. New Germantown assumed all the assets of Old Germantown (valued at just over $72 million), including Old Germantown's claim for a Medicare loss on a statutory merger, and Old Germantown's liabilities (approximately $34 million). Einstein committed $6 million in funding to be paid to New Germantown over a period of five years to increase services to the community and ensure increased access to healthcare services.

In its Medicare cost report for the cost period ending August 1, 1997, Einstein claimed a loss of $15 million on the disposal of assets through the merger, and claimed reimbursement for Medicare's share of the loss for over $4 million. The FI initially denied the claimed loss, claiming that the merger was not a bona fide sale and that it was a transaction between related parties. Einstein appealed to the PRRB, which allowed the claim; but the CMS Administrator subsequently reversed the PRRB's decision, finding that the merger was between related parties and did not constitute a bona fide sale. Einstein sought review of the Administrator's decision in district court, which granted summary judgment for the Secretary, holding that the Secretary's interpretations of the relevant regulations were reasonable and consistent with CMS' prior interpretations and that the Secretary's factual findings were based on substantial evidence. On appeal, the Third Circuit affirmed the district court's decision.

In its appeal, Einstein first argued that the merger was not subject to the Bona Fide Sales Provision. In response, the Third Circuit echoed its prior decision in *Mercy Home Health,* noting that the Statutory Merger Regulation specifically references 42 C.F.R. § 413.134(f), which identifies bona fide sale as a specific means through which a depreciable asset can be disposed. On that basis, the Secretary's interpretation of the merger regulation to require the transaction to constitute a bona fide sale was reasonable. Einstein next argued that the Administrator's interpretation of the Bona Fide Sales Provision was inconsistent with prior agency statements. The Third Circuit disagreed, finding that the agency's requirement that a bona fide sale be one in

which "reasonable consideration" is exchanged was not inconsistent with the agency's previous statements. In particular, as far back as 1982, the agency had looked to the fair market value when conducting the bona fide sales inquiry; further, in cases where the agency had determined that sales were bona fide even though the consideration paid was less than the appraised value of assets, parties with adverse interests had negotiated at arm's length to arrive at reasonable consideration. The Third Circuit further opined that requiring reasonable consideration was consistent with the long-standing purpose of the Medicare Act, to reimburse for actual and reasonable costs. On that basis, the Court held that the 2000 PRM Amendment and 2000 PM offered clarification to the Bona Fide Sales Provision that was not inconsistent with prior agency policy.

The Third Circuit also concluded that the Administrator's finding that the merger was not a bona fide sale was supported by substantial evidence in the record. It did not appear that the parties negotiated at arm's length; Old Germantown acted with the interests of the new entity in mind and had no incentive of its own to bargain for more. The Court likewise found that the Administrator's finding that New Germantown did not give reasonable consideration was supported by ample evidence; Old Germantown surrendered $72 million in assets for New Germantown's assumption of $34 million in debt and $6 million in contingent consideration. Further, there was another offer on the table that, on its face, could have resulted in a net gain of $27 million. Old Germantown did not pursue that proposal at all.

Because the Third Circuit concluded that the Administrator's interpretation of the Bona Fide Sales Provision was reasonable and his application of the rule to the Germantown merger was based on substantial evidence, it upheld the Administrator's denial of the loss claim on the ground that the merger did not constitute a bona fide sale. The lack of bona fide sale was an independent ground on which the Administrator denied the claim, so the Third Circuit found it unnecessary to reach the related parties issue, and declined to do so. In concluding its opinion, the Third Circuit addressed Einstein's arguments that the Administrator's interpretations effectively constituted a new regulation and that on that basis, the Administrator was required more formal rulemaking procedures in implementing them. The Third Circuit disagreed, finding that the agency's interpretation of the Bona Fide Sales Provision was consistent with previous agency statements and in keeping with the underlying policy of the Medicare Act, and these interpretations did not retroactively alter Einstein's legal rights or duties. Accordingly, the Third Circuit held that the 2000 PM and the 2000 PRM Amendment were interpretive rules that did not require notice and comment rulemaking.

B. *St. Luke's Hospital v. Sebelius*, 662 F.Supp.2d 99 (D.D.C., Sept. 29, 2009)(Merger Does Not Qualify as Bona Fide Sale)

The D.C. district court also determined that a marked disparity between a hospital's purchase price and the net book value of its assets indicated the lack of bona fide sale, and on that basis, a post-merger hospital could not recover on a loss on the depreciable assets that it claimed was recognized in the merger. In this case, Allentown Osteopathic Medical Center ("Allentown") merged with St. Luke's Hospital ("St. Luke's"); upon merger, all of Allentown's assets (valued at $ 25.1 million) passed to St. Luke's, and St. Luke's became responsible for all of Allentown's liabilities (valued at $4.8 million). The assumption of liability was the only consideration St. Luke's gave in exchange for the assets. In its cost report, St. Luke's sought to

recover a loss on Allentown's depreciable assets for $2.9 million, representing depreciation on Allentown's assets that had never been booked or claimed in annual depreciation. The FI initially denied the claim on the ground that the merger was not a bona fide sale, but the PRRB reversed the bona fide sale determination on appeal. The Administrator then overruled the PRRB decision, holding that Allentown did not receive reasonable consideration for its assets and that the merger was not an arm's length transaction; thus, the merger failed to qualify as a bona fide sale from which Allentown suffered any compensable losses. St. Luke's appealed to the district court, which ultimately affirmed the Administrator's decision.

The district court, citing the Third Circuit's decision in Albert Einstein, the Ninth Circuit decision in Robert F. Kennedy, and the Tenth Circuit's decisions in Via Christi, first explained that the Secretary's interpretation making statutory mergers subject to the bona fide sales requirement is supported by the text of the regulations and by common sense. As an aside, the Court mentioned that the Secretary's interpretation does not mean that no statutory merger can ever result in revaluation of depreciable assets; where a merger involves assumption of liabilities that closely mirrors the true value of the depreciable assets, or involves competitive bidding for those assets, it might satisfy the bona fide sale requirements. In response to St. Luke's argument that the Secretary's interpretation was post-hoc rationalization that departed from previous policy that all statutory mergers automatically trigger the reassessment of depreciable assets, the Court responded that agencies may change their informal interpretations at any time, so long as their new position is adequately explained. Here, the Program Memorandum provided sufficient rationale to support the Secretary's interpretation. Further, the Court explained that because the policy at issue was an informal interpretation, it did not require notice and comment. Finally, the Court held that the Secretary's determination that the merger was not a bona fide sale was supported by substantial evidence, namely the sizable gap between the purchase price and the value of Allentown's assets.

The D.C. Circuit later affirmed the district court's decision, finding that the merger was not a bona fide transaction, and thus the hospital was not eligible for reimbursement for a loss on the acquired assets. See *St. Luke's Hospital v. Sebelius*, 2010 WL 2651285 (July 6, 2010).

C. ***Provena Hospitals v. Sebelius*, 662 F.Supp.2d 140 (D.D.C., Oct. 13, 2009)(Merger Does Not Qualify as Bona Fide Sale)**

In Provena, the D.C. district court concluded that the Secretary properly denied a hospital system's reimbursement claims of depreciation-related losses after a merger because the consolidation was not between unrelated parties and further, there was no bona fide sale. Three Illinois hospitals merged to form a new entity in 1997, with the stated purpose of effecting a commonality of ownership and control allowing an integrated affiliation of the entities into a single Catholic-identified integrated health care and human services delivery system. Prior to the merger, Mercy Center was a non-profit corporation that operated a hospital, and on the date of consolidation, Mercy Center merged with two other corporations that operated hospitals to form a new entity, Provena Hospitals ("Provena"). At that time, all three corporations surrendered their assets to Provena. The Mercy Center board continued as the local governing body for the hospital that had been operated by Mercy Center, and the president of Mercy Center became the chief executive of Provena. After the merger, Provena, as Mercy Center's successor-in-interest, submitted a cost report claiming $4.5 million in depreciation-related losses. The FI denied the

claim, and the PRRB affirmed denial on the grounds that the consolidation was a "related party" transaction, for which the recognition of a gain or loss is not permitted. The Administrator affirmed the denial of the claim on the ground that the consolidation was a related party transaction, but also on the ground that the transaction was not a bona fide sale, there was an absence of an arm's-length negotiation between unrelated parties, and further, there was no reasonable consideration transferred for the depreciable assets. On appeal, the district court granted summary judgment for the Secretary, finding that the Secretary reasonably applied the bona fide sale requirement and that substantial evidence supported the determination that there was no bona fide sale here.

According to the Court, the single focal point of Provena's challenge was its contention that, in denying the claim, the Secretary had retroactively applied to this 1997 consolidation an interpretation of the regulations that was not announced until the issuance of the 2000 PM. The Court rejected this argument, explaining that arguments along this line had been "flatly rejected by every Court" that had considered them. The Court emphasized the decision in *Via Christi*, where the Tenth Circuit concluded that the bona fide sales requirement is a reasonable construction of 42 C.F.R. § 413.134(k)(3)(i), supported by the text of the regulations. Further, the Court found it persuasive that, as far back as 1982, the Secretary and the district court reviewing the agency's decision took the position that the concept of bona fide sale included the receipt of reasonable consideration. The Court also pointed out that Provena's position, that the Secretary should only look to net book value and not reasonable consideration, would allow a provider to recognize a loss on consolidation whenever the liabilities assumed were less than the net book value, regardless of whether the provider actually experienced a true loss. On these grounds, the Court concluded that the Secretary's interpretation of the regulations was entitled to deference.

The Court further found that there was substantial evidence to support the Administrator's determination that the consolidation was not a bona fide sale. First, there was no evidence that the consolidation was an arm's length transaction; nothing suggested that the parties bargained or negotiated over the sales price for Mercy Center's assets. Mercy Center made no efforts to find another purchaser, nor did it obtain an appraisal of its assets prior to consolidation. Second, the Court found that there was substantial evidence in support of the determination that Mercy Center did not receive reasonable consideration for its assets; Provena received assets valued at over $100 million in exchange for assuming $45.6 million in liabilities. Provena tried to argue that it assumed contingent liabilities that should have been factored into the price paid for assets, but the Court explained that Courts have consistently rejected similar arguments based on the existence of "contingent liabilities."

D. *UPMC St. Margaret Hospital v. Sebelius*, 2009 WL 3367630 (3d Cir., Oct. 21, 2009) (not published)(Merger Does Not Qualify as Bona Fide Sale)

St. Margaret Memorial Hospital ("SMMH") entered into a statutory merger agreement with UPMC St. Margaret Hospital ("UPMC"). SMMC had assets totaling $87 million and liabilities totaling $71.6 million; upon merger, UPMC received $87 million in monetary assets in exchange for "consideration" of $71.6 million. UPMC also acquired SMMC's depreciable assets, appraised at approximately $36.9 million. On its terminating cost report for its fiscal year that ended on February 28, 1997, UPMC St. Margaret claimed a loss resulting from the merger,

but the FI disallowed the claimed loss. On appeal, the PRRB reversed the FI and decided in UPMC St. Margaret's favor, but the decision was appealed to the Administrator, who reversed the PRRB and affirmed the FI's disallowance. The Administrator based its disallowance on its conclusions that 1) UPMC St. Margaret and SMMH were related entities and 2) the transaction was not a bona fide sale. The Secretary declined review of the Administrator decision, rendering the Administrator's ruling final. UPMC sought judicial review in district court, which denied UPMC's motion for summary judgment and granted the Secretary's motion for summary judgment. UPMC then appealed to the Third Circuit.

The Third Circuit affirmed the district court's judgment, relying heavily on its decision in *Einstein*. In particular, the Court found that the $15 million disparity between the purchase price and the acquired monetary assets was substantial evidence to support the Secretary's determination that the merger did not constitute a bona fide sale. SMMC had argued that the Secretary had looked at the book value of the depreciable assets when assessing the disparity in consideration and instead should have looked at the fair market value; the Court, however, found it unnecessary to even reach the issue of the true value of the depreciable assets given the $15 million disparity between the purchase price and acquired monetary assets. As in *Einstein*, the Secretary's determination that the merger did not constitute a bona fide sale served as an independent ground on which the Secretary denied the claim; thus, the Court concluded that it did not need to address whether the parties were related, and declined to do so.

E. *UPMC-Braddock Hospital v. Leavitt*, 592 F.3d 427 (3d Circ., Jan. 10, 2010)(Secretary Must Analyze Both Prongs of Bona Fide Sale Test; Related Parties Analysis Applies to Relationship Between Parties Pre-Merger)

Braddock Medical Center ("BMC") merged into a subsidiary of its parent corporation, Heritage Health Foundation (the "Foundation"). UPMC-Braddock became the sole surviving corporation, with BMC retaining a significant role in UPMC-Braddock's Board of Directors. As part of the merger, the Foundation agreed to provide $3 million in funding to UPMC-Braddock, and BMC transferred all its assets and liabilities to the new entity. An appraisal was obtained only after the entities merged. The appraisal showed that BMC transferred to UPMC-Braddock cash and hard assets totaling approximately $23.7 million and liabilities valued at approximately $13 million. However, the record revealed that appraisal considerably overvalued BMC's depreciable assets.

Following the merger, UPMC-Braddock submitted a claim for reimbursement of losses related to the transfer of depreciable assets through the merger. The FI flatly disallowed UPMC-Braddock's claim, but the PRRB reversed the disallowance on appeal. The CMS Administrator, however, reversed the PRRB's decision and affirmed the intermediary's disallowance, stating that the disparity between the $24 million assets transferred and the $13 million liabilities assumed indicated that the merger was not a "bona fide sale." Further, because of BMC's "significant participation" in the governance of UPMC-Braddock, the Administrator also concluded that the parties were related and thus were not permitted by the Medicare regulations to use the "sale price" as a stand-in for the UPMC-Braddock's fair market value. The appeal reached the district court on cross motions for summary judgment. The Court found in favor of the Secretary on the grounds that the sale was not a "bona fide sale" and declined to address the plaintiff's other arguments. UPMC-Braddock appealed to the Third Circuit, which vacated the

district court's grant of summary judgment and remanded for further review consistent with its opinion.

In its opinion, the Third Circuit cited the PRM manual, and explained that a bona fide is a transaction that (1) is negotiated at arm's length and (2) results in exchange of reasonable consideration. On the first point, the district court had found that there was substantial evidence to support the Secretary's conclusion that the reasonable consideration was not exchanged; the Third Circuit disagreed. In particular, the Third Circuit noted that the Administrator and the district court used the incorrect figure of $13 million for the value of the depreciable assets; the correct figure, as determined by an independent appraiser, was approximately $3 million. Further, the Third Circuit noted that the Administrator and district court failed to analyze the values assigned to the other assets. Both the Administrator and district court included a $3 million obligation from the Foundation in determining the total assets, but the Foundation was to apply the Fund at its discretion. On that basis, the Third Circuit explained that the district court should have at least considered whether the asset was properly valued at $3 million, or whether it should have been valued at something less. Second, the Administrator and the district court accepted a figure of just over $10 million as the amount of current/cash assets, but only $2 million of that amount represented cash on hand; at least $5 million represented accounts receivable. The Third Circuit noted that the district court should have at least considered whether to discount the fair market value of such assets to adjust for the fact that they were limited use. Accordingly, the Third Circuit determined that the conclusion that the transaction did not result in an exchange of reasonable consideration was not supported by substantial evidence, and remanded so that the district court could consider the question of the reasonableness of consideration in light of the correct figure and after evaluating whether the proper values were assigned to the Fund and to the current/cash assets. The Third Circuit also noted that the district court failed to consider the second prong of the bona fide sale test, (i.e. whether the merger was negotiated at arm's length), and instructed it do to so on remand unless it properly determined there was not enough evidence to support a finding of reasonable consideration.

The Court next turned question of whether the merger was between unrelated parties. Though the district court did not reach this issue, the Third Circuit explained that the question of whether merger was between related parties turns on whether the Court accepts the Secretary's interpretation of the regulation, i.e. that the agency considers whether the parties were related both pre-merger and post-merger. If the Court did not accept the Secretary's interpretation, it was clear that the merger was not between related parties. Accordingly, and because there would be no need to remand unless the Court found the transaction was between unrelated parties, the Third Circuit analyzed the issue. The Third Circuit concluded that the only permissible reading of the regulation is that "between" parties means "pre-merger;" that is, for purposes of the related parties inquiry under §§ 413.134 and 413.17, the agency is only to look at whether the parties were related before the merger. Accordingly, the Tenth Circuit held that the Secretary's interpretation was unreasonable and contrary to the plain language of the regulations. Judge Padova issued a dissenting opinion, in which he agreed with the majority's conclusion that the regulation contemplates inquiry into relatedness pre-merger only, but insisted that the district court should have undertaken a factual inquiry that explored all indicia of relatedness rather than focusing only on the element of shared control between the parties.

F. *Osteopathic Founders Foundation v. Sebelius*, 2010 WL 2990176 (N.D.Okla. July 26, 2010)(Sale Proceeds May Be Allocated to Intangible Assets for Purposes of Calculating Loss on Sale)

The Osteopathic Founders Foundation ("OFF") owned and operated Tulsa Regional Medical Center until it was sold to Notami Hospital of Oklahoma in 1996. In OFF's cost report for that year, the intermediary disallowed certain closing costs which OFF had deducted from the sale proceeds as costs incurred in selling the hospitals, as well as the allocation of the sale proceeds for the appraised value of OFF's medical records ("MR") and assembled work force ("AWF"). OFF appealed to the PRRB, and the PRRB reversed the ruling on closing costs, but affirmed the disallowance of any allocation of sales proceeds for the appraised value of the MR and AWF. The Administrator declined to review and OFF filed this litigation in the district court.

The Court ruled that Secretary's refusal to allocate a portion of a hospital's net sales proceeds to the appraised value of the MR and AWF was arbitrary and capricious and inconsistent with 42 C.F.R. §413.134(f)(2)(iv). The PRRB had found that medical records and an assembled workforce were intangible assets that only existed when the sales proceeds exceeded the value of the tangible assets, and therefore could not be considered among the assets. The Court disagreed, finding that the regulation does not differentiate between tangible and intangible or depreciable and nondepreciable assets, and does not permit an intermediary to accept and reject different parts of an appraisal. The plain language of the regulation permits parties to allocate a lump sum sales price among all assets, without regard to the character of those assets. The regulation further provides that in the event an independent appraisal establishing fair market value is obtained, the intermediary will made an allocation of the sales price in accordance with that appraisal. Here, the sales agreement explicitly allocated portions of the sales price to MR and AWF and an independent appraisal established fair market values and corresponding allocations of net sales proceeds to those assets. While the Secretary's decision to decline to allocate a portion of the net sales proceeds to MR and AWF was imminently reasonable, it was inconsistent with the existing CMS rule.

IV. DISPROPORTIONATE SHARE HOSPITAL PAYMENTS

Under Medicare, hospitals are reimbursed through the Prospective Payment System ("PPS"). In recognition of the fact that hospitals that serve a disproportionately large number of low-income patients incur greater costs than can be met by the standard PPS calculation, such hospitals are provided a disproportionate share hospital ("DSH") adjustment to their PPS payment. A hospital's disproportionate patient percentage is defined as the sum of two fractions expressed as percentages, commonly referred to as the Medicare Low Income Proxy and the Medicaid Low Income Proxy. The Medicaid Low Income Proxy is at issue in the following cases. The numerator of the Mediaid Low Income Proxy is "the number of the hospital's patient days…which consist of patients who…were eligible for medical assistance under a State plan approved under [Title] XIX of the [Social Security Act], but who were not entitled to benefits under [Medicare Part A]." 42 U.S.C. § 1395ww(d)(5)(F)(vi)(II). The denominator is the "total number of the hospital's patient days for such period." *Id.*

A. *Phoenix Memorial Hospital v. Leavitt*, Order Granting Summary Judgment, Case No. 2:07-cv-1720-HRH (D. Ariz. Jan. 13, 2009)(Expansion Population Excluded from Medicaid Proxy for Purposes of DSH Calculation)

Arizona participates in Medicaid pursuant to a section 1115 demonstration project waiver, which is administered by Arizona Health Care Cost Containment System (AHCCCS). AHCCCS provides acute care services to four categories pertinent to this case: (1) Title XIX Categorically Needy (Mandatory Medicaid); (2) Medically Needy/Medically Indigent ("MN/MI"); (3) Eligible Low Income Children ("ELIC"); and (4) Eligible Assistance Children ("EAC") . Of the four categories, Arizona receives Federal Financial Participation (FFP) only for Mandatory Medicaid services; the other three categories are funded entirely with state and county funds.

Plaintiffs are eight Arizona hospitals which challenged the Secretary's decision that Plaintiffs were not entitled to include MN/MI, ELIC and EAC days ("Expansion Population Days") for the purposes of calculating the Plaintiffs' DSH adjustments for fiscal years ending 1994 through 2000. As a result of the Secretary's decision, Plaintiffs alleged that they had received $22 million less in Medicare reimbursement payments than they should have received.

The Court held that because the Medicaid Low Income Proxy is "the number of the hospital's patient days…which consist of patients who…were eligible for medical assistance under a State plan approved under [Title] XIX of [the Social Security Act], but who are not entitled to benefits under [Medicare Part A]," MN/MI, ELIC and EAC days could not be counted since they were not part of Arizona's Medicaid plan, but rather a separate component which is the state-funded health care program for indigent persons. The Court concluded that AHCCCS consisted of two components, the section 1115 demonstration project, and the state-funded health care program for indigent persons, based on the following factors: 1) Arizona did not need federal approval or waivers for the MN/MI, ELIC or EAC patients because in its original application for a section 1115 waiver, it did not seek federal funds for those patients; 2) Arizona sought to expand its demonstration project in 1997 to include MN/MI patients, suggesting that previously they had not been part of the project; and 3) during the relevant time period, Arizona received FFP only for patients in the Mandatory Medicaid category, suggesting that MN/MI, ELIC or EAC patients were outside the Medicaid plan.

The Court recognized that other states had historically allowed hospitals to include Expansion Population Days in their calculation of DSH adjustments, and that in the mid-1990s, intermediaries began to change their policy on the issue (prohibiting the inclusion of Expansion Population Days) and began to notify hospitals that erroneously paid funds would be recouped. Congress intervened and the Department agreed to forego its efforts to recoup the DSH payments in question (the "hold harmless" policy). In addition, the "hold harmless" policy allowed hospitals who had not received erroneous funds to reopen costs reports and get additional payments reflecting the inclusion of Expansion Population Days. However, the hospital had to have filed "a jurisdictionally proper appeal to the PRRB on the issue of the exclusion of these types of days from the Medicare DSH formula before October 15, 1999" in order to qualify for this additional payment.

The Court held that the "hold harmless" policy was not applicable to the Hospitals because they had failed to file a proper appeal within the time limit specified. The "hold harmless policy" reflected a desire by the Secretary to prevent hardship for hospitals which expected to be paid for state-only days and were relying on such payments because of past practice where such days were included in the calculation of the Medicaid Low Income Proxy. However, in this case, the Hospitals stopped receiving funds based on state-only days in 1990, some four years before the alleged underpayment occurred, and could not therefore argue that as a "past practice" they had been receiving funds based on the inclusion of state-only days. In addition, the "hold harmless" policy specifically applied only to hospitals that had "filed a jurisdictionally proper appeal to the PRRB on the issue of the exclusion of [state-only] days from the Medicare DSH formula before October 15, 1999." Only two of the eight plaintiff Hospitals had filed an appeal before October 15, 1999, and those two appeals did not specifically raise the issue of the exclusion of state-only days from the Medicare DSH formula.

B. *Cooper University Hospital v. Sebelius*, 2009 WL 3234625 (D.N.J. Sept. 28, 2009)(Expansion Population Excluded from Medicaid Proxy for Purposes of DSH Calculation)

The New Jersey Charity Care Program ("NJCCP") is a state program that covers some or all of the costs for uninsured hospital patients who are "ineligible for any private or governmental sponsored coverage (such as Medicaid)." The NJCCP was funded through the New Jersey Health Care Subsidy Fund, which itself receives partial funding through the New Jersey Medicaid plan. A New Jersey hospital, which, between 1996 and 1999, was permitted to include NJCCP days in the numerator of the Medicaid Proxy, was not permitted to include such days in its 2000 Medicare DSH calculation. The intermediary relied on a Program Memorandum issued by CMS in December 1999 stating that the "focus [of the Medicaid fraction] is on the patient's eligibility for Medicaid benefits as determined by the State, not the hospital's eligibility for some form of Medicaid payment" (emphasis added). The Hospital filed a timely appeal to the PRRB, which reversed the decision of the fiscal intermediary, but the CMS Administrator reversed the PRRB decision. The Hospital then brought suit in district court, seeking judicial review of the Administrator's decision.

The district court granted summary judgment against the Hospital, holding that the Administrator's decision was reasonable, and that a permissible construction of the Medicare DSH statute was that NJCCP days were excluded from the calculation, because NJCCP patients are not eligible for medical assistance under a state plan, even if the NJCCP program is partially funded through the state plan. Although the Hospital argued that NJCCP days were included under the calculation for Medicaid DSH payments, the Court held that the calculation Medicare DSH payments were more narrowly constructed, a logical distinction given that "Medicaid is an acutely income-dependent program concerned broadly with low-income patients, [whereas] Medicare is focused specifically on the elderly and disabled and less tethered to income."

C. *University of Washington Medical Center v. Sebelius*, 674 F.Supp.2d 1206, 2009 WL 3185592 (W.D. Wash. Sept. 30, 2009) (Expansion Population Excluded from Medicaid Proxy for Purposes of DSH Calculation)

For the period relevant to this lawsuit, Washington's state plan covered the categorically needy and the medically needy, as required by Medicaid, and created programs covering the Limited Casualty-Medically Indigent ("MI") (low-income patients without health insurance who have an emergent medical condition) and the General Assistance Unemployable ("GAU") (low-income individuals unemployable for 90 days). Eighteen Washington hospitals ("Plaintiffs") brought this lawsuit, challenging the Secretary's exclusion of MI and GAU patient days from the Medicaid proxy in calculating their DSH payments.

For the cost-reporting periods between 1994 and 2000, the Plaintiffs' FI refused to include MI and GAU patient days in the calculation of the Medicaid proxy. Plaintiffs appealed to the PRRB as a group, and the PRRB reversed the Fiscal Intermediary. The Fiscal Intermediary appealed, and the acting CMS administrator reversed the PRRB's decision based on his finding that MI and GAU patients were not eligible for medical assistance under Medicaid. The Plaintiffs then filed this lawsuit in district court.

The Court found this case indistinguishable from *Phoenix Memorial* and granted summary judgment for the Secretary, holding that it was proper to exclude MI and GAU days from the Medicaid proxy. According to the Court, though those programs were part of the State Plan, they were not eligible for medical assistance. The Court determined that the days at issue were only mentioned in the State Plan because they are used in the computation of the Medicaid DSH payment, not because they are considered eligible for medical assistance as Medicaid patients under the State Plan. Specifically, the Court held that these patients were not eligible for federal Medicaid matching funds under a State plan and thus the Secretary properly excluded them from the Medicare DSH computation.

D. *Northeast Hospital Corporation v. Sebelius*, 699 F.Supp.2d 81 (D.D.C. Mar. 29, 2010) (DSH Calculation: Charity Care Days, Dual Eligible Medicare Advantage Enrollees, Labor and Delivery)

In Northeast Hospital Corporation v. Sebelius, the D.C. District Court weighed in on a number of DSH calculation questions. Northeast Hospital appealed the Secretary's final decision concerning Medicare DSH payments for the 1999-2002 fiscal years. The Court granted in part and denied in part both parties' motions for summary judgment, vacated the Secretary's final decision, and remanded to the Secretary for further proceedings.

The intermediary had excluded the hospital's charity care days from the numerator of the Medicaid fraction, but the PRRB reversed. The Administrator then reversed the PRRB determination, reinstating the intermediary's determination. The Court affirmed, and rejected the hospital's attempt to have charity care days included in the Medicaid fraction of its DSH calculation. The hospital argued that such charity care days were incorporated into payments made for Medicaid DSH under the state's Title XIX plan, but, following a recent line of cases, the Court refused to include such days in the Medicaid fraction. Charity care cases neither met

the definition of "medical assistance" or "care provided under the State's Medicaid plan." The individuals that received charity care did not meet any of the 13 categories for medical assistance under Medicaid Act; further, the state payment of a DSH adjustment for Medicaid services based on charity care did not constitute care provided under the state's Medicaid plan. Although federal dollars were used to pay for the Medicaid DSH adjustment, and the charity care cases were used to determine payment, that did not qualify those charity care cases to be have been included under the state's Medicaid plan. If those cases were under a state's Medicaid plan, they would have received a Medicaid payment and would not have been charity care cases.

The intermediary had also excluded from the numerator of the Medicaid fraction the days associated with dual-eligible Medicare Advantage enrollees. The PRRB affirmed the determination, and the Administrator affirmed the PRRB. The Court, however, decided in favor of the hospital on this issue. The Secretary had excluded Medicare Advantage days from the numerator of the Medicaid fraction based on the reasoning that individuals may only enroll in a Medicare Advantage plan if they are "entitled to benefits under part A," and thus the Medicare Advantage patients were necessarily entitled to benefits under Part A.. The court disagreed, finding that once an individual enrolls in Medicare Advantage, he/she no longer is entitled to have payments made under Part A. The Secretary's exclusion of Medicare Advantage days, therefore, was incorrect. Further, the Court pointed out that the Secretary's conclusion that Medicare Advantage patients remain entitled to Medicare Part A directly conflicts with her interpretation of identical language elsewhere in the Medicare statute.

The hospital's intermediary had also excluded days associated with labor and delivery services that were attributable to patients who were eligible for Medicaid and not entitled to Medicare Part A benefits. The PRRB reversed the determination, but the Secretary had reversed the PRRB. The Court, however, determined that the administrator had incorrectly excluded labor and delivery days from the numerator of the Medicaid fraction used to calculate the DSH payment. The Secretary acknowledged that she had erroneously determined that costs attributable to labor and delivery room patients were not treated as inpatient operating expenses, and requested that the Court remand to the agency for further proceedings. The hospital, however, sought to have the Court declare the decision invalid and direct the Secretary to include the costs in the DSH calculation. The court remanded, explaining that its task was to determine whether the agency made an error of law; its inquiry ended there. Therefore, it had jurisdiction only to vacate the Secretary's decision and remand to the agency for further action.

Finally, the hospital contended that the Secretary's own data could not support her calculation of the Medicare fraction for the 1999 year. The Secretary acknowledged that the case presented the same allegations of systematic flaws that were raised in *Baystate*, and the Court vacated the final decision and remanded to the agency to determine whether the agency would follow the court's ruling in *Baystate*.

E. *Metropolitan Hospital, Inc. v. United States Department of Health and Human Services*, 2010 WL 1379600 (W.D.Mich., April 5, 2010)(Inclusion of Part A-Exhausted Dual-Eligible Days for Purposes of DSH Calculation)

In this case, Metropolitan Hospital ("Metropolitan") challenged 42 C.F.R. § 412.106(b) (the "DSH regulation"), arguing that it violated the Social Security Act by failing to afford different meanings to "eligible" and "entitled to." The United States District Court for the Western District of Michigan granted summary judgment for Metropolitan, finding that the hospital should include Medicare-Medicaid dual-eligible patient days in the Medicaid fraction of the DSH adjustment but that such days must be excluded from the Medicare fraction. The court invalidated the DSH regulation to the extent it mandated exclusion of these days from the Medicaid fraction but inclusion in the Medicare fraction. The court also ordered the Secretary to instruct intermediaries to allow hospitals to include these days in their Medicaid fractions.

The court invalidated the CMS' interpretation of 42 C.F.R. § 412.106(b), which calls for the inclusion of Medicare Part A-exhausted dual-eligible patient days in the numerator of the Medicare fraction of the DSH calculation (where the patients were also entitled to Supplemental Security Income payments) and the exclusion of those days from the numerator of the Medicaid fraction, for discharges on or after October 1, 2004. Specifically, the court found that CMS' regulation violated the plain and unambiguous language of 42 U.S.C. § 1395ww(d)(5)(F)(vi)(I), which requires only patients "entitled" to Medicare Part A to be included in the Medicare fraction. Under the court's ruling, where a dual-eligible patient has exhausted Part A benefits, the patient is not "entitled" to Medicare Part A for such days. Under the plain language of Section 1395ww(d)(5)(F)(vi)(I), those days must be included in the numerator of the Medicaid fraction and excluded from the Medicare fraction.

The court relied on the Sixth Circuit's decision in *Jewish Hospital Inc. v. HHS*, 19 F.3d 270 (6th Cir. 1994), and found that CMS' regulation failed to distinguish between the terms "eligible" and "entitled." In *Jewish Hospital*, the Sixth Circuit held that the term "eligible" in the Medicaid fraction meant that a person was eligible for Medicaid regardless of whether payment was actually made for the days in question, while the term "entitled" meant that a person had the right to receive payment for those days.

The court rejected the Secretary's argument that it should rely on 42 U.S.C. § 426(a), which generally describes what it means to be entitled to Medicare Part A benefits. Specifically, the court stated that when a statute contains two provisions addressing the same issue, the provision that specifically addresses the situation in question prevails over the more general provision. Further, the court pointed out that 42 U.S.C. § 426(c), another subsection of this same provision, actually supported the provider's argument by explaining that "entitlement of an individual to hospital insurance benefits for a month shall consist of entitlement to have payment made under" Medicare. Because a patient that has exhausted his or her Medicare Part A benefits no longer has a right to payment for such benefits, that patient is no longer "entitled" to Part A benefits for purposes of the Medicare fraction used to calculate the hospital's DSH adjustment.

F. *Banner Health v. Sebelius*, 2010 WL 2265039 (D.D.C. June 7, 2010)(Expansion Population Days Excluded from Medicaid Proxy for Purposes of DSH Calculation; Application of Hold Harmless Provision)

In *Banner,* an Arizona hospital system challenged the Secretary's decision to deny DSH adjustments to four hospitals in return for the expenses the hospitals incurred providing services to low-income individuals. The D. C. district court held that Secretary properly denied DSH adjustments to three of the hospitals, but that the Secretary may have erred in denying the adjustments to a fourth Arizona hospital. The hospital system argued that its treatment of Medically Needy/Medically Indigent ("MN/MI") patient groups should have been included in Medicare DSH calculations because the groups were "eligible for medical assistance under a state plan," even though they were not actually covered by Medicaid. The court, however, determined that the Secretary's decision to exclude the MN/MI groups from the Medicaid fraction of the Medicare DSH calculation was not arbitrary and capricious and was supported by substantial evidence. Since the MN/MI groups were not members of the Medicaid plan, but rather a State-funded portion of the Arizona Health Care Cost Containment System, their treatment did not qualify for DSH adjustments. The hospital system's prior receipt of federal Medicaid funding for the MN/MI patient groups did not prove that these patients were eligible for "medical assistance" under Medicaid. Though the Medicaid DSH provision specifically allows states to adjust DSH payments for low income patients who are ineligible for Medicaid, the Medicare DSH provision does not.

In 1999, the Secretary had determined that it was necessary to clarify the definition of eligible Medicaid days for purposes of calculating the Medicaid fraction and issued a Program Memorandum that clarified that "Medicaid days" refers to days on which the patient is eligible for medical assistance benefits under an approved Title XIX State plan. At that time, the Secretary had adopted a hold harmless policy that, under certain circumstances, allowed hospitals that had received DSH payments based on the erroneous inclusion of ineligible patient days (specifically, Medicaid days) to retain those payments. The policy was not applicable to three of the hospitals here because they never received erroneous Medicare DSH payments containing otherwise ineligible days during the fiscal years under review. The fourth hospital, however, had received erroneous interim Medicare DSH payments that never became final payments, which possibly qualified it for the hold harmless policy. Accordingly, the court remanded the case to the Secretary for a closer examination of that hospital's practice during the appealed cost years.

V. GME/IME

A. *Cottage Health System v. Sebelius*, 631 F. Supp.2d 80 (D.D.C. July 7, 2009)(Notice of Claims Filings Requirements; Written Agreement Requirement for Residents in Non-Hospital Settings)

Cottage Health System addressed two IME/GME reimbursement issues: (1) whether providers had adequate notice of the claims filing requirements for IME/GME payments related to Medicare Part C beneficiaries; and (2) CMS' authority to require providers to enter into a

written agreement with non-hospital providers before they may claim IME/GME reimbursement for residents.

Claims Filing Procedure

Prior to the passage of the Balanced Budget Act of 1997 ("BBA"), only services provided to Medicare Part A and B beneficiaries were counted in calculating a hospital's IME/GME payments. The BBA, however, directed CMS to make IME/GME payments, phased in over five years, for services provided to Medicare HMO enrollees under Medicare Part C. Cottage Health System ("Plaintiff") is a non-profit corporation that owns and operates Santa Barbara Cottage Hospital. In fiscal years 1998 through 2001, the Plaintiff timely submitted UB-92 forms to the Medicare Part C beneficiaries' Medicare HMO to claim the additional IME/GME payments pursuant to BBA. However, the Plaintiff's FI denied the claims because the UB-92s were sent to the Medicare HMO, not the FI.

Plaintiff appealed and asserted that it did not receive adequate notice of the claims filing procedure for the additional IME/GME payments authorized by BBA. The PRRB agreed concluding that no regulation gave notice that hospitals would "be required to file a separate IME/GME claim with the intermediary that was virtually identical to the claim filed with the HMO." The CMS Administrator reversed the PRRB decision, relying on several pieces of sub-regulatory guidance that purported to inform providers that they would have to submit claims associated with Medicare Part C enrollees to their FIs. This guidance included: (1) anticipatory language in a May 12, 1998 rule published in the Federal Register; (2) a July 1, 1998 Program Memorandum; (3) A July 13, 1998 Bulletin; and (4) an August 20, 1998 letter from the FI to the hospital. In addition, the Administrator also found that Plaintiff had not filed its claims within the time limits set forth in 42 C.F.R. §§ 424.30 and 424.44, which govern the timeframe for submitting IME/GME claims for Medicare Part A beneficiaries.

The Court affirmed the Administrator's decision that the Plaintiff received notice it would have to submit claims for the additional IME/GME payments to its fiscal intermediary, but took issue with the Administrator's finding that the Plaintiff notice that that the time limits set forth in 42 C.F.R. §§ 424.30 and 424.44 applied to IME/GME claims for services provided to Medicare Part C enrollees. Specifically, the Court found that "the Administrator did not explain his reasoning in sufficient detail to permit the Court to test his conclusion" and that several aspects of the Administrator's decision were "too conclusory" to permit review. As a result, the Court remanded the issue to Secretary for further administrative proceedings.

Written Agreements

The Court also addressed when a hospital may include residents who are training in non-hospital settings in its resident count. Under the Medicare Act, residents in non-hospital settings may only be included in the provider's IME/GME resident count if: (1) their time is related to patient care and (2) the hospital incurs substantially all of the costs of their training in the non-hospital setting. 42 U.S.C. §§ 1395ww(h)(4)(E), 1395ww(d)(B)(iv). In addition, the regulations governing resident counts require that the hospital have a written agreement with the non-hospital site establishing that the hospital will incur the costs of the residents' training. *See* 42 C.F.R.413.86(f)(4). Here, the FI determined that a post-dated MOU did not satisfy the regulation

requiring a written agreement. The FI's determination was left undisturbed by both the PRRB and the Administrator.

The Plaintiff argued that the Secretary exceeded his authority by requiring a written agreement, in addition to the requirements set forth in the statute. Applying *Chevron* deference, the Court concluded that the Secretary's interpretation of the statute, requiring a written agreement, was reasonable. The Court further concluded that the Secretary's requirement of a contemporaneous written agreement was also reasonable.

B. *Loma Linda University Medical Ctr. v. Sebelius*, 684 F.Supp.2d 42 (D.D.C. Feb. 16, 2010)(Secretary Improperly Determined that Hospital's Claims for GME and IME Costs for Part C Enrollees Were Insufficient and Untimely)

In this case, Loma Linda University Medical Center ("Loma Linda") was unable to submit claims for medical education costs associated with some Medicare Part C beneficiaries because the hospital did not have those patients' HIC numbers. Unlike the cards that Part A beneficiaries present upon registration at a hospital, Part C beneficiaries' insurance cards do not include HIC numbers. Loma Linda made efforts to collect HIC numbers from Part C enrollees by telephone and by letter and through the "Common Working File," a Medicare database, but was only partially successful in its efforts. Loma Linda requested that the FI use information it provided, rather than requiring UB-92 forms, to calculate the payments due. The FI denied the requested reimbursement and the hospital appealed to the PRRB. The PRRB ruled for the hospital, concluding that the FI improperly disallowed the hospital's requested reimbursement for additional GME and IME costs for the three cost years at issue. The majority of the board concluded that CMS should have announced by regulation the system for requesting GME and IME payments associated with Part C services. The Administrator, however, reversed the PRRB, finding that no new regulation was required and rejecting Loma Linda's argument that the inability to collect HIC numbers was the cause of its missing claims. It found that the claims were both insufficient and untimely.

On appeal, the district court disagreed with the Secretary that by specifying the UB-92 as the method for claiming such costs, the hospital was put on notice that the Part A rules applied, including the timely filing limit applicable to Part A claims. After determining that untimeliness was not a valid reason for rejecting the hospital's claims, the Court turned to the issue of whether the form of the information submitted by the hospital was reason for denying the claims.

The Court noted that the Administrator did not refute the hospital's contention that the information it provided was identical to the data that would be included in UB-92 forms, but rather decided that the complications arising from receiving the data in a form other than the one designed to "interface with" the Provider Statistical and Reimbursement Report (PS&R) system were too great. The Court stated that the parties did not identify any evidence in the record pertinent to the assessment of how much labor is involved in or how much inaccuracy is likely to result from inputting data not provided as UB-92 forms. The Court also noted that the Administrator gave no response to the hospital's argument that a letter it received from its FI indicated that use of the PS&R was not mandatory and that in certain instances, the hospital could elect to use its records in part or in total in filing the cost report. Accordingly, the Court

remanded the case to the Secretary for further explanation of or investigation into whether the FI is able to process the hospital's claims.

C. *Hospital of University of Pennsylvania v. Sebelius*, 634 F.Supp.2d 9 (D.D.C. July 10, 2009)(Timely Filing of UB-92s)

Hospital University of Pennsylvania also examined whether CMS gave providers adequate notice of the requirement to file IME/GME claims for services provided to Medicare Part C beneficiaries. Here, three Philadelphia hospitals ("Plaintiffs") challenged the Secretary's decision to deny certain supplemental medical education payments. Relying on its *Cottage Health System* decision, the District Court for the District of Columbia found that providers had adequate notice of the requirement to file UB-92s with the intermediary when it treats Medicare Part C enrollees. The Court then turned its attention to the factual dispute regarding whether the hospital did, in fact, submit UB-92s to its FI.

During the PRRB hearing, Plaintiffs submitted testimonial evidence that UB-92s were timely mailed to the intermediary as well as documentary evidence that circumstantially made the same point. Nevertheless, the CMS Administrator decided that the evidence in the record was insufficient to show that the UB-92s were in fact sent to the FI. Thus, the Court sought to determine "whether the Administrator's decision to disregard plaintiffs' testimonial and circumstantial evidence, and to require direct documentary proof instead, was in accordance with the law." Citing several U.S. Supreme Court and Federal Circuit Court cases, the Court determined that "Courts have long held that proof of receipt may be established circumstantially by proof of mailing." As a result, the Court held that "the Administrator's focus on the lack of documentary evidence was not in accordance with the law" and remanded the issue of whether the testimonial and documentary evidence submitted by the hospital was sufficient to prove the UB-92s were mailed to the FI.

D. *Covenant Medical Center, Inc. v. Sebelius*, 2009 WL 2926442 (E.D. Mich. Sept. 10, 2009)(Secretary Reasonably Required Written Agreement Between Provider and Non-Hospital Site for Provider to Qualify for GME Reimbursement)

Medicare statute allows reimbursement to hospitals for time spent by residents in patient care activities in a non-hospital setting if the hospital incurs all or substantially all of the costs for the training program in that setting. 42 U.S.C. § 1395ww(d)(5)(B)(iv). Prior to 2004, the Medicare regulations required hospitals seeking such Medicare reimbursement to have a written agreement in place with each non-hospital site. The Secretary rescinded that regulation in 2004.

Covenant Medical Center owns Synergy Medical Education Alliance, which is accredited to conduct medical education programs. Synergy operates clinics at which residents assigned to Covenant provide medical services to Medicare beneficiaries and other patients. The residents were employed and compensated by Synergy, but according to Covenant, Covenant funded Synergy in proportion to the percentage of time that its residents were assigned to the hospital. Prior to 1999, the intermediary reimbursed Covenant for training costs associated with the Synergy resident program. For fiscal years 1999, 2000, and 2001, however, the intermediary denied reimbursement for training costs associated with Synergy offsite residents because Covenant did not have a written agreement with Synergy, as required by the regulations.

Covenant appealed the decision to the PRRB, which reversed, but upon review, the Administrator reversed the PRRB and upheld the FI's denial. Covenant then appealed to the district court. The district court granted the Secretary's motion for summary judgment, denied Covenant's motion for summary judgment, and entered judgment for the Secretary.

The Court ultimately concluded that the written agreement requirement was not arbitrary, capricious, or contrary to the Medicare Act, as it ensured it was a reasonable way to verify that the hospital was incurring the costs for which it sought reimbursement and it ensured that both the hospital and non-hospital were not being paid for the same cost. Covenant had first argued that the written agreement was invalid because it conflicted with the Medicare statute, which required (1) that the costs were for "patient care" and (2) that the hospital incurred all or substantially all of the costs for the training program. The Court disagreed, finding first that the statute was silent with respect to whether a written agreement was required and second that the written agreement requirement ensured that the hospital and non-hospital were not paid for the same cost and provided a reasonable way to verify that the hospital was actually incurring the costs claimed. The Court further opined that the fact that the regulation was ultimately rescinded, in itself, had no bearing on its validity while it was in effect. Covenant also argued that it and Synergy were "related parties," and thus, that the Medicare related parties regulation would require costs incurred by Synergy to be considered costs incurred by Covenant. The Court, however, explained that the related party regulation prevents companies controlled by a provider from making a profit at Medicare's expense, while the written agreement regulation ensures that the provider was actually incurring the claimed cost. Simply because Covenant and Synergy were related parties did not mean that the hospital was financially responsible for paying all or substantially all of the training costs in the non-hospital setting. In concluding its opinion, the Court rejected Covenant's argument that it had substantially complied with the written agreement requirement because it submitted hundreds of documents that showed that it did incur the costs requested. According to the Court, while the documents may have shown that Covenant funded 75% of Synergy, none of the documentation demonstrated that Covenant incurred all or substantially all of the costs associated with training residents, such as resident salaries and benefits.

E. *Medcenter One Health Systems and St. Alexius Medical Center v. Leavitt*, 666 F.Supp.2d 1043 (D.N.D. Oct. 13, 2009)(Non-Hospital Sites)

Two hospitals in North Dakota – Medcenter One Health Systems and St. Alexius Medical Center ("Plaintiffs") – participated in a family practice residency program operated in conjunction with the University of North Dakota School of Medicine. As part of the program, Plaintiffs established the Family Practice Center in Bismarck, North Dakota and rotated their residents to receive training there. Plaintiffs ensured that Medicare only paid once for the costs of training the FTE residents that rotated through the Family Practice Center.

Plaintiffs' FIs denied the hospitals' Medicare GME claims for the costs incurred in training the residents at the Family Practice Center in 1999 through 2001. The Secretary contended that the adjustments were appropriate because: (1) the hospitals did not have a written agreement to indicate who would bear all or substantially all of the costs of the residency training program; (2) that a 1998 revision to the GME regulations provided the hospitals with notice that they were required to have a written agreement with the non-hospital site apportioning "all or

substantially all" of the costs of the resident training program; and (3) that the 2003 and 2007 regulations provided further notice that "if two (or more) hospitals train residents in the same accredited program, and the residents rotate to the same non-hospital site(s), the hospitals cannot share the costs of that program at that non-hospital site." The Court rejected each of the Secretary's arguments and found for the hospitals.

First, the Court found that the fiscal intermediary had conceded that the hospitals had compliant written agreements during the PRRB proceedings and that concession bound the government.

Second, the Court found the 1998 regulations to be inapposite to the present situation. Specifically, the Court determined that the revised 1998 GME regulations governed non-hospital providers reimbursement for GME costs.[1] Accordingly, the Court held that the 1998 regulations did not address "a situation in which two or more hospitals split the total cost of a medical residency training program with each hospital paying for the costs incurred in training its own residents" and did not establish a policy prohibiting hospitals from splitting the total costs of a medical residency training program.

Third, the Court determined that the Secretary's interpretation of the Medicare Act, included in an August 1, 2003 final rule, forbidding hospitals from sharing the cost of an accredited residency training program, was a substantive change in policy from prior interpretations and not simply an administrative interpretation. As a result, the government's application of this 2003 policy to cost years 1999 through 2001 was an impermissible retroactive application of Medicare regulations.

F. *Hackensack University Medical Center v. Johnson,* 2009 WL 2168719 (D.N.J. July 17, 2009)(not published)(Providers May Not Use FTEs From Unaffiliated Hospitals to Increase FTE Count)

Hackensack University Medical Center brought suit in district court in New Jersey, challenging the intermediary's calculation of its graduate medical education ("GME") intern and resident full time equivalent ("FTE") count.

In February 1997, United Hospital ("United") declared bankruptcy and permanently closed. At that time, United had 49.5 FTEs rotating through its facility as part of the University of Medicine and Dentistry of New Jersey's ("UMDNJ") training programs. The residents generally rotated between several hospitals to complete their academic program, so UMDNJ ultimately reassigned the displaced residents to UMDNJ, Morristown Hospital, St. Michael's Medical Center, and Hackensack. In June 1998, the hospitals negotiated and entered into an "Agreement for an Aggregated Count of Residency Positions" ("Agreement"), which specified the number of residents that were at all hospitals participating in the UMDNJ residency program as of December 31, 1996. Twelve of the positions were allocated to Hackensack for the 1997 and 1998 academic years. UMDNJ, Morristown, St. Michael's and Hackensack signed the agreement, but United did not. In

[1] Prior to the 1998 regulations, non-hospital providers were not eligible for GME reimbursement.

December 1998, CMS issued written guidance to the Intermediary, explaining that the Balanced Budget Act of 1997 ("BBA") permitted the Secretary to develop rules allowing hospitals which are part of the same affiliated group to reallocate their aggregate FTEs under the 1996 FTE cap so long as the agreements meet the requirements specified in the regulations. CMS further explained that since the Agreement was not signed by United, United's residents could not be included in the aggregate cap.

Accordingly, the Intermediary did not allow a permanent increase of 12 FTEs to Hackensack's FY 1996 base year cap, and initially did not allow for a temporary adjustment. When Hackensack appealed, however, the Intermediary reviewed figures and documents from United and Hackensack to compute a temporary cap adjustment of 4.74 FTEs for indirect medical education costs and 4.38 FTEs for direct GME costs for the fiscal year 1998.

Hackensack appealed the revised Notice of Program Reimbursement to the PRRB, but the PRRB affirmed the decision of the Intermediary, finding that the Agreement did not meet the definition of an "affiliation agreement" and that the Intermediary's temporary adjustment made to Hackensack's fiscal year 1996 cap (for purposes of the fiscal year 1998 count) was appropriate. The CMS Administrator declined to review the PRRB decision, and Hackensack subsequently filed its complaint in the District of New Jersey.

The Court granted the Secretary's motion for summary judgment. In its opinion, the Court first clarified that the statutory purpose of the resident caps is to limit the number of residents reimbursed by Medicare. Although the BBA was enacted to help control costs, the BBA also recognizes the need to address situations in which two or more hospitals jointly train residents in a given program and, thus, empowered the Secretary with broad discretion to define what constitutes an aggregation agreement. The Secretary's definition contemplates several hospitals sharing their residents, i.e. if three hospitals have 10 residents each for a total of 30 residents, they can agree to share all 30 residents. The definition does not contemplate a situation where, for example, two of the three hospitals agree to share the residents without participation from the third hospital. If the Secretary's definition did allow for such an arrangement, it would not address the concern that providers would be able to game the system by trading or selling residency positions to other sites.

On that basis, the Court determined that the Secretary's decision denying the permanent increase of FTEs for Hackensack was not arbitrary or capricious; it would be beyond the Secretary's authority to create a permanent exception to the cap imposed by the legislature in the BBA. The Court likewise found that the Secretary's decision as to the temporary increase was not arbitrary or capricious because the Secretary's decision was based on the information provided to him; Hackensack had failed to provide any evidence supporting its allegation that the methodology was arbitrary.

In an unpublished decision, the Third Circuit affirmed, finding that the Secretary's decisions to (1) deny the permanent increase in FTE residents and (2) deny the temporary adjustment to the hospital's FTE cap were supported by substantial evidence. See *Hackensack University Medical Center v. Johnson,* 2010 WL 1936264 (May 14, 2010).

G. *University of Chicago Medical Center v. Sebelius*, 645 F.Supp.2d 648 (N.D.Ill. Aug. 3, 2009)(Secretary Improperly Disallowed Research Time)

Here, the University of Chicago Medical Center ("Plaintiff") challenged the FI's exclusion of educational research conduced by the hospital's residents from its IME payment. As a result, the Court sought to determine whether a resident who performs educational research may be included in a hospitals IME resident count under the 1996 version of 42 C.F.R. § 412.105(g).[2]

In 1996, the fiscal year at issue, 42 C.F.R. § 412.105(g) stated that residents will be included in a teaching hospitals IME resident count if: (1) the resident is enrolled in an approved teaching program; and (2) the resident is assigned to "a portion" of the hospital subject to PPS. The government defended the adjustment by arguing that the term "a portion" of the hospital has a functional definition. Under this interpretation, a resident involved in educational research, regardless of where the research occurs, should be excluded from the IME resident count. In contrast, the hospital argued that the term "portion" refers to a geographic location within the hospital.

The Court agreed with the Plaintiff and held that "the term 'portion' unambiguously refers to a geographic location." The Court found that the Seventh Circuit had "clearly imparted a geographic meaning to the term 'portion' in *Rush University Medical Center*, 535 F.3d 735 (7th Cir. 2008). The Court also found that "in order to give meaning to each word used in the regulation, the term 'portion' must possess a geographic meaning." Finally, the Court noted that the Medicare Intermediary Manual never advised auditors to investigate a resident's function and instead directed auditors to exclude residents from the resident count only when they were in geographic locations that were not subject to PPS (e.g., working at another provider, assigned to excluded units, or assigned to freestanding clinics).

H. *Rhode Island Hospital v. Sebelius*, 670 F.Supp.2d 148 (Nov. 24, 2009, D.R.I. 2009)(Secretary Improperly Disallowed Research Time)

Rhode Island Hospital also addressed whether research unrelated to patient care may be counted toward a hospitals FTE count under the 1996 version of 42 C.F.R. § 412.105(g). Prior to 1996, all resident research time had been counted toward the hospital's resident count. Here, Rhode Island Hospital ("Plaintiff") challenged its FI's denial of resident time for research unrelated to patient care in the hospital's fiscal year 1996 cost report. Specifically, the FI reduced the hospital's IME request by 12.06 FTEs resulting in a disallowance of approximately $1 million. Plaintiff appealed the disallowance arguing: (1) the 1996 regulation required reimbursement of research activities, regardless of whether they related to patient care; and (2) 7.49 of the disputed FTEs involved caring for patients.

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[2] In 2001, this regulation was amended to state "[t]he time spent by a resident in research that is not associated with the treatment or diagnosis of a particular patient is not countable." 42 C.F.R. § 412.105(f)(1)(iii)(B). As a result, under the current regulation, a hospital is not able to include a residents educational research time in its resident count.

The first issue was resolved by the First Circuit Court of Appeal in favor of the Secretary. In *Rhode Island Hospital v. Leavitt,* 548 F.3d 29 (1st Cir. 2008), the First Circuit held that under the 1996 regulation only research time related to patient care was properly included in hospital's FTE count. As a result, the issue before the Court was limited to the Secretary's determination that Plaintiff did not demonstrate that the residents were involved in research related to patient care.

The Court then proceeded to reverse the Secretary's decision that the hospital failed to demonstrate that the resident's research time was related to patient care on two grounds. First, the Court found that the Secretary decision used inconsistent and confusing criteria for assessing patient care. Specifically, in her decision, the Secretary referenced three distinct standards, including: (1) whether the residents' time "related to the treatment or diagnosis of particular patient;" (2) whether the residents' time "related to patient care;" and (3) whether the record demonstrated "the percentage of time the residents saw patients during a monthly research rotation." The Court held that "these dissonant criteria, crowded into a single paragraph of explanation, cloud the precise reasons relied upon by the Secretary in holding that Plaintiff's proof was insufficient."

Second, the Court held that the Secretary impermissibly relied on the 2001 version of 42 C.F.R. § 412.105(g) in making her decision. In 2001, the regulation was amended to explicitly limit reimbursement to research "associated with the treat or diagnosis of a particular patient." The Court held that the Secretary "wielded the 2001 Amendment improperly" to the extent that it required the hospital to show the research was "associated with the treatment or diagnosis of a particular patient" or to specify when the "residents saw" particular patients.

As a result, the Court remanded the case to the Secretary with instructions to provide a "reasoned explanation" for its decision and to address the following issues: (1) set forth the evidentiary criteria applicable under the 1996 regulation for documenting that research relates to patient criteria (without having the effect of replicating the substantive standard embodied in the 2001 regulation); (2) review the record and explain the extent to which the documentation Plaintiff provided does or does not meet the criteria; (3) state, for each department at the hospital where research is at issue, how many of the contested FTEs qualify for reimbursement and how many do not.

I. *Henry Ford Hospital v. Sebelius*, 680 F.Supp.2d 799 (E.D.Mich. Dec. 30, 2009)(Research Time; FTE Cap Increase)

Henry Ford Hospital involved two IME/GME issues: (1) whether residents engaged in educational research may be excluded from the hospital's IME resident count under the 1996 version of 42 C.F.R. § 105(g)(1); and (2) what constitutes a "new program" under the FTE cap imposed by Congress in 1996.

<u>Research Time</u>

The pertinent version of 42 C.F.R. § 105(g)(1) provided that in order to be counted, residents must "be assigned to one of the following areas: (A) The portion of the hospital subject to the prospective payment system; (B) the outpatient department of the hospital." As in

University of Chicago Medical Center, the Secretary argued that the words "areas" and "portion" in the regulation have a functional meaning and that the residents' physical location alone cannot trump the requirement to provide inpatient services. Here, Henry Ford Hospital (the "Plaintiff") argued that the terms "area" and "portion" denotes geographic areas of the hospital rather than activities pursued in those geographic areas.

The Court began by noting that it must defer to the Secretary's interpretation unless: (1) an alternative reading is compelled by the regulation's plain language; or (2) an alternative reading is compelled by evidence of the Secretary's intent at the time of the regulation's promulgation. The Court then proceeded to reject the Secretary's position holding that the Secretary's interpretation is at odds with both the plain language of the regulation and the Secretary's intent at the time of promulgation. With regard to the regulations plain language, the Court held that although the word "areas" is "susceptible to more than one possible definition . . . reference to the context of the word's usage within the structure of the regulation renders the word 'areas' unambiguous" and clearly has a geographic, not functional, connotation. With regard to the Secretary's intent at the time of the regulation, the Court held "[t]he record is replete with evidence that, when the Secretary first promulgated 42 C.F.R. § 412.105, only a *geographic* usage of the word 'areas' was envisioned."

<u>FTE Cap</u>

In 1997, Congress capped Medicare reimbursement for IME at the number of residents that the hospital trained in 1996, but instructed the Secretary to provide an exception for residency programs "established" after January 1, 1995. Plaintiff argued that although two of its residency programs – the Vascular and Interventional Radiology program and the Clinical Neurophysiology program – were training residents prior to the January 1, 1995 cutoff, they were not "established" as defined by regulations due to the fact that those programs were not accredited until March 9, 1995 and July 1, 1996, respectively. According to the Plaintiff, the regulation allows them to obtain an increase in their FTE cap for their "new medical residency programs that either began training residents between January 1, 1995 and August 5, 1997 *or* gained accreditation during the period." In contrast, the Secretary argued that because the programs at issue were training residents before January 1, 1995 they were not established on or after January 1,1995.

The Court held in favor of the hospital finding that 42 C.F.R. § 413.89(g) "clearly states that there are two separate and distinct ways for a residency program to be considered 'new' for purposes of the FTE cap adjustment," either begin training new residents on or after January 1, 1995 or receive accreditation on or after January 1, 1995. Thus, the Court found that because the programs at issue received initial accreditation between January 1, 1995 and August 5, 1997, residents from these program are eligible to be added under the plain language of the cap. In the alternative, the Court also found that the Secretary's contention that a program can be "established" before it is new is contrary to indications of the Secretary's intent at the time of the regulations promulgation.

J. *Hillcrest Riverside, Inc. v. Sebelius* 680 F.Supp.2d 30 (D.D.C. Jan. 12, 2010)(Application of Correct 1996 Base Year Cap in Later Cost Reports Did Not Constitute Reopening of the 1996 Cost Report)

In *Hillcrest Riverside, Inc.* the District Court for the District of Columbia ruled that an intermediary's determination, in 2005, that the IME FTE count in a provider's 1996 cost report was incorrect did not constitute a reopening of that cost report.

Plaintiff's 1996 cost report, the cost report subject to the "FTE cap" discussed in *Henry Ford Hospital*, referenced two different figures as the IME FTE count. Worksheet E of the cost report referred to Workpaper M-7-2, a document that was not included in the cost report, but indicated that the cost report's IME FTE count was 88.14. Worksheet S-3, which was included in the 1996 cost report, listed the IME FTE count as 107.00. For fiscal years 1999-2002, Plaintiff reported its IME payment with a cap of 85.79. When the FI issued its NPRs following Plaintiff's submission of the 1999-2001 cost reports, however, it adjusted the IME FTE cap up to 104.15. Plaintiff then filed its cost reports for 2003 and 2004 using the cap of 104.15 IME FTEs. In late 2004 or early 2005, CMS identified the error in the cap, and in 2005, the FI reopened the cost reports for fiscal years 1999 through 2004 and issued revised NPRs for those years, reducing the IME FTE cap from 104.15 to 85.79.

After concluding that the 88.14 figure reflected in Worksheet E was the correct IME FTE count, the PRRB had determined that the FI's action was not a reopening of the 1996 cost report, but rather, an application of the correct 1996 base year FTE cap. The district court agreed, finding that (1) the FI's 2005 determination that the IME FTE count contained in the 1996 cost report was 88.14 (and not 104.15) did not constitute reopening of the 1996 cost report and (2) the FI's determination did not violate the three-year state of limitations on reopening a cost report.

K. *Langley Porter Psychiatric Institute v. Sebelius*, 2010 WL 3118687 (N.D.Cal. Aug. 3, 2010) (Election to Aggregate FTEs Required for GME Reimbursement)

Langley Porter Psychiatric Institute ("Langley") and the University of San Francisco Medical Center ("UCSFMC") were operating under a single California license, with Langley serving as a sub-provider of UCSFMC for purposes of Medicare costs. For purposes of GME reimbursement, the intermediary had assigned a single aggregated FTE cap to UCSFMC (539.37, which accounted for 505.87 at UCSFMC and 33.5 at Langley). In 1997, Langley and UCSFMC separated, and Langley obtained its own Medicare provider number, but the hospitals continued to operate as before, with UCSFMC training its psychiatric residents at Langley. The intermediary continued to use the aggregated FTE cap for UCSFMC. Langley sought reimbursement for GME on its 1999 and 2000 cost reports up to the 33.5 FTE cap that the intermediary had established in calculating UCSFMC's aggregated cap. The intermediary denied Langley's claim on the grounds that there was no written affiliation agreement to aggregate FTEs between the hospitals for the time in question. Langley appealed the intermediary's decision, and the PRRB found that Langley failed to meet the regulatory requirements necessary to secure reimbursement for GME during the years in question. Specifically, the PRRB found that Langley and UCSFMC met the definition of an affiliated group and that Langley had trained residents and incurred the costs of training, but that the

hospitals had not made an election to affiliate for purposes of GME. The Administrator declined to review and Langley filed a complaint for review of the PRRB's decision in district court.

The Court denied Langley's motion for summary judgment and granted the Secretary's motion for summary judgment. There was substantial evidence to support the PRRB decision that Langley and UCSFMC failed to make an election to aggregate the FTE count for the residents they counted in claiming reimbursement for GME. Although the PRRB found that Langley and UCSFMC met the requirements to be an affiliated group, they failed to make an election to aggregate FTEs because UCSFMC's FTE cap for fiscal years 1999 and 2000 was not reduced to reflect Langley's reported FTE cap for those years. Though there was a negative adjustment to UCSFMC's FTE cap during 1999 and 2000, the submitted evidence demonstrated that the adjustment did not, and was not intended to, correspond with any positive adjustment in Langley's FTE cap. The PRRB had characterized this reporting discrepancy as a failure to meet the requirements of the regulation that would have secured reimbursement for these costs, a decision that was consistent with regulatory guidance. In this case, UCSFMC's failure to satisfy this requirement was adequate support of the PRRB's conclusion. Ultimately, the PRRB's decision to focus on the hospital's failure to adjust its FTE cap for FYs 1999 and 2000 is reasonable and consistent with the interpretive guidance. The Court explained that its task was to determine whether the PRRB's decision was based on a permissible interpretation of the controlling regulations and reasonably grounded in the administrative record. Here, the Court found that PRRB's decision that Langley and UCSFMC failed to make an election to aggregate FTEs was neither plainly erroneous nor inconsistent with the regulation.

VI. MISCELLANEOUS MEDICARE ISSUES

A. *Alta Bates Summit Medical Center v. Sebelius*, 660 F.Supp.2d 73 (D.D.C 2009)(TEFRA)

Congress excluded certain types of hospitals and hospital units, such as inpatient psychiatric hospital units, from the Prospective Payment System ("PPS") because of their atypical patient populations. Until recently, these non-PPS units are reimbursed based upon the "reasonable costs" of their services. However, under the Tax Equity and Fiscal Responsibility Act of 1982 ("TEFRA"), non-PPS hospitals are given financial incentives to keep costs below a "target amount" and penalized when costs exceed that amount. *See* 42 U.S.C. § 1395ww(b). A hospital's TEFRA target amount is determined by the amount of allowable operating costs of inpatient hospital services during the year before TEFRA applied to the unit, known as the "base year," plus an annual percentage increase to account for inflation.

In 1992, Alta Bates acquired a psychiatric unit as part of a merger, which it operated for a short time, but ultimately closed in June 1992. Alta Bates subsequently removed psychiatric services from its state license and did not have an active psychiatric unit for several years. In 1997, Alta Bates opened a geriatric inpatient psychiatric unit and received a new Medicare certification for that unit. When Alta Bates submitted its first cost report for its new geriatric

facility in 1998, it reported the unit as a "new unit" with no existing TEFRA target rate limit. Upon review, the hospital's fiscal intermediary determined that the proper TEFRA base year for the new unit was 1984 – the base year that had been established for the "old unit" and determined that the per discharge target amount was $7,434.31, opposed to $16,108.41 claimed on the hospital's cost report. The PRRB affirmed the intermediary's decision to use 1984 as the TERRA base year. On appeal, the district court affirmed the PRRB decision.

In court, the hospital contended that its geriatric psychiatric unit was "newly established" and that the base year for the unit should be the 12 months following the new unit's certification to participate in Medicare. 42 C.F.R. § 413.040(b)(1). The court noted that the regulation do not define the term "newly established excluded unit" and acknowledged that each party presented plausible interpretations of the applicable regulations. However, the court found that its review was limited to whether the PRRB's interpretation of the regulation was reasonable and determined that the PRRB's interpretation easily satisfied this deferential standard. The court explained that while "newly established" might mean "newly certified," it could also be interpreted to apply only to a completely new facility or to apply only to units operated by providers who have never operated a similar excluded unit with an established TEFRA amount. Further, the court found that it was proper for the PRRB to consider the adverse policy consequences of an alternative interpretation – *i.e.* a hospital could obtain a new base year anytime it wanted simply by closing and reopening.

B. *Chalmette Medical Center, Inc. et al. v. U.S. Department of Health & Human Services*, 2009 WL 2488265 (E.D.La., Aug. 10, 2009)(Secretary's Regulation Establishing Target Amounts under TEFRA is Reasonable)

In 1982, Congress imposed limits on cost reimbursement to certain hospitals and units under the Tax Equity and Fiscal Responsibility Act ("TEFRA"). If a hospital's operating costs exceeded a target amount set by TEFRA, the hospital was subject to a reduction in the amount of reimbursement. Between 1998 and 2002, Congress subjected reimbursement rates for certain hospitals and hospital units to a cap scheme under the Balanced Budget Act of 1997. After the cap scheme ended, CMS calculated the target amount for a hospital based on target amounts in previous cost reporting years. 42 U.S.C. § 1395ww(b)(3)(A) explains that the target amount in the first year is defined as the allowable operating costs of an inpatient hospital services for that hospital for a 12-month reporting period; for subsequent years the target amount is the target amount for the preceding 12-month cost-reporting period, increased by an applicable percentage rate. 42 U.S.C. § 1395ww(b)(3)(H) explains that the cap was based on the 75th percentile of target amounts of hospitals within the same class for fiscal years 1998-2002. The applicable regulation, 42 C.F.R. § 413.40(c)(4)(i)-(iii) states that for 1997-2002, for a psychiatric hospital or unit, the target amount <u>is</u> the lower of either the hospital-specific target amount, or the 75th percentile of target amounts for the previous year for hospitals in the same class, subject to a percentage increase.

Chalmette Medical Center and Pendleton Methodist Hospital, LLC ("Plaintiffs") challenged the regulation in district court, contending that it conflicts with the Medicare statute by erroneously equating the target amount with the 75th percentile cap of target amounts for similar hospitals, thereby extending the cap scheme. Plaintiffs also sought judgment finding that

for the fiscal years at issue, their TEFRA limits were to be calculated using each hospital's initial, hospital-specific, pre-cap target amount as updated through 2003 and 2004.

The Court denied Plaintiffs' motion for summary judgment, and granted DHHS's motion for summary judgment. The Court explained that the unambiguous statutory language required that when the hospital-specific target amount exceeded the cap, the target amount become the cap amount. Thus, as applied to the Plaintiffs, the target amount in 2002 was the target amount actually applied based on the cap in 2002. DHHS had appropriately calculated the target amount in subsequent years based in part on the target amount applied in pervious years. Normally, when the Court finds that the language of the statute unambiguously resolves the issue in dispute, the Court would conclude its analysis. Here, however, the Court acknowledged that other Courts had found the statute to be silent on the definition of target amount, and thus went on to explain that even if it determined the statute was silent on the issue, it would arrive at the same conclusion. The Court explained that, during the capped years for providers whose hospital-specific costs exceeded the 75th percentile cap amount, the target amount was the cap amount. Thus, where target amounts were based on prior years' target amounts, and some of those prior years were subject to cap (i.e. 2002), the new target amounts would be affected by the fact that the cap existed for those prior years. If Congress had wanted the target amount to be the hospital-specific target amount after 2002, Congress could have done so; instead, the statute directed that the target amount be based on the prior year's target amount, modified by an update factor. On those grounds, the Secretary's regulation was consistent with the terms of the statute.

C. *Hardy Wilson Memorial Hospital v. Sebelius,* 2010 WL 3259995 (5th Cir. Aug. 19, 2010) (TEFRA)

Five hospitals ("Providers") alleged that CMS's method for calculating reimbursement payments for costs incurred by their psychiatric units between 2003 and 2005 violated the TEFRA statute and was inconsistent with the agency's own regulations.

In 2003, after the Balanced Budget Act cap provisions expired, Providers submitted their reimbursement requests on the basis of the hospital-specific target amounts in 42 C.F.R. § 413.40(c)(4)(iii)(A). The intermediary rejected those figures and instead calculated reimbursements based on 42 C.F.R. 413.40(c)(4)(ii) (the capped amount). The Providers appealed to the PRRB, which granted expedited judicial review. The district court granted summary judgment for CMS, finding that the agency's method for calculating target amounts for psychiatric hospitals and units was consistent with the governing statutes and regulations and further, that the method CMS used to calculate payments between 2003 and 2005 was permissible. The Providers appealed to the Fifth Circuit, and the Fifth Circuit reversed.

The Fifth Circuit ruled that CMS's decision to use capped amount, rather than hospitals' individual costs, to calculate Medicaid reimbursements for years 2003, 2004, and 2005 did not violate TEFRA, but that CMS's interpretation of its regulations was not entitled to deference. It was only in 2005, well after the expiration of the caps, that CMS amended 42 C.F.R. § 413.40(c)(4)(iii) to expressly limit the entire subsection to "cost reporting periods beginning on or after October 1, 1997 through September 30, 2002." CMS had stated that it intended the amendment to clarify the language to emphasize that because the section was "no longer applicable for cost reporting periods beginning on or after October 1, 2002…the target

amounts for FY 2003 would be the cap amount paid in FY 2002, updated to FY 2003." The Court found that CMS's "clarification" was a substantive change to the regulatory text, and that the Secretary was bound by her own regulations until they were changed.

D. *Catholic Health Initiatives v. Sebelius*, 2010 WL 3198787 (D.C. Cir. August 13, 2010) (The Manual Provision Disallowing Insurance Premium Payments to Offshore Captive Insurer from Hospital Reasonable Cost Reimbursement was Outside the Secretary's Authority)

Catholic Health Initiatives (CHI) filed suit to challenge the PRRB decision to uphold the cost report disallowance of malpractice insurance premiums that CHI paid to First Initiatives Insurance Ltd. ("FIIL"), its wholly-owned insurer that is domiciled in the Cayman Islands and invests forty to fifty percent of its assets in equity securities. The PRRB's decision was based on a Provider Reimbursement Manual provision (PRM § 2162.2.A.4.) that disallows insurance liability premiums paid to captive insurers (those that are wholly-owned by the provider hospitals) that are domiciled offshore and invest more than ten percent of their assets in equity securities. After the Administrator declined to review, CHI appealed to the district court, which granted summary judgment for the Secretary on the ground that the Board's adherence to the Manual's interpretation was not plainly erroneous or inconsistent with the statute or regulation. CHI then brought this appeal before the D.C. Circuit. The D.C. Circuit reversed the district court's judgment, and remanded with instructions to set aside the PRRB's decision.

The D.C. Circuit limited its review to the question of whether the Manual's investment limitations for offshore captives is an "interpretive rule." The Secretary argued that the Manual provision was an interpretation of the statute and regulations governing "reasonable costs." The D.C. Circuit, however, disagreed, finding that there was no indication that the Manual provision was an interpretation of the Medicare Act or of the regulations. Accordingly, it was not exempt from the notice and comment procedure.

E. *Gundersen Lutheran Medical Center, Inc. v. Johnson*, 2009 WL 596974 (D.D.C., Mar. 9, 2009)(Secretary Followed Regulatory Procedure in Making Determination on ESRD Exception Request)

Under 42 U.S.C. § 1395rr(b)(7)(2001), Medicare reimbursement payments are determined by "a method (or methods) for determining prospectively the amounts of payments to be made for dialyses services furnished by providers of services." The statute authorizes providers to obtain exceptions to such methods as may be warranted by unusual circumstances. The Secretary has promulgated regulations enumerating the circumstances warranting such exceptions, explaining that providers seeking such exception must submit specific materials for CMS to make its determination of whether an exception applies. 42 C.F.R. § 413.180. The statute further provides that each application for exception shall be deemed approved unless the Secretary disapproves it by not later than 60 days after the date the application is filed.

Gundersen Lutheran Medical Center ("Gundersen") submitted a request for an exception to its FI, predicated upon its contention that it met the Atypical Service Intensity Criterion developed by CMS. Within 60 working days of that application, the Secretary advised the FI that Gundersen's request was denied. On the 64th working day following Gunderson's request,

the FI sent Gundersen a letter notifying it of CMS's denial of the exception request. Gundersen appealed to the PRRB, and the Board deemed Gundersen's exception request approved because CMS failed to notify Gunderson of the determination within 60 working days. The Administrator, however, reversed, finding that because the Secretary denied the exception request within 60 working days, it had satisfied the statutory and regulatory requirements. The Administrator noted that the regulation and statute did not state that notice of disapproval must be issued by the Secretary or received by the provider within 60 days of the application. Gundersen sought judicial review, and the district court granted summary judgment for the Secretary.

The Court first determined that the Administrator's interpretation of the statute and regulation was reasonable. According to the Court, the statute was clear and unambiguous in requiring only that the Secretary make its determination within 60 working days of the request. There was no authority for the proposition that a request for an exception should be deemed approved where the Secretary failed to notify the provider of its timely denial within the 60 day period. Even if the Court were to find that the statute was ambiguous, the legislative history supported the Administrator's interpretation; the Committee Report discussing the statute was silent on the issue of providing notification. Further, the Committee Report indicated that the statute was intended to urge the Secretary to make prompt determinations with respect to these exception requests. Finally Gundersen argued that the denial letters were subject to the indexing and publishing requirements of the Freedom of Information Act ("FOIA"), and because the Secretary failed to index or publish the denial letter in the publication known as the CMS rulings, the denial could not be relied upon until actual notice was received. The Court, however, concluded that the FOIA requirements were neither relevant nor material to the issues presented in this action.

F. *KGV Easy Leasing Corp. v. Sebelius*, 2010 WL 342598 (C.D. Cal., Jan. 29, 2010)(Secretary Reasonably Denied IDTF Claims Due to Lack of Proper Documentation of Medical Necessity)

In *KGV Easy Leasing*, the Court found that the Secretary properly denied an IDTF's claims for electrodiagnostic tests because of lack of medical necessity. 42 C.F.R. 410.33(d) establishes the documentation requirements that IDTFs must meet to be eligible for reimbursement, including the requirement that the test be ordered by the treating physician and that the test be used in the management of the beneficiary's specific problem. A Local Coverage Determination L13569 ("LCD L13569") further requires that the ordering physician clinically assess the patient and advise that the symptoms only are not adequate for presumptive diagnoses needing electrodiagnostic tests. The LCD also notes that the clinical picture and presumptive diagnoses dictate the reasonableness and necessity of electrodiagnostic tests and that documentation of patient assessment prior to testing is expected.

KGV's FI denied 386 of its Medicare IDTF claims for lack of medical necessity. KGV submitted requests for ALJ hearings based on those denials, and the ALJ concluded that KGV was not entitled to reimbursement on the claims because of lack of documentation of medical necessity. The ALJ also determined that because KGV knew or should have known about the documentation requirements, it did not qualify for the waiver provision under the Social Security Act. The MAC affirmed the ALJ decision on appeal, and KGV filed this action in district court.

The district court found that the Secretary's denial of the IDTF claims was reasonable and was supported by substantial evidence. The Court first determined that the documentation KGV had submitted in support of its claims for payment failed to comply with the requirements in the IDTF regulation. KGV submitted preprinted physician order forms that only identified the referring physician and not the referring physician; none of the other documentation it submitted indicated that the referring physician was the beneficiary's treating physician. Further, none of the documentation that KGV submitted to support its claims indicated that the tests were used in the management of the beneficiary's specific medical problem. The Court also found that KGV's documentation failed to comply with the LCD requirements. The only information that KGV submitted regarding a beneficiary's clinical picture came from the preprinted forms, which only allowed the physician to select preprinted symptoms and possible diagnoses. Second, since the date of the order was the same as the date of service for all the claims, there was no indication that a relationship existed between the beneficiaries and the ordering physician prior to the ordering of the test. Finally, the preprinted order forms did not indicate that the dates shown on the orders were the dates that the physician actually examined or consulted with the patient, and therefore there was no indication that the beneficiary was assessed prior to the ordering of the test. The Court also noted that, despite having multiple opportunities to verify the information in the forms or present additional evidence to support the medical necessity of its claims, KGV continued to rely on its preprinted forms. Finally, the Court rejected KGV's argument that the waiver provision of the Social Security Act, which allows payment to be made when the neither the beneficiary nor the provider knew or could have known that services would be excluded, applied here. In particular, the Court noted that as a Medicare supplier, KGV was charged both with knowledge of the regulations and the understanding that Medicare would not reimburse services that were not demonstrably medically necessary and otherwise properly documented.

G. *Heartland Regional Medical Center v. Leavitt*, 566 F.3d 193 (D.C.Cir. May 12, 2009)(SCH Status)

From 1992 to 1998, a hospital located less than 35 miles from other like hospitals could qualify as a sole community hospital ("SCH") if it was located in a rural area and met at least one of three additional criteria. 42 C.F.R. § 412.92(a)(1992). The regulations define rural as "any area outside an urban area" and define "urban area" as a Metropolitan Statistical Area. 42 C.F.R. § 412.62(f)(ii),(iii)(1992).

In May 1992, Heartland Regional Hospital ("Heartland") submitted a request for SCH status, but the request was denied on the grounds that Heartland was located in an "urban area," less than 35 miles away from the nearest like hospital. Heartland appealed to this decision to the PRRB, and the Board granted expedited judicial review. Heartland then brought suit against HHS in district court, arguing that the rural requirement was arbitrary and capricious and therefore invalid under the Administrative Procedure Act ("APA"). *Heartland Hospital v. Shalala*, No. 95-951 (D.D.C. June 15, 1998) ("*Heartland I*"). The Court granted summary judgment in favor of Heartland, stating that the failure of the Secretary to respond to reasonable alternatives raised during the comment period rendered the requirement arbitrary and capricious, and consequently, invalid. The order remanded the action to HHS for "action consistent with the foregoing opinion."

On remand, HHS requested proposals on how to interpret the order, and determined that the order remanded the case for further explanation of the choice to use MSAs to define urban areas, but did not vacate the regulation itself. Thus, HHS issued a final ruling, applying the rural requirement based on the MSA-based definition of urban areas, and again denying Plaintiff's request for SCH status based on the MSA-based definition of urban areas.

Plaintiff moved the Court to enforce the judgment in *Heartland I* and reverse and remand HHS's final decision for violating the APA. *Heartland Hospital v. Thompson*, 328 F.Supp.2d 8 (D.D.C. 2004). The Court stayed the APA challenges and denied Heartland's motion to enforce, reasoning that the prior judgment only required HHS to reconsider alternatives to the MSA and conclude that they are inferior; it did not intend to grant the plaintiff SCH status. The D.C. Circuit affirmed, stating that if Heartland wanted to obtain further relief, it must do so through a separate APA challenge. *Heartland Regional Medical Center v. Leavitt*, 415 F.3d 24 (D.C. Cir. 2005).

Plaintiff then filed an APA action in district court, and the Court granted the Secretary's motion for summary judgment, finding that the rural location requirement had not been vacated, and further, the statutory amendment did not apply retroactively. The Court of Appeals for the District of Columbia affirmed. The Court analyzed two factors in determining that the rule was not vacated: (1) how likely the agency would be able to justify its decision on remand and (2) the disruptive consequences of vacatur. The Court found that the first factor pointed toward remand without vacatur; the district court in *Heartland I* had declared the rural requirement invalid because of the Secretary's failure to respond to alternative ways of defining urban areas, and remanded for the Secretary to respond to such alternatives. The second factor pointed in the same direction; vacating the requirement would have required the Secretary to make payments to those hospitals for those years and any subsequent years until the agency re-promulgated the rule and gave a reason for rejecting the alternatives. Finally, because the Plaintiff did not argue that the Secretary failed to cure the deficiencies identified in *Heartland I*, it followed that in the 2000 adjudication, the agency was free to reinstate the original result based on that rule. The Court did not reach the Plaintiff's argument regarding the agency's adjudication of its application for SCH status from 1992 through 1999, because those challenges were based on the premise that the Court in *Heartland I* had vacated the 1992 rule.