HEALTH FINANCIAL SYSTEMS

USER MEETING

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Medicare Litigation Update

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I. JURISDICTION

A. *Sharp Healthcare v. Leavitt,* 555 F.Supp.2d 1121 (S.D. Cal. April 4, 2008) (Plaintiffs Granted Preliminary Injunction to Halt Medicare Lab Demonstration Project)

Three San Diego-area laboratories ("Plaintiff laboratories") filed suit in federal court against the federal government to halt a Medicare Demonstration Project slated for clinical laboratories in the San Diego-Carlsbad-San Marcos region.

The government implemented the demonstration project on the application of competitive acquisition for payment of clinical diagnostic laboratory tests that would otherwise be covered by the Medicare Part B fee schedule. The Secretary announced the San Diego-Carlsbad-San Marcos area as the first demonstration project site in the Federal Register on October 17, 2007. Under the project, labs were required to submit bids for laboratory tests and the collection and handling of lab specimens. CMS would evaluate the bids based on its determination of "best value for the Medicare program" and wining bidders would be the only lab providers to receive Medicare payments for their services.

In their complaint, the Plaintiff laboratories argued: (1) that the federal Department of Health and Human Services failed to follow the legally-required notice and comment rulemaking procedure to implement the project; (2) that the rules included a number of arbitrary policies; (3) that the rules constituted a taking under the Fifth Amendment; and (4) that DHS violated statutory mandate by expanding the scope of the project to the collecting and handling of laboratory specimens, and not just testing.

The Plaintiff laboratories first sought a temporary restraining order to enjoin the project before the application deadline, but the Court rejected the order the day before the applications were due. Subsequently, the laboratories filed a motion for preliminary injunction, seeking to prohibit the Secretary from announcing the winners of the Medicare demonstration project for clinical laboratory tests. The Court granted the motion for injunction, enjoining DHS from announcing winners in the competitive bidding project, otherwise implementing the project, and from further disclosing any information included in the bid applications submitting as part of the project.

In its analysis, the Court found that the Plaintiff laboratories had successfully established irreparable injury by demonstrating the likelihood of direct economic injury to the labs (through disruption of integrated patient care networks, layoffs and unemployment) and to Medicare beneficiaries. Under these circumstances, the Court also determined that the balance of hardships between the parties if the injunction was not granted tipped seriously in the laboratories' favor. The Court further found that the Plaintiff laboratories successfully demonstrated that they were likely to succeed on the merits of three of their four arguments. First, the labs were able to show that the Secretary violated notice and comment requirements by failing to hold appropriate public hearings and allow Medicare recipients, physicians, and others to provide input into the process. Second, the Plaintiff laboratories showed that the Secretary had altered the unambiguous language of the statute, which clearly authorized a demonstration project for labs that did not have face-to-face encounters with individuals. The Secretary had unjustifiably limited the exception by interpreting it to include only those labs located in physicians' offices or hospitals; he required all other types of labs to

submit bids, without considering whether those labs actually engaged in face-to-face encounters with patients and should fall under the exception. Finally, the labs were able to show that the Secretary violated the statute authorizing laboratory demonstration projects, which clearly authorizes such projects on laboratory tests but not on specimen collection.

B. *Atlantic Urological Associates v. Leavitt,* 549 F.Supp.2d 20 (D.D.C. May 5, 2008) (Plaintiff Must Exhaust Administrative Remedies)

In *Atlantic Urological Associates,* three physician practice groups, a pathologist, a lab management company, and the lab management company's director of clinical operations (collectively, "the AUA Plaintiffs") sought to invalidate an HHS Final Order and Anti-Markup Rule, both of which relate to Medicare payment for laboratory testing services. In 2004, CMS became publicly concerned about the growing tendency of so called "pod" laboratories, in which various physician groups utilize laboratories miles from the physician's practice and then claim that physicians in both locations are "sharing the practice" for purposes of billing Medicare. In response to such arrangements, CMS proposed the Anti-Markup Rule, effective for services rendered after January 1, 2008, which limited the payment for diagnostic testing services provided in a "centralized building" that does not qualify as the "same building" under the physician self-referral exception to the Stark Law. CMS subsequently received informal comments and published a Final Order which effectively omitted payment of any overhead associated with the use of a laboratory owned by a physician group when the laboratory is not located in the group's physician practice offices. Notably, the Final Order delayed for one year the application of the Anti-Markup Rule to services other than anatomic pathology diagnostic testing.

AUA Plaintiffs sought a preliminary injunction to preclude implementation of the CMS Final Order. In effect, AUA Plaintiffs alleged that an administrative challenge to the Final Order would drive the group out of business because the process would be costly and time consuming and ultimately result in "no review." The Court dismissed AUA Plaintiffs' claims.

In reaching its decision, the Court first considered whether AUA Plaintiffs had standing to challenge the rulemaking at issue. AUA Plaintiffs insisted that they had standing to challenge the Final Order because the Secretary issued the Final Order without formal notice and comment rulemaking. However, the Court held that the Final Order did nothing to change the billing landscape implemented by the Anti-Markup Rule, which went through extensive multi-year consideration and administrative process. The Court insisted that invalidating the Final Order would not afford AUA Plaintiffs any relief under these circumstances. Further, the Court ruled that the management company and its director completely lacked standing to challenge the Final Order or the Anti-Markup Rule because neither performs or bills for laboratory tests or interpretations, and further, neither has a legally protected interest in the receipt of Medicare payment for such services provided by physicians.

The Court next considered whether it had subject matter jurisdiction to hear the claim. AUA Plaintiffs alleged that the "channeling rule," in which the Medicare Act requires that the claim be exhausted through HHS's administrative claims process, was inapplicable pursuant to *Bowen v. Michigan Academy of Family Physicians*, 476 U.S. 667 (1986) because they were not challenging "amount" determinations, but the method by which such determinations were made. The Court rejected this distinction and found that the Medicare Act does not limit the channeling rule only to

claims involving "amounts." The Court also noted that the *Michigan Academy* exception is limited to cases in which review pursuant to the Medicare Act would result in no review at all. Since AUA Plaintiffs could not demonstrate hardship sufficient to show that the delay caused by the channeling requirement effectively precluded judicial review, the Court held that AUA Plaintiffs must first exhaust their administrative remedies before it could exercise jurisdiction over the matter.

C. *Griego v. Leavitt,* 2008 WL 2200052 (N.D. Tex. May 16, 2008) (Plaintiff Must Exhaust Administrative Remedies)

Dr. Griego, a physician owner of a medical clinic, brought suit to recover monies recouped by the government and sought to certify a class action on behalf of all providers participating in the Medicare program against whom the government illegally recouped overpayments before a provider obtained a reconsideration decision by a qualified independent contractor. In June 2007, Dr. Griego received notice from the fiscal intermediary that his medical clinic had been overpaid $487,708.19 in Medicare benefits. After receiving the notice of overpayment, Dr. Griego timely filed a request for redetermination contending that the fiscal intermediary had relied on an improper sampling methodology in calculating the overpayment. In addition, Dr. Griego challenged, as an illegal recoupment pursuant to 42 U.S.C. § 1395ddd(f)(2)(A), the recoupment of $42,344.44 of Medicare benefits owed to him that was used to reduce the alleged overpayment. After the fiscal intermediary denied the request for redetermination, Dr. Griego immediately filed suit in the District Court for the Northern District of Texas against the Secretary, the Administrator, the President of his fiscal intermediary, the President of the agency that assisted the intermediary with its calculations, and unknown defendants who aided the named defendants ("Defendants").

At the District Court, Dr. Griego alleged a constitutional violation on the basis that the Defendants prematurely recouped allegedly overpaid Medicare benefits and acted under a clandestine HHS policy in authorizing recoupment prior to a reconsideration decision. Further, Dr. Griego alleged a direct statutory claim for illegal recoupment under 28 U.S.C. § 1395ddd(f)(2)(A). However, the Defendants moved to dismiss the complaint for lack of subject matter jurisdiction since Dr. Griego failed to file for reconsideration.

On appeal, the Court granted the Defendants' motion to dismiss for lack of subject matter jurisdiction. Dr. Griego's claim arose under the Medicare Act, which in turn, "demands the 'channeling' of virtually all legal attacks through the agency." Thus, pursuant to 42 U.S.C. § 405(h), since Dr. Griego did not obtain a final decision, i.e., a decision that is reached after the claimant has pressed his claim through all designated levels of administrative review, the Court found that jurisdiction was not proper. Further, the Court rejected Dr. Griego's contention that requiring the exhaustion of administrative appeals would amount to the practical equivalent of a total denial of judicial review. The Court concluded that the administrative appeals process embodied in 42 U.S.C. § 1395ff permits a provider to appeal an "initial determination" of Medicare benefits, a determination that was applicable in the context of recoupment of Medicare benefits.

Moreover, the Court rejected Dr. Griego's argument that he was entitled to a judicial waiver of the exhaustion requirement. Pursuant to *Matthews v. Eldridge*, a court may allow judicial waiver upon the consideration of three factors: (1) whether the claim is collateral to a demand for benefits, (2) whether the exhaustion would be futile, and (3) whether the Provider would suffer irreparable harm if required to exhaust administrative remedies. First, the Court found that Dr. Griego's

complaint was fundamentally a claim for Medicare benefits and thus not collateral to such a claim. Second, since HHS had the competence to adjudicate Dr. Griego's illegal recoupment claim, the channeling requirement was not futile. Finally, the Court concluded that irreparable harm was not established merely because Dr. Griego may go out of business if forced to exhaust his administrative remedies.

D. *Cape Cod Hospital, et al., v. Leavitt,* 565 F.Supp.2d 137 (D.D.C. July 21, 2008) (Plaintiff Must Exhaust Administrative Remedies)

A group of hospitals ("Plaintiffs") sought injunctive and declaratory relief in an action for a review of rates for inpatient hospital services paid under the Medicare prospective payment system. Specifically, Plaintiffs challenged the method of calculating the budget neutrality adjustment for inpatient hospital rates pursuant to the Medicare statute. Plaintiffs sought review of the Secretary's determinations from the PRRB, and requested the Board to determine that it lacked authority to decide the legality of Secretary's implementation of the "rural floor" budget adjustments. Instead, the PRRB concluded that the applicable statute and regulations precluded review, and therefore, disclaimed jurisdiction.

In its motion to dismiss Plaintiffs' appeal before the District Court in the District of Columbia, the Secretary conceded that the Board's jurisdictional determinations were erroneous and requested that the Court dismiss and remand the case to the PRRB so that the Board could conduct administrative proceedings on the merits. The Secretary maintained that the Court lacked subject matter jurisdiction at this time because the PRRB neither rendered a final decision nor had the opportunity to determine that it lacked authority over the matter. Plaintiffs, however, argued that the Court may assume jurisdiction over the case since the PRRB failed to act on their requests for expedited judicial review ("EJR") within 30 days pursuant to 42 C.F.R. § 405.1842. Alternatively, Plaintiffs contended that 42 C.F.R. § 405.1842 was inconsistent with the Medicare Act in that hospitals "have the right to obtain judicial review . . . whenever the Board determines . . . that it is without authority to decide the question."

In granting the Secretary's motion to remand, the Court held that Plaintiffs had failed to exhaust their administrative remedies, and the Court thus lacked subject matter jurisdiction to evaluate the merits of the case. In so holding, the Court acknowledged that EJR was improper since the regulation clearly states that the 30 day period within which the PRRB must act on EJR requests does not start to run "until such time as the [PRRB] accepts jurisdiction of the case." Further, the Court was satisfied that 42 C.F.R. § 405.1842 did not conflict with the Medicare Act, as the former asks whether the PRRB has authority to reach the merits of providers' claim, and the latter asks whether the providers may obtain a hearing at all. Here, the Board only ruled on the jurisdictional question. Though the Secretary had subsequently conceded that the Board came to the wrong conclusion as to jurisdiction, the Board never had the opportunity to hear the merits of the case. Accordingly, Plaintiffs failed to exhaust their administrative remedies. Accordingly, the Court granted Secretary's motion to dismiss and remand the case to the PRRB to afford it the opportunity to consider the merits of the case.

**** The Plaintiffs subsequently submitted renewed requests for EJR to the PRRB. In reviewing the requests, the Board determined that it had jurisdiction but lacked the authority to decide the legal issue, and thus granted EJR. Plaintiffs again submitted a complaint to the D.C. District Court, where their case challenging the rural floor budget neutrality adjustment is currently pending. Another case, challenging the same issue and involving over 300 hospitals, is also currently pending before the Court. See St. Helena Hospital, et. al. v. Leavitt.*

E. *Jordan Hospital v. Leavitt*, 571 F.Supp.2d 108 (D.D.C. Aug. 15, 2008) (Federal Court Jurisdiction)

Jordan Hospital filed suit against the Secretary challenging a remand decision of the Administrator of CMS and review of CMS's determination that it did not qualify for a new provider exemption. Jordan Hospital, a not-for-profit hospital, obtained the right to operate a skilled nursing facility and, in turn, applied to its fiscal intermediary for a new provider exemption pursuant to 42 C.F.R. § 413.30(c). CMS denied the request. Jordan Hospital subsequently appealed this decision to the PRRB. The Board reversed the CMS determination as to the hospital's fiscal year 1998 cost report and granted it a new provider exemption for three years by operation of law. However, after the Administrator reviewed the record, he vacated the Board's decision and remanded the matter to CMS to consider the criteria set forth in a recent decision of the D.C. Circuit, *St. Elizabeth's Medical Center of Boston, Inc. v. Thompson*, 396 F.3d 1228 (D.C. Cir. 2005). The Provider thereafter filed a complaint in the District Court for the District of Columbia.

Jordan Hospital alleged that the Administrator's remand to the agency violated the Medicare statute and its implementing regulations. At the same time, on remand from the Administrator, CMS issued a "final determination" denying the Jordan Hospital's request for a new provider exemption, which Jordan Hospital appealed to the PRRB. Thus, at the time Jordan Hospital filed suit in the district court, the administrative proceedings were ongoing.

Though both parties agreed that an order for remand is not a final agency action subject to review, Jordan Hospital alleged that the Administrator lacked authority to remand the matter directly to CMS, and thus his action was ultra vires, and jurisdiction was proper pursuant to *Leedom v. Kyne*, 358 U.S. 184 (1988). In that case, the Supreme Court held that a federal district court had jurisdiction to vacate a National Labor Relations Board's determination where the Board acted in excess of its delegated powers. As part of its decision, the Court announced a two part test to justify the exercise of *Leedom* jurisdiction: (1) the agency has acted in excess of its delegated powers and contrary to a specific prohibition that is clear and mandatory, and (2) barring review by the district court would wholly deprive the party of a meaningful and adequate means of vindicating its statutory rights. Though the Court acknowledged the split of authority regarding the Administrator's right to remand, the Court found that the Administrator's decision here did not contravene a clear and specific statutory mandate as required by *Leedom*. Likewise, the Court concluded that Jordan Hospital had not been wholly deprived of a meaningful and adequate means of vindicating its statutory rights since the Secretary conceded that Jordan Hospital would be able to raise all claims of error once a final decision had been reached.

The Court similarly rejected Jordan Hospital's contentions that jurisdiction was proper pursuant to 28 U.S.C. §§ 1331 and 1361. The hospital argued that the Court could exercise federal question jurisdiction because failure to review the Administrator's remand decision would be akin to

no review at all. However, the Court was unconvinced that absent federal question jurisdiction, Jordan Hospital would have no avenue for review since the Secretary conceded that the hospital would be able to raise all issues in an appeal following final agency action. Further, Jordan Hospital alleged that it was entitled to jurisdiction under the common law writ of mandamus. Again, the Court dismissed this contention since "mandamus jurisdiction is only available where a Provider has exhausted all other avenues of relief."

Lastly, Jordan Hospital argued that, at the very least, the Court had jurisdiction over the Administrator's decision as to fiscal years 1996 and 1997 since the Administrator's decision to remand arguably reversed the Board's decision to grant the provider exemption for three years by operation of law, and therefore, review of the Board's decision for fiscal years 1996 and 1997 was proper pursuant to 42 U.S.C. § 1395oo(f)(1). The Court disagreed and held that the outcome for fiscal years 1996 and 1997 was completely dependent on the resolution for fiscal year 1998 and thus, it was both impractical and improper to retain jurisdiction over years 1996 and 1997.

F. *Sutter Health Sacramento Sierra Region v. Leavitt,* Case No. 2:08-cv-03051-MCE-KJM (E.D.Cal., February 13, 2009) (Plaintiff Must Exhaust Administrative Remedies)

Sutter Medical Center Sacramento's ("Sutter") heart transplant program was initially certified by CMS under the rules established in the 1987 National Coverage Determination (**"NCD"**), which established a minimum volume guideline for heat transplant centers at twelve transplants per year. In 2006, the Secretary had requested data from Sutter because it did not satisfy Medicare's volume guidelines. Sutter was thereafter afforded the opportunity to submit a Corrective Action Plan, in which it pointed to mitigating factors, like good clinical results, and various explanations for its low volume. In the meantime, in March 2007, CMS issued new conditions of participation for organ transplant centers, providing guidelines of ten or more transplants per year. Heart transplant centers that were previously approved had until June 28, 2007 to comply wit the new COPs and apply for initial approval thereunder. CMS worked with Sutter to revise its CAP and eventually approved in July 2007. Nonetheless, Sutter still performed only three transplants in 2007 and three in 2008. In July 2008, CMS again notified Sutter that its program would be terminated for failure to meet volume requirements Sutter again supplied further information explaining its mitigating circumstances, but CMS concluded that the circumstances were not sufficient to warrant approval. On December 12, 2008, CMS notified Sutter that its approval would be withdrawn under the 1987 NCD based on low volume.

Sutter brought suit against the Secretary in the Eastern District of California, alleging that Medicare's proposed termination of its heart transplant program runs counter to Medicare's own provisions for administering such programs. The Secretary moved to dismiss, arguing that the court lacked subject matter jurisdiction because Sutter failed to exhaust its administrative remedies, or, alternatively, because Sutter failed to state a viable cause of action. The Court granted the Secretary's motion, finding that Sutter failed to exhaust its administrative remedies.

The Court first looked to 42 U.S.C. § 405(g) and § 405(h), and determined that, barring extenuating circumstances, Sutter could seek review in court only after it had exhausted Medicare's internal review system and received a final administrative decision.

The Court concluded that Sutter did not fall within any exception to the exhaustion requirement. Sutter had argued that the irreparable harm it would suffer (i.e. possible closure of its facility) made mandated administrative review the practical equivalent of no review at all. Sutter further argued that its procedural challenges to the manner of termination could fall outside the scope of the administrative review process. The Court rejected both arguments, finding that inconvenience would not suffice to establish the practical equivalent of no review and that CMS should have the opportunity, through the administrative appeal process to analyze the application of its own rules and regulations. Further, the Court noted that even if some of Sutter's due process claims were beyond the scope of administrative appeal, that did not mean that the overall action was excused from the administrative process.

Sutter also claimed that it was excepted from the exhaustion requirement because judicial review of collateral constitutional claims challenging a non-final agency decision were permitted. The Court noted that, in order to qualify for that exception, Sutter needed to bring a "colorable constitutional claim," along with an entirely collateral challenge to the merits of its substantive claim, and a finding that full relief could not be afforded through the administrative process. Sutter could not meet any of these requirements. Its sole alleged constitutional claim was procedural due process, but the Court pointed out that the Ninth Circuit had previously found that Medicare providers are not entitled to an evidentiary hearing or completed administrative appeal before termination. Further, the Court found that the Secretary had provided adequate due process by giving Sutter advance notice of the proposed termination and over a year to come into compliance with regulations. The Court went on to point out that the Ninth Circuit has explicitly ruled that a Medicare provider's termination does not affect any property interest protected by due process, and impinges on a liberty interest only when accusations are contested and impair the provider's reputation for honesty and morality. That was not the case here, as Sutter recognized that it did not meet the volume requirements, but instead sought to be excused from termination for other extenuating reasons. Finally, the Court determined that the substantive issues underlying Sutter's termination were inexplicably intertwined with the procedural requirements necessary to effect the termination. The Court also emphasized the purpose of the exhaustion requirement – to prevent premature interference with agency processes so that the agency may function efficiently, have the opportunity to correct its own errors, and allow the parties and the courts the benefit of its experience and expertise.

The Court also rejected Sutter's argument that federal jurisdiction could be predicated on the federal mandamus statute, which confers jurisdiction "only if the plaintiff has exhausted all other avenues of relief and only if the defendant owes him a clear nondiscretionary duty." The Court had already determined that Sutter had not exhausted its administrative remedies, but it determined that Sutter also failed to establish that the Secretary had a clear, nondiscretionary duty to act under these circumstances. First, it rejected Sutter's notion that the language in the 2007 Final Rule established a legal duty to provide a follow-up survey, and explained that, in any event, the 2007 regulations were irrelevant because Sutter was terminated for a failure to meet the requirements under the NCD. The Court likewise rejected Sutter's argument that 42 C.F.R. § 402.5 established the required duty, because that regulation required pretermination review under particular circumstances, none of which were present here. Finally, the Court rejected Sutter's attempt to rely on language in the State Operations Manual, which suggested that CMS should have given 210 days to cure volume deficiency; on this point, the Court noted that the termination process extended well beyond two

years and further, the timeframe stated in the manual was a maximum; CMS could terminate more quickly so long as it met the regulatory notice requirements, which it did here.

Because the Court concluded that it did not have subject matter jurisdiction, it did not reach the Secretary's alternative contention that the suit should be dismissed for failure to state a claim.

II. SUBSTANTIVE PAYMENT ISSUES

A. Bad Debt

1. *Foothill Hosp. – Morris L. Johnson Memorial v. Leavitt,* 558 F.Supp.2d 1 (D.D.C., May 30, 2008) (Presumption of Collectability Violates Medicare Bad Debt Moratorium)

Foothill Presbyterian Hospital ("Foothill") challenged CMS' policy of rejecting claims for Medicare Bad Debt solely because such debt remained at an outside collection agencies ("the presumption of collectability"). Specifically, Foothill contended that this policy violated the Medicare Bad Debt Moratorium (the "Moratorium"), which prohibits CMS or its agents from changing the bad debt policy that was in effect prior to August 1987.

Foothill attempted to collect accounts through its in-house collection procedures. When those efforts failed, the hospital determined that the debts were uncollectible and claimed them as Medicare bad debts for reimbursement on its cost report. Despite its determination that the accounts were uncollectible, the hospital forwarded all its bad debts to an outside collection agency where the accounts remained unless collected. Foothill's claims for bad debt reimbursement were denied solely because the debts were still subject to the collection efforts of outside collection agencies.

The PRRB held that these bad debts were properly considered uncollectible, even though they remained at an outside collection agency. The PRRB found that the Foothill's collection efforts met the regulatory requirements and such efforts were completed before the hospital determined the accounts to be uncollectible and worthless. Further, the PRRB found that a conclusive presumption of collectability based on outside collection agency account status ran afoul of well-established precedent. Subsequently, the CMS Administrator reversed the PRRB's decision, holding that a bad debt could not be deemed worthless and uncollectible as long as it remained at an outside collection agency.

The D.C. District Court, however, reversed the Administrator's decision and determined that the presumption of collectability violates the Moratorium. First, the Court held that the Moratorium limits the Secretary's ability to change the Department's policies related to bad debt. Second, the court held that the presumption of collectability was indeed a change in agency policy as it did not exist prior to the effective date of the Moratorium. Accordingly, the Court held that the presumption of collectability ran afoul of the Moratorium. The Secretary voluntarily dismissed her appeal, and, thus, the D.C. District Court decision is final.

2. *Mesquite Community Hospital v. Leavitt,* 2008 WL 4148970 (N.D. Tex., Sept. 5, 2008) (Presumption of Collectability Is Reasonable Interpretation of Bad Debt Regulations)

Mesquite Community Hospital also dealt with the "presumption of collectability." There, the fiscal intermediary disallowed approximately $263,006 in Medicare bad debts because those accounts had been sent to an outside collection agency and had not been returned as uncollectible. Mesquite Community Hospital ("Mesquite") argued that not withstanding the fact that the debts remained at an outside collection agency, its collection efforts satisfied the regulatory requirements in 42 C.F.R. § 413.89(e), which provide that Medicare bad debts may be claimed if: (1) the debt is related to covered services and derived from deductibles and coinsurance; (2) reasonable collection efforts were made; (3) the debt was uncollectible when claimed as worthless; and (4) sound business judgment established that there was no likelihood of recovery in the future. As such, Mesquite asserted that the presumption of collectability "constitutes an abuse of discretion" because it imposes additional requirements not set forth in the Medicare bad debt regulations.

The PRRB agreed with Mesquite's position finding that the hospital "properly claimed Medicare bad debts even though the accounts were still with the collection agency." However, the CMS Administrator reversed the PRRB and found that until a provider's reasonable collection effort has been completed, including both in-house efforts and the use of a collection agency, a Medicare bad debt may not be reimbursed as uncollectible.

Relying on *Battle Creek Health Systems v. Leavitt*, 498 F.3d 401 (6th Cir. 2007), the Northern District of Texas Court upheld the Administrator's decision. Specifically, the Court held that "only when the provider recalls the account and ceases collection efforts is the account deemed uncollectible. Plaintiff has failed to establish that such an interpretation of 42 C.F.R. § 413.89(e) is plainly erroneous, inconsistent with the Medicare regulations, or contrary to law."

Importantly, the Court noted that Mesquite failed to make any argument related to the Medicare Bad Debt Moratorium and thus the court did not have an opportunity to consider the successful arguments raised in *Foothill*.

3. *El Centro Regional Medical Center v. Leavitt,* 2008 WL 5046057 (S.D. Cal., Nov. 24, 2008) (Collection Process Must Be the Same For Medicare and Non-Medicare Accounts)

El Centro Regional Medical Center involved the interpretation of Section 310 of the Provider Reimbursement Manual ("PRM"), which provides that in order for a collection effort to be deemed "reasonable," a provider's effort to collect Medicare bad debt must be similar to the efforts put forth to collect comparable amounts from non-Medicare patients. Relying on this provision, El Centro Regional Medical Center's ("El Centro") fiscal intermediary denied $275,691 of Medicare bad debt claims because the El Centro's in-house collection efforts for Medicare accounts were less than the efforts to collect non-Medicare accounts. In particular, the fiscal intermediary found that: (1) skip tracing, legal action, interest expense and liens were only imposed on non-Medicare accounts; (2) there were more telephone contact attempts to non-Medicare patients; (3) the Provider's outside collection agencies worked on non-Medicare accounts longer than Medicare accounts; (4) letters sent to Medicare accounts used different language than letters sent to non-Medicare accounts; and

(5) written procedures to outside collection agencies treated Medicare and non-Medicare accounts differently. As such, the fiscal intermediary found that Mesquite's internal and external collection efforts were not similar for Medicare and non-Medicare patients.

The PRRB reversed the intermediary's decision finding that Mesquite had "established that reasonable collection efforts were made and that the debts were actually uncollectible when claimed as worthless," thus satisfying the regulatory requirements. Furthermore, the PRRB found that PRM Section 310 does not apply to outside collection agency's efforts and that Section 310 only requires that when a provider uses a collection agency, it must refer all like amounts of Medicare and non-Medicare receivables for outside collection.

The CMS Administrator reversed the PRRB. The Administrator found that there was no evidence in the record demonstrating that Mesquite had engaged in similar, reasonable collection efforts for both Medicare and non-Medicare bad debts. As a result, the Administrator held Mesquite had not established that the bad debts were "actually uncollectable when claimed as worthless" as required by the Medicare bad debt regulations.

In its motion for summary judgment, Mesquite made two arguments. First, it argued that its in-house collection efforts were substantially similar for its Medicare and non-Medicare bad debts, and that its Medicare bad debts were uncollectible when claimed as worthless. Second, it asserted that CMS was seeking to implement a policy that Medicare bad debts may never be recovered when comparable non-Medicare bad debts remain at an outside collection agency and that attempting to implement this policy through the adjudicative process violates the notice and comment requirements of the Administrative Procedure Act ("APA"). In its Cross Motion for Summary Judgment, CMS asserted that Mesquite's efforts to recover amounts owed by Medicare patients was significantly less vigorous than its efforts to collect comparable non-Medicare debts, thus precluding a finding that reasonable efforts were made to collect the bad debts.

The Court held that the Secretary reasonably interpreted PRM Section 310 as being applicable to both in-house and outside collection efforts and that the Administrator's conclusion that Mesquite's collection efforts were not substantially similar was supported by the evidence. Furthermore, the Court found that the Administrator's interpretation of the pertinent regulation and PRM Section 310 did not create a new policy subject to the APA's notice and comment provisions.

4. *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.

5. *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 in the District of Columbia, where the court 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.

6. *Baptist Healthcare System dba Baptist Regional Medical Center v. Sebelius* (2009 WL 2514065 (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.

B. Wage Index

1. *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.

2. *Anna Jacques Hospital, et al. v. Sebelius*, 2009 WL 2902082 (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."

C. Capital Costs

In two cases involving a dispute over an intermediary's disallowance of depreciation losses resulting from a statutory merger, the Ninth Circuit and a Pennsylvania district court both found in favor of the Secretary's interpretation of a "bona fide sale."

1. ***Robert F. Kennedy Medical Center v. Leavitt,*** **526 F. 3d 557 (9th Cir. May 19, 2008) (Merger Does Not Qualify as Bona Fide Sale)**

In *Robert F. Kennedy Medical Center*, Robert F. Kennedy Medical Center ("RFK") and St. Francis Medical Center (owned by Catholic Healthcare West), agreed to a statutory merger. Under the terms of the agreement, RFK merged into St. Francis and ceased to exist as a corporate entity. The merged entities became CHW-SC. Represented by their own counsel, RFK and St. Francis agreed that RFK would transfer almost $50 million in assets, including its building and land, in exchange for St. Francis assumption of nearly $30.5 million of RFK's liabilities. Following its dissolution, RFK filed its terminating cost report. Pursuant to 42 C.F.R. § 413.134(f), which allows providers to receive an adjustment for a disposable of depreciable assets pursuant to a bona fide sale, RFK claimed a depreciation loss adjustment for the assets it transferred to CHW-SC as part of the merger.

The fiscal intermediary denied the adjustment on the grounds that RFK and St. Francis were related parties and thus were barred under section 413.17 from claiming a depreciated loss. In addition, the intermediary stated that the merger did not qualify as a "bona fide sale" under section 413.134(f)(2); rather, the intermediary considered the merger to be a "pooling of interests" with no resulting gain or loss.

The Board reversed the intermediary's decision, concluding that the intermediary's audits were incorrect. The CMS Administrator, however, reversed the PRRB's decision, finding specifically that RFK was related to the surviving entity and that the statutory merger was not a "bona fide" sale. Specifically, the Administrator concluded that the $20 million disparity between the assets transferred and the consideration received indicated that the transaction was not at "arm's length" and thus was not a bona fide sale. The district court, affirming the Administrator's decision,

agreed that the merger was not a "bona fide sale." It did not reach the issue of whether the parties were related prior to the sale.

In its appeal to the Ninth Circuit, RFK argued that the Secretary acted arbitrarily in imposing the "bona fide sale" requirement in its specific context of a statutory merger. The Secretary, on the other hand, maintained that its position was consistent with both the text and the intent of Medicare. The Ninth Circuit affirmed the lower court's decision. It agreed with the Secretary's position that Medicare only recognizes a gain or loss on a disposal of depreciable assets through a statutory merger if the merger is the result of a "bona fide sale." The Ninth Circuit further deferred to the Secretary's interpretation of the definition of a "bona fide sale." Specifically, a sale of assets between two unrelated parties is bona fide if there is "reasonable consideration" and a "comparison of the sales price with the fair market value of the assets." The court noted that these requirements ensure that Medicare reimburses providers for their actual losses, "instead of providing a windfall to providers."

Finding a Tenth Circuit case, *Via Christi Regional Medical Center v. Leavitt*, persuasive, the Ninth Circuit concluded that there was "substantial evidence" supporting the Secretary's determination that the merger between RFK and St. Francis was not a "bona fide sale." The court referenced the disparity between the assets and liabilities exchanged, concluding that CHW-SC essentially "paid almost nothing" for RFK's building and equipment, valued at almost $12 million. Additionally, the Court agreed with the Administrator's finding that RFK did not, at any point, seek "fair market value" for its assets. Both factors indicated that the transaction lacked reasonable consideration.

Because the "bona fide sale" issue was dispositive, the Ninth Circuit declined to reach the "related parties" issue and upheld the district court's decision. For a similar case and disposition under different facts, see *UPMC-Braddock Hospital v. Leavitt*, 2008 WL 4442056 (W.D. Pa. 2008).

2. *UPMC-Braddock Hospital v. Leavitt*, 2008 WL 4442056 (W.D. Pa., Sept. 29, 2008) (Merger Does Not Qualify as Bona Fide Sale)

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, for the "purported consideration" of UPMC-Braddock's assumption of its $13 million debt. However, the record revealed that appraisal considerably overvalued BMC's depreciable assets.

The fiscal intermediary flatly disallowed all of BMC's claim for a loss on sale. The disallowance was reversed by the PRRB decision 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 BMC's fair market value.

The appeal reached the district court on cross motions for summary judgment. Among other arguments, UPMC-Braddock argued that the statutory merger did constitute a "bona fide sale" under the applicable Medicare regulations, and that there was no substantial evidence to support the Secretary's findings that BMC and UPMC-Braddock were related parties. The Secretary urged the court to uphold the Administrator's decision on the grounds that the merger was not a "bona fide sale" and that the merger was a "related party" transaction. 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.

Similar to the Ninth Circuit in *Robert F. Kennedy Medical Center*, the district court was persuaded by the Tenth Circuit's analysis last year in *Via Christi.* Specifically, the court agreed with the Secretary's position that depreciable losses in a statutory merger only may be recognized if there is a bona fide sale. Deferring to the Secretary's interpretation of the phrase, the court agreed that a "bona fide sale" was a transaction reflecting arms length bargaining and reasonable consideration. Substantive evidence supported the Secretary's determination that no bona fide sale occurred here because of the disparity between the value of assets and liabilities transferred to the new corporation. The fact that BMC did not obtain an appraisal prior to the merger also indicated that reasonable consideration was not exchanged. Accordingly, the court granted summary judgment in favor of the Secretary.

D. Disproportionate Share Payments

1. *Adena Regional Medical Center v. Leavitt,* 527 F.3d 176 (D.C. Cir. May 30, 2008) (Ohio indigent care days do not count in Medicare DSH computation)

In *Adena Regional Medical Center*, a group of 25 hospitals (the "Hospitals") challenged the Secretary's exclusion of costs related to services they provided under Ohio's Hospital Care Assurance Program ("HCAP") from the calculation of their disproportionate share ("DSH") payments.

Under HCAP, Ohio hospitals must provide "basic, medically necessary hospital-level services" at no charge to indigent residents who are not participants in the state's Medicaid program. Here, the Hospitals maintained that HCAP beneficiaries were eligible under the state-approved Medicaid plan, so costs related to their services should be included in their DSH formula for reimbursement under 42 U.S.C. § 1395ww(d)(5)(f). The Secretary contended that these beneficiaries were not eligible for Medicaid and thus properly were excluded from the calculation.

The Hospitals prevailed at the district court level last year. On appeal this year, however, the District of Columbia Court of Appeals Court reversed the lower court's decision and granted the Secretary's motion for summary judgment.

Because the DSH calculation is based in part on the number of patients that are "eligible for medical assistance under a State plan approved under [Medicaid]," the Court first analyzed whether HCAP was, in fact, a State-approved plan. Because Medicaid requires state plans to reimburse providers for their services and HCAP does not contain any reimbursement provisions, the Court concluded that HCAP was not a State-approved plan.

Further, even if HCAP was an approved plan, the Court concluded that the Hospitals could not be reimbursed under Medicare for services they provide to HCAP patients because HCAP patients are not eligible for medical assistance under Medicaid. The Court concluded that the applicable definition of "medical assistance" came from the federal Medicaid statute, 42 U.S.C. § 1396d(a), which "defines 'medical assistance' as 'payment of part or all of the cost' of medical 'care and services' for a defined set of individuals." Since HCAP does not entail any payment, the Court concluded that HCAP beneficiaries "do not obtain, and are not eligible for, 'medical assistance' within the meaning of the Medicare DSH provisions."

2. *Cookeville Regional Medical Center v. Leavitt,* 531 F. 3d 844 (D.C. Cir. June 27, 2008)(Expansion Populations)

Fifteen Tennessee hospitals originally brought suit against the Secretary seeking a declaration that his method of calculating (and denying) reimbursements for "expansion populations" under the Medicare statute's DSH formula, 42 U.S.C. §1395ww(d)(5)(f)(vi), was unlawful. *See Cookeville Regional Medical Center v. Leavitt,* 2006 WL 2787831. (D.D.C. 2006). In that case, the district court agreed with plaintiffs and granted their motion for summary judgment on the basis that the Secretary's exclusionary method of calculating the DSH adjustment contravened clear and unambiguous statutes. After Congress passed the Deficit Reduction Omnibus Act of 2005 (**"DRA"**), however, the Secretary filed a motion to alter the judgment based upon the fact that the DRA explicitly reflected the Secretary's position that "expansion populations" (i.e. patients who would not otherwise be eligible for Medicaid but who become eligible solely because of the Secretary's waiver of certain Medicaid program requirements as part of a demonstration project) were not eligible for medical assistance under Medicaid. The district court held that the DRA constituted a valid retroactive change in the law and granted summary judgment in favor of the Secretary.

Two hospitals (the "Hospitals") appealed the district court's decision, arguing (1) that the pre-DRA law unambiguously required the inclusion of the expansion waiver patients in the DSH formula; (2) that the DRA was a substantive change in the law; and (3) that Congress did not intend the DRA to have any retroactive effect and thus could not be applied retroactively.

In affirming the district court's holding, the D.C. Circuit dismissed the Hospitals' arguments. Taking the last of the arguments first, the court noted that the presumption against retroactivity "exists to protect settled expectations." In this case, however, because the Secretary's policy during the relevant cost reporting period was *not* to include the expansion waiver population in the DSH adjustment, the Hospitals were sufficiently on notice that their waiver population may not be included in the DSH formula. This notice was valid even if some fiscal intermediaries included the waiver population in their calculations. Further, in expressly disagreeing with the Ninth Circuit on this issue, the Court did not believe that pre-DRA policy clearly required the inclusion of the expansion waiver patients in the DSH formula. To the contrary, the Court believed that the

promulgating laws and regulations granted the Secretary discretion to include, or not include, these costs in the reimbursement methodology. To that end, the DRA "clarified an ambiguity in the existing legislation" and affirmed the Secretary's discretionary authority in this area.

3. *Baystate Medical Center v. Leavitt*, 587 F.Supp.2d 44 (D.D.C. Dec. 8, 2008) (Calculation of SSI Percentage)

Baystate Medical Center ("Baystate") challenged the Secretary's calculation of the SSI fractions used to determine its Medicare DSH payments for fiscal years 1993 through 1996. Medicare DSH payments depend, in part, on the "SSI Fraction," the numerator of which is the number of the hospital's patient days which were made up of patients who were entitled to benefits under Part A and who were entitled to supplement security income ("SSI") benefits and the denominator of which is the number of hospital's patient days made of patients who were entitled to Medicare part A. The greater the number of patient days involving SSI beneficiaries, the greater the hospital's DSH adjustment. Baystate initially appealed to the PRRB, arguing that its FI understated the SSI fractions for those years by relying on Social Security Administration ("SSA") records that contained inaccurate or incomplete information on the eligibility of patients for SSI and further, that the intermediary's process of matching individual Medicare billing records to individual SSI records was flowed. The PRRB granted in part and denied in part, and remanded to the intermediary for recalculation. The Administrator, however, reversed the Board's decision and affirmed the Secretary's calculations as proper. Baystate then appealed to the District Court for the District of Columbia, and the Court granted, in part, its motion for summary judgment.

The Court first addressed Baystate's argument regarding omission of patients, who, under Section 1619(b) of the Social Security Act, had income that rendered them ineligible for SSI payments but were conferred special status that enabled them to remain eligible for Medicaid. Baystate argued that these individuals should be counted in the numerator of the SSI fraction, but Court concluded that the legislative history of the provision made it clear that Congress did not intend for patients who were ineligible for SSI payments to be counted.

Next, the Court concluded that the Administrator's finding that the Secretary relied on the best data available in calculating the SSI fraction was arbitrary and capricious. In particular, the Court found that the Secretary failed to use superior readily-available data in its calculation, including: (1) updated SSI data furnished to CMS within the normal 2–3 year cost report settlement process; (2) SSI records for individuals who received manually processed SSI payments; and (3) inactive SSI records (which were omitted from the Secretary's calculations before 1995).

With respect to the Secretary's process of matching individual Medicare billing records to individual SSI records, the Court remanded the case to the Administrator to (1) determine whether SSI recipients without a particular kind of patient identifier (a "Title II" number) were categorically omitted from the calculation and (2) to explain, if possible, why individuals' own social security numbers and other patient identifiers (i.e. patient name) were not the "best data available" for the match process.

The Court also found that the Administrator abused his discretion in determining that retrospective relief was inappropriate to correct errors in this case. The Court saw no basis for interpreting the DSH statute or the DSH regulation to impose a per se rule prohibiting retrospective

relief, and, further, the hospital met its burden to show that its SSI fraction was adversely impacted by errors. The Court also determined that the interest in administrative finality was not nearly as strong for DSH payments (which involve the use of data from an earlier period to determine payment for the past fiscal year) as for other PPS payment determinations (which involve the use of historical data to determine future payments). Moreover, the Court stated that the Administrator pointed to no evidence of substantial administrative burden in correcting errors and further declared that the burden of having to correct errors for all similarly situated providers would not outweigh the substantial public interest in making DSH payment determinations in accordance with law.

The Court dismissed the issue that Baystate raised concerning the standard for counting days attributable to patients entitled to benefits under Medicare Part A. In particular, the Court found stated that Baystate's appeal was limited to the computation of the SSI fraction; since Baystate admitted that the resolution of the Medicare Part A issue would not affect the SSI fraction, the Court was without jurisdiction to rule on the Part A issue.

The Court remanded the case to the Secretary for further proceedings consistent with the Court's decision, but declined to devise a specific remedy for the agency to follow. The Secretary voluntarily dismissed her appeal to the D.C. Circuit, and, thus, the D.C. District Court decision is final.

4. *University of Washington Medical Center v. Sebelius,* 2009 WL 3185592 (W.D. Wash. Sept. 30, 2009) (Washington general assistance days do not count in Medicare DSH computation)

Following the holding of the *Adena* case discussed above, the district court held that it was proper to exclude certain charity care and general assistance days that are mentioned in Washington's Medicaid State Plan but that are not considered, according to the Court, eligible for medical assistance. The Court determined, consistent with *Adena*, 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..

E. GME

1. *County of Los Angeles v. Leavitt,* 521 F.3d 1073 (9th Cir. Mar. 31, 2008) (Secretary's Interpretation that "Available Bed" Count Reflects Facility Size was Not Arbitrary)

As a teaching hospital subject to the prospective payment system, Los Angeles County/University of Southern California Medical Center ("County/USC") is entitled to an additional payment to cover indirect medical education ("IME") costs. The IME adjustment is based on the hospital's ratio of full time equivalents ("FTE")to available beds. Though the calculation is complicated, the higher the number of beds, the lower the eventual payment.

The Provider Reimbursement Manual provides further guidance on the relevant regulation, C.F.R. § 412.105(b), as to the definition of available bed, requiring that an available bed be

"permanently maintained for lodging inpatients," and further explaining that the term is not intended to capture day-to-day fluctuations in patient rooms and wards, but rather to capture changes in the size of he facility. *See* Provider Reimbursement Manual §2405.3G.

USC/County submitted its 1994 fiscal year cost report to its fiscal intermediary ("FI"), claiming 1,197 budgeted beds for purposes of calculating its IME payment. The FI, which had previously accepted a calculation based on budget beds, this time determined that there were 1,320 beds physically available in the hospital's inpatient areas, and thus increased the count. County/USC appealed the FI's determination to the PRRB. Prior to the hearing, the parties stipulated that there were 1,320 beds physically present in the hospital and that 1,197 beds were budgeted beds, leaving 123 beds at issue.

The PRRB concluded that the Secretary properly used the number of physical beds in the facility as a measure of available beds and the Administrator declined review. County/USC sought review before the district court, which granted summary judgment to the Secretary. County/USC appealed the district court's decision to the Ninth Circuit, and the Ninth Circuit affirmed.

Before the Ninth Circuit, County/USC claimed that it was arbitrary for the Secretary to move from using budgeted beds to using physical beds without an explanation. In rejecting this argument, the Court explained that the FI had previously approved claims for IME reimbursement based on budget beds, but that the Secretary had never explicitly taken the position that "available beds" may be measured by budgeted beds instead of physical beds. County/USC argued that its FI's bulletin, in which the FI deemed beds to be available only when they could adequately be covered by nurses, demonstrated that counting the 123 beds at issue was a change in position. The Court rejected this argument, however, finding that the FI's staffing discussion only pertained to beds in rooms or floors that were temporarily unoccupied, which was not the case here.

The Court also rejected County/USC's alternative argument, that it was arbitrary and capricious for the Secretary to reject budgeted beds in favor of a physical bed count. The Court noted that the Secretary's judgment, that facility size relates to teaching load, and that the best measure of this is the number of beds maintained for patient use, was reasonably grounded in the statutory scheme and consistent with the purpose of the IME adjustment and the Manual. The Court opined that County/USC could not properly rely solely on the statement in the manual that the term available beds is not intended to capture the day-to-day fluctuation in patient rooms and wards; subsequent provisions in the manual stated that the count is intended to capture changes in the size of the facility.

Finally, the Court determined that substantial evidence supported the PRRB's finding that County/USC's budgeted beds calculus was a proxy for services, not size, and did not establish a ceiling on bed availability. The beds were used for patient care from time to time, and were not taken out of service or in an area that was closed. In short, the term "budgeted beds" did not mean that beds were not available for patient care on a particular day; the PRRB was not compelled to find that the nature of County/USC's budget limitations excluded any physical beds from being available during any time in the cost reporting period.

Notably, a dissenting judge concluded that though the Secretary's interpretation of available beds was entitled to deference, the PRRB's decision was arbitrary and capricious, on the grounds

that County/USC successfully rebutted the presumption and showed that the 123 beds should have been excluded.

2. *Rhode Island Hospital v. Leavitt,* 548 F.3d 29 (1st Cir. Nov. 17, 2008) (Secretary's Determination That Research Time Should Not be Included in FTE Count Was Not Arbitrary)

Rhode Island Hospital involves the interpretation of 42 C.F.R. § 412.105(g)(1), which governs the calculation of a teaching hospital's full time equivalent ("FTE") count. The regulations contains two basic requirements: first, that the resident be enrolled in an approved teaching program and second, that the resident 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, or (c) certain entities under the "ownership or control of the hospital," if the hospital incurs "all, or substantially all, of the costs of the services furnished by those residents."

For its 1996 fiscal year, Rhode Island Hospital ("RIH") requested that its fiscal intermediary ("FI") include 290 FTEs in the calculation of its indirect medical education ("IME") adjustment. The FI, however, determined that governing Medicare regulations precluded counting research time in the hospital's FTE count, and thus reduced RIH's FTE total by 12.06.

RIH appealed to the PRRB, which reversed the FI, finding that the FTE regulation was unambiguous and did not exclude residents' educational research time from the FTE count. The Administrator, however, reversed the PRRB, concluding that the IME payment was only intended to reimburse teaching hospitals for increased patient care costs and that residents performing research were not assigned to an eligible area of the hospital under the FTE regulation. Last year, RIH appealed to the district court, which concluded that (1) the Secretary had misread the plain language of the governing regulation and (2) even if the Secretary's reading was reasonable in the abstract, it was unreasonable in light of Congress's purpose in establishing the IME adjustment. The Secretary appealed to the First Circuit, contesting both of these contentions. The First Circuit reversed.

RIH had interpreted the assignment language of the FTE regulation in geographic terms, such that, in order to be counted, a resident must be assigned to an area or portion of the hospital that is subject to PPS; RIH argued that the regulation does not require that a resident's work be reimbursable under PPS. The Secretary, however, read the language of the statute to mean that a resident must be integrated into a hospital unit dedicated to a form of patient care subject to PPS. The Secretary had thus concluded that residents assigned to research rotations, presumably in labs, were not integrated into a unit of the hospital dedicated to patient services reimbursable under PPS. The First Circuit recognized that both parties' interpretations of the regulatory language were plausible. However, it went on to note that, unless RIH could show that the Secretary's reading was unreasonable or counter to statutory commands or the regulation's underlying purpose, it was required to give deference to the Secretary's interpretation.

The Court analyzed both the statutory and the regulatory history and concluded that the Secretary's determination, that educational research expenses do not directly increase the costs teaching hospitals incur in providing patient care, was consistent with the policies Congress sought to implement by providing an IME adjustment to teaching hospitals. The Court thus concluded that

the Secretary's interpretation was not arbitrary, capricious, an abuse of discretion or otherwise not in accordance with the law and refused to substitute its own judgment for that of the Secretary.

3. *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 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.

F. Miscellaneous Payment Issues

1. *Pleasant Care Corporation v. Leavitt,* 283 Fed.Appx.568 (9th Cir. June 26, 2008) (not published)(FICA Taxes Belong in the Employee Benefits Cost Center)

Pleasant Care Corporation ("Pleasant Care"), a Medicare provider, challenged the classification of Federal Insurance Contributions Act ("FICA") taxes for purposes of Medicare Part A reimbursement. Pleasant Care had requested that its FICA tax expenses be placed in the administrative and general cost center, but its fiscal intermediary refused, instead finding that such expenses qualified as fringe benefits, which belong in the employee benefits cost center. Upon review of the intermediary's decision, the PRRB affirmed. The district court affirmed the Board's decision, and Pleasant Care appealed to the Ninth Circuit.

The Ninth Circuit affirmed the district court's decision, concluding that there was no abuse of discretion. In particular, the Ninth Circuit explained that the Board could reasonably conclude that allocating FICA tax expenses only to those cost centers with employees or direct salary expenses was the most appropriate and accurate methodology for determining reasonable costs. The Ninth Circuit rejected Pleasant Care's contention that the Provider Reimbursement Manual's definition of fringe benefits (as benefits paid "to, or on behalf of, an employee") disposed of the question of how FICA tax expenses should be classified. The Court explained that neither the manual pronouncement nor various letters sent to a third party by CMS, which made conflicting statements about FICA tax classification and did not have the force of law, unambiguously resolved the question of FICA tax classification or countermanded the Board's resolution of the issue. The Court also rejected Pleasant Care's argument that the Board's decision was arbitrary because it had classified employer expenses of unemployment compensation and workers compensation differently from FICA, explaining that its review was limited to whether the Board's allocation of FICA expenses was arbitrary or capricious. Finally, the Court concluded by explaining that the 11th Circuit's decision in *Sarasota Memorial Hospital v. Shalala,* 60 F.3d 1507 (11th Cir. 1995) did not affect its decision in this case because *Sarasota* dealt only with the question of whether employees' FICA payments voluntarily paid by their employer entered the calculation of wage index for the geographic area of the hospital.

2. *Community Care v. Leavitt,* 537 F.3d 546 (5th Cir. July 29, 2008) (Hospital-Based SNF May Qualify as "New Provider" and Have Different Cost Reporting Period Start Date than Hospital)

Community Care Hospital (**"CCH"**), a forty-bed hospital in Louisiana, was certified as a Medicare provider in 1994. Its 1998 cost reporting period covered April 1, 1998 to April 30, 1999. In early April, Medicare certified one floor of CCH as a SNF, and the SNF admitted its first skilled nursing patient on April 10, 1999. CCH submitted a single cost report for the hospital and the SNF, using only the hospital's cost reporting period. On the report, CCH claimed reimbursement for the SNF on the reasonable-cost basis, because the cost reporting period began on April 1, 1998 – before the July 1, 1998 effective date for implementation of the prospective payment system for SNFs. CCH's intermediary initially accepted CCH's cost report, but then reversed itself, stating that it would apply PPS reimbursement for the SNF. After CMS indicated that reasonable cost methodology was proper for the SNF, the intermediary reversed itself again. A few months later, CMS indicated that the proper start date for the SNF's cost report was April 8, 1999, so the intermediary withdrew its reversal and refused to accept CCH's cost report. This resulted in a disallowance of over $300,000 in costs that CCH had incurred.

CCH appealed the decision to the PRRB, which found that CCH properly submitted a single cost report for the hospital and the SNF, and thus, reasonable cost-based methodology was warranted. The Administrator, however, reversed, finding that the beginning of the cost reporting period could be different for a newly certified SNF provider, and further, that the start of the cost reporting period was controlled by the date the provider first rendered services which could be covered by Medicare. CCH appealed this decision to the district court, which granted the Secretary's motion for summary judgment, finding that the Secretary's conclusions were not arbitrary or capricious. CCH appealed to the Fifth Circuit, and the Fifth Circuit affirmed.

The Fifth Circuit's decision rested largely on the interpretation of Provider Reimbursement Review Manual Section 102.1, which states, inter alia, that a provider's initial cost reporting period may not start before the beginning of the month in which it first renders services which could be covered by Medicare. Section 102.1 also defines new provider as one who enters the program t the inception of or during its initial business year.

CCH argued that PRM Section 102.1 did not apply because the SNF was a subprovider, and not a new provider. The Secretary, however, asserted that CCH's SNF was a new and separate provider under the relevant statute, regulations and interpretive guidelines, such that it was a new provider under PRM Section 102.1. In particular, the Secretary pointed to (1) the Medicare statuettes and regulations list both hospitals and SNFs as providers of services; (2) CCH's SNF was certified by CMS as a provider five years after the hospital was certified as a provider; (3) the SNF had its own provider number; (4) the SNF had its own provider agreement; (5) the SNF had to meet specific regulatory requirements the provision of services, quality of care and relationships with other providers that were different than the requirements applicable to hospital providers; and (6) Medicare regulations provide that the SNF is "always the entity that participates in the program..." The Fifth Circuit agreed with the Secretary, finding that the Secretary had sufficient basis for his conclusion that CCH's SNF was a new and separate provider subject to PRM Section 102.1. The Court explained that CCH had failed to show that the Secretary's treatment of the SNF as a new provider was arbitrary or capricious. In particular, the Court pointed out that statutory language

referred to hospital-based SNFs as "providers of services," that several PRM provisions distinguish between hospital-based SNFs and "subproviders," and further, that the requirement that CCH and its SNF file a single cost report existed in the interest of efficiency and did not make the SNF a subprovider.

CCH argued that manual provisions required it to file a single cost report covering a single cost reporting period, which it did. The Secretary, however, read PRM Section 102.1 to modify the single cost report requirement in the case of a new provider; specifically, in instances where a SNF is a new provider, Section 102.1 may require the beginning of the cost reporting period for the SNF be different from the beginning of the cost reporting period for the hospital. In this case, the SNF's cost reporting period could not begin before April 1, 1999. The Secretary explained that CCH and its SNF could have filed a single cost report for the same period by reducing the hospital's cost reporting period to 12 months (April 1, 1999 to March 31, 1999); this way, the required beginning dates for the SNF's cost reporting period and the hospital's cost reporting period could be the same. The Fifth Circuit concluded that the requirement that CCH and its SNF file a single cost report could be harmonized with the requirements of PRM Section 102.1; therefore, the Secretary's decision was not arbitrary or capricious.

III. Procedural Issues at the PRRB

A. *Saint Mary's Hospital of Rochester v. Leavitt,* 535 F.3d 802 (8th Cir. July 28, 2008) (Adjustment Requests Must Be Received By The Fiscal Intermediary Within 180 Days of the NPR)

Saint Mary's Hospital of Rochester received its fiscal year 1994 NPR on June 2, 1997. Believing that it qualified for an exception to the applicable rate-of-increase ceiling under the Tax Equity and Fiscal Responsibility Act of 1982 ("TEFRA"), Saint Mary's prepared an adjustment request and placed the request in the mail on December 22, 1997. The intermediary received the adjustment request on December 24, 1997, but rejected it as untimely because the request was not received until 183 days after the date of the NPR – three days beyond the 180-day deadline.

Saint Mary's appealed the intermediary's denial to the PRRB, asserting that the applicable regulations merely required that the adjustment to be mailed, not received, within 180 days of the NPR. The PRRB ruled in Saint Mary's favor and ordered the intermediary to consider the request on the merits. However, the CMS Administrator reversed the PRRB's decision and held that adjustment requests must be received by the intermediary within the 180-day period. Saint Mary's appealed to the U.S. District Court for the District of Minnesota, which ruled in favor of the Secretary, finding that CMS had consistently interpreted the regulatory language as requiring adjustment requests be received within 180 days.

On appeal to Eight Circuit, Saint Mary's emphasized the fact that CMS had changed the applicable regulation, 42 C.F.R. § 413.40(e)(1), in 1995. In 1994, the regulation read that a hospital's request must be "made" within 180 days from the date of the NPR. In 1995, the regulation was amended to read the hospital's request "must be received by the hospital's fiscal intermediary" within 180 of the NPR. Saint Mary's argued that the 1994 regulations were applicable to appeals of fiscal year 1994 cost reports and that under the 1994 regulations it was sufficient to mail its request within 180 days of the NPR. The Secretary maintained that it had consistently

interpreted the word "made" in the 1994 regulation to mean "received by the fiscal intermediary" since the regulation was promulgated in 1982.

The Court of Appeals rejected Saint Mary's arguments. First, the Court noted that the 1995 regulation, which unambiguously required appeals to be received by the fiscal intermediary within 180 days, went into effect two years before Saint Mary's appealed its 1994 reimbursement. Second, the Court found that even under the 1994 regulation, CMS had interpreted the word "made" to mean "received by the intermediary." In making this finding, the Court relied on statements published in the Federal Register along with the amended rule that expressly stated CMS had consistently interpreted the word "made" as "received by the fiscal intermediary" and that the regulatory change was merely to avoid confusion among providers and fiscal intermediaries. The Court noted that Saint Mary's provided no evidence that CMS had ever taken a position inconsistent with the "received by" interpretation. Accordingly, the Court found for the Secretary and held "under either version of the regulation, the rule has been consistently applied to require a TEFRA adjustment request to be received by the intermediary no later than 180 days from the date of the NPR."

Furthermore, the Court rejected Saint Mary's argument that it detrimentally relied on section 3004.2 of the Provider Reimbursement Manual ("PRM"), which provides that adjustment requests must be "submitted" no later than 180 days after the date of the NPR. The court found that the PRM does not define the word "submit" and thus the PRM provision did not support Saint Mary's argument that "submit" means mailed. Additionally, the Court found that any reliance on the PRM was unreasonable given the clarifying change to the regulation in 1995.

B. *St. Anthony's Health Center v. Leavitt,* 579 F.Supp.2d 115 (D.D.C., Sept. 30, 2008) (Provider May Not Appeal Costs From Revised NPR for the First Time if the Costs Could Have Been Appealed From Original NPR)

St. Anthony's Health Center involves the question whether the issuance of a revised NPR allows a provider to appeal the entire cost report or only those portions of the cost report that were affected by the revision. St Anthony's Health Center operated a skilled nursing facility ("SNF"). In 1993 and 1994, St. Anthony's fiscal intermediary issued initial NPRs for the 1991 and 1992 fiscal years, respectively, which St. Anthony's did not appeal. In 1996, the fiscal intermediary issued revised NPRs for fiscal years 1991 and 1992 and St. Anthony's filed exception requests to the revised NPRs. The intermediary granted St. Anthony's exceptions, but only for the "incremental increase in the amount of the costs that exceeded the cost limit between the original NPR and the revised NPR." St. Anthony's appealed the fiscal intermediary's decision to limit its exception request to the PRRB. The PRRB found that "there is no basis to limit a provider's exception request made from a revised NPR." However, the Administrator reversed the PRRB and found "a revised NPR does not give a provider new appeal rights for costs that could have been appealed under the original NPR."

St. Anthony's appealed the decision to the Federal District Court for the District of Columbia. The hospital argued that the regulation governing exceptions to the cost limit allows a SNF to appeal the entire amount of its exception request from a revised NPR, even if it did not request an exception from the initial NPR. The Secretary maintained that an exception request made to a revised NPR will not cover costs that could have been appealed from the initial NPR.

The Court granted the Secretary's motion for summary judgment. The Court found that St. Anthony's "had the opportunity to appeal the original application of the cost limit upon receipt of the initial NPR and failed to do so." As a result, the Court held that the agency's decision was not "not arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law."

IV. Miscellaneous Medicare Issues

1. *County of Santa Clara v. Astra USA Inc.*, 540 F.3d 1094 (9th Cir. Aug. 27, 2008) (Section 340B Program)

The county of Santa Clara and a number of county-operated medical facilities ("Santa Clara") brought a putative class action alleging that, as 340B covered entities, they had been overcharged by drug manufacturer defendants ("Manufacturers") for outpatient prescription drugs in violation of the pharmaceutical pricing agreements between the Secretary of Health and Human Services ("Secretary") and the Manufacturers. Under the federal Section 340B program, certain federally funded medical clinics qualify as "340B covered entities," making them eligible to purchase drugs at a discount from drug manufacturers under a standardized agreement between the federal government and the drug companies. The discount scheme was designed, in part, so that "certain Federally-funded clinics obtain lower prices on the drugs that they provide to their patients." As such, pursuant to a Pharmaceutical Pricing Agreement ("PPA") with the Secretary, drug manufacturers are obliged to charge 340B covered entities a price that does not exceed the average manufacturer price for the covered outpatient prescription, reduced by a rebate percentage.

Santa Clara originally brought a class action suit in state court against Manufacturers for violations of the California False Claims Act and California Unfair Competition Law, claiming that the Manufacturers were systematically overcharging covered entities. The Manufacturers had the case removed to federal court, where their initial motion to dismiss was granted. Santa Clara subsequently filed a second amended complaint, alleging breach of the PPA, breach of the implied covenant of good faith and fair dealing, negligence, and quantum meruit. Again, the court granted the Manufacturers' motion to dismiss. Santa Clara then brought their case to the Ninth Circuit, appealing the court's rejection of their breach of contract claim, in which they had claimed that 340B covered entities are third party beneficiaries of the PPA.

The Ninth Circuit reversed the district court's dismissal of Santa Clara's claim, holding that the parties to the PPA clearly intended to grant covered entities enforceable rights as intended beneficiaries of that agreement. In particular, the court was unable to "discern any substantial purpose of the PPA other than to grant eligible covered entities a discount on covered drugs." Consideration of the governing statute specifying the PPA's terms reinforced the Court's interpretation: "the legislative history makes plain that Congress intended to accomplish its objective [to stretch scarce federal resources as far as possible] by enabling covered entities [] to obtain discounted prices on covered drugs through the PPAs."

Likewise, the Court opined that Santa Clara had enforceable rights under the PPA as third party beneficiaries despite there being no private federal cause of action under 42 U.S.C. § 256b. The Manufacturers argued that Congress "necessarily did not intend to allow covered entities to make an 'end-run' around the statutory scheme by pursuing contractual remedies under the federal common law." However, because Section 256b did not expressly provide any remedies to covered

entities and HHS's regulations merely established an informal, non-exclusive dispute resolution process, in which neither covered entities nor manufacturers are required to participate, the Court found that permitting covered entities to sue as third party beneficiaries of the PPA was entirely consistent with the Section 340b program objectives.

Moreover, since there was nothing "particularly complicated" about the Santa Clara's contract claim that warranted agency resolution, the Court disregarded the Manufacturers' claim that the doctrine of primary jurisdiction precluded its review. Accordingly, the Court held that as indirect beneficiaries of the PPA, covered entities could enforce the Manufacturers' ceiling price obligations under the federal common law of contracts.

2. *Estate of Landers v. Leavitt,* 545 F.3d 98 (2nd Cir. Oct. 1, 2008)(Medicare Coverage of SNF Services: Three-Day Stay Requirement)

Medicare beneficiaries ("Plaintiffs") brought a putative class action in district court, challenging the Secretary's implementation of a statutory requirement concerning Medicare coverage of skilled nursing facility ("SNF") services. Under the statute, Medicare covers SNF services if an individual is transferred from a hospital "in which he was an inpatient for not less than three consecutive days." *See* 42 U.S.C. § 1395x(i). The Secretary's longstanding policy was that, for purposes of this requirement, the inpatient stay begins at the time of formal admission and further, that a patient is eligible for SNF coverage when he/she has been hospitalized for at least three consecutive calendar days. Plaintiffs contended that time in the emergency room and/or in observation status prior to admission must be counted toward the three-day stay requirement. The three named plaintiffs were all Medicare beneficiaries from Connecticut who were denied Medicare coverage for SNF care because they did not have a prior inpatient hospital stay of at least three days, but would have met the three-day stay requirement if their time in the emergency room and/or observation status had been counted.

The district court, which had certified a nationwide class (over the government's objections) in an interlocutory ruling, granted the Secretary's motion for summary judgment, holding that the Plaintiffs had not spent the requisite amount of time in the hospital as inpatients. Plaintiffs appealed, and the Second Circuit affirmed the district court's decision on the merits.

Neither the governing statute nor the applicable regulations provided a definition of "inpatient," so the Second Circuit addressed the proper standard of deference applicable to the agency interpretation at issue in this case, which was reflected in manual provisions. The Second Circuit declined to give the interpretation Chevron deference, reasoning that "agency manuals, as a class, are generally ineligible" for such deference; however, the Court went on to state that "an agency interpretation that does not qualify for Chevron deference is still entitled to 'respect according to its persuasiveness." In its opinion, the Second Circuit explicitly recognized the "Supreme Court's repeated suggestion that HHS interpretations, in particular, should receive more respect than the mine-run of agency interpretations." The Court also reiterated an observation from a previous decision that in cases such as this, involving a highly expert agency administering a complex regulatory scheme, the various possible standards of deference - specifically, Chevron and Skidmore - "begin to converge."

Ultimately, with respect to the proper standard of deference the Second Circuit concluded that the agency interpretation at issue was "entitled to a great deal of persuasive weight," based on a number of factors, including (1) the interpretation was longstanding, (2) CMS was consistent in its interpretation, (3) CMS had reconsidered its position on the public record, and (4) the policy at issue was the product of an interpretation that was "relatively formal within the universe of informal interpretations." Applying this standard, the Court found that the agency interpretation was persuasive and upheld CMS's interpretation of "inpatient." The Court did, however, acknowledge that the Medicare statute did not unambiguously require this construction and that if the Secretary were to adopt a different interpretation, that interpretation would be entitled to Chevron deference.

The Second Circuit next addressed Plaintiffs' other arguments. The Court rejected Plaintiffs' equal protection challenge in part on the grounds that "CMS's legitimate interest in administrative efficiency is sufficient to uphold this rule against a rational basis challenge." The Court also rejected Plaintiffs' argument that the district court erred in refusing to consider evidence outside the administrative record, finding that the court could not properly consider the statements of facts, interrogatories, and declarations that Plaintiffs sought to submit because the record before the court was sufficient to shed light on the rationale for CMS's decision. Further, the Court found that the declarations and statements regarding the nature of medical services rendered to the Plaintiffs were immaterial because they could not alone establish eligibility for SNF coverage.

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Jonathan P. Neustadter received his B.A. degree in Economics with Distinction from the University of Virginia in 1991 and his J.D. from the University of California at Los Angeles in 1994. While at UCLA, Mr. Neustadter was active in the UCLA Moot Court Honors Program, winning the award for best brief writer and writing the brief for the UCLA National Moot Court Team.

Mr. Neustadter joined Hooper, Lundy & Bookman in October 1994, and he specializes in Medicare and Medicaid reimbursement and fraud and abuse disputes. He represents hospitals, laboratories, home health agencies, DME suppliers, skilled nursing facilities, and physicians in reaching negotiated settlements, pursuing administrative remedies, and in litigating federal and state court cases.

Mr. Neustadter has handled complex Medicare and Medicaid disputes before the Provider Reimbursement Review Board, Federal district courts across the country, various federal courts of appeal, and in state courts. His practice includes Medicare/Medicaid fraud and abuse issues including compliance and disclosure obligations, and he has defended providers in federal false claims investigations and cases.

For nearly three years, Mr. Neustadter was a leader on the regulatory legal team that represented a large hospital system in its civil defense of thousands of alleged false claims. During the course of the investigation, Mr. Neustadter analyzed allegations of cost reporting fraud, helped develop the company's positions, and assisted in all phases of the false claims litigation.

Mr. Neustadter has lectured to the American Health Lawyers Association, the California Clinical Laboratory Association, and Healthcare Financial Management Association on payment and fraud related issues. He is a member of the American Health Lawyers Association and the California Society for Healthcare Attorneys.