IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF HAWAII

GAYLE S. GLASER, Plaintiff, vs. U.S. DEPT. OF HEALTH AND HUMAN SERVICES SECRETARY, KATHLEEN SEBELIUS, IN HER OFFICIAL CAPACITY, Defendant, and KAISER FOUNDATION HEALTH PLAN, INC., Defendant-Intervenor.	CIV. NO. 08-00443 DAE-BMK

ORDER AFFIRMING DECISION OF MEDICARE APPEALS COUNCIL

On September 8, 2009, the Court heard Plaintiff's appeal of a decision by the Medicare Appeals Council ("MAC"). Robert G. Klein, Esq., and Dayna H. Kamimura-Ching, Esq., appeared at the hearing on behalf of Plaintiff Gayle S. Glaser ("Glaser"); Assistant United States Attorney Harry Yee appeared at the hearing on behalf of Defendant U.S. Department of Health and Human Services

Secretary, Kathleen Sebelius[1] ("HHS"); and Diane Winter Brookins, Esq., appeared at the hearing on behalf of Defendant-Intervenor Kaiser Foundation Health Plan, Inc. ("Kaiser"). After reviewing the appeal, the supporting and opposing briefs, and the administrative record, the Court AFFIRMS the decision of the MAC.

BACKGROUND

I. The Medicare System

Medicare is a federal medical insurance program for the aged and disabled which provides insurance benefits and supplemental medical insurance benefits. See 42 U.S.C. §§ 1395-1395ggg. Medicare is administered by the Centers for Medicare & Medicaid Services ("CMS"), a component of HHS.

In 2003, Congress established the Medicare Advantage ("MA") Program under Part C of Title XVIII of the Social Security Act. The MA program allows eligible individuals to elect to receive Medicare benefits through enrollment in health maintenance organizations ("HMO") offered by "Medicare Advantage plans." See 42 U.S.C. § 1395w-27. By enrolling in an MA plan, the beneficiary generally agrees to receive covered benefits from the HMO "directly or

[1]Kathleen Sebelius is substituted for her predecessor, Michael O. Leavitt, as Secretary, Health and Human Services.

through arrangements" made by the HMO with health care providers outside of the organization. 42 U.S.C. § 1395w-22(d)(1). Although the HMO generally has discretion whether to approve out-of-plan services, they are required to provide payment for certain services, including ambulance services, emergency and urgently needed services, and services found on appeal to be ones for which the HMO should have authorized. 42 C.F.R. §§ 422.2, 422.100(b)(1).

II. The Benefit Decision

At the time at issue, Glaser was a 74-year-old woman who was enrolled in the Kaiser Permanente Senior Advantage plan, an MA organization. (Administrative Record ("AR") at 3.) As a Senior Advantage enrollee, Glaser selected Kaiser as her required plan provider. (Id.)

In 2006, Glaser presented with a chronic cough. On August 10, 2006, Glaser received a computerized axial tomography ("CT") scan of her chest. (Id. at 209-13.) The CT scan showed a 5.5 cm mass in the liver, which was centrally located at the portal region. (Id. at 155.) Another CT scan of the abdomen, conducted on August 17, 2006, indicated an ill-defined lesion on the liver. (Id. at 215.) An initial biopsy was negative for malignancy but a repeat liver biopsy conducted on September 27, 2006 revealed adenocarcinoma (cancer of the liver glands) favoring cholangiocarcinoma (cancer of the bile ducts). (Id. at 219-222.)

On October 3, 2006, Glaser's case was reviewed by Kaiser's multidisciplinary Tumor Board. (Id. at 204.) The Tumor Board is comprised of Kaiser and non-Kaiser physicians in various specialties, who convene to discuss proper treatment approaches to carcinogenic tumors in patients under Kaiser's care. (Id. at 155.) Over thirty physicians participated in the review of Glaser's tumor. (Id.) The conclusion of the Tumor Board was that the tumor was unresectable due to its location and the amount of liver which would have to be removed. (Id.) The potential for serious complications was very high, and the Tumor Board was concerned that resection would mean that Glaser would not have sufficient liver to survive. (Id.) The Tumor Board recommended chemotherapy as the proper course of treatment. (Id. at 204.)

Three days later, on October 6, 2006, the General Surgery Department at Kaiser reviewed Glaser's case and agreed with the Tumor Board that surgery was not medically advisable. (Id. at 156.) Glaser's surgical oncologist, Dr. Ryan Takamori ("Dr. Takamori"), informed Glaser that the tumor would require extensive liver resection, and that only approximately 20% of her liver would remain intact after surgery. (Id. at 156.) As such, Dr. Takamori informed Glaser that surgery would incur high morbidity and mortality and that it

was not advisable to conduct the resection. (Id.) Glaser was scheduled for a second opinion with an oncologist within the Kaiser system. (Id.)

On October 10, 2006, Glaser requested that Kaiser refer her to Dr. Lin-Hurtubise ("Dr. Lin-Hurtubise"), an out-of-plan physician. (Id. at 191.) Dr. Lin-Hurtubise had advised Glaser that her tumor was resectable and that he was able to perform the surgery at Maui Memorial Medical Center ("MMMC"), a hospital that is not part of Kaiser's network. (Id. at 131.) Kaiser denied Glaser's referral request on the basis that Kaiser's Moanalua Medical Center on Oahu, where Glaser lived, was fully capable of performing the requested procedure, had it been advisable to do so. (Id. at 191.)

Kaiser's General Surgery Chief, Dr. Eric Matayoshi ("Dr. Matayoshi"), informed Glaser that there would be no coverage for surgery performed by Dr. Lin-Hurtubise at MMMC. (Id. at 156.) During that conversation Dr. Matayoshi, although not Glaser's treating physician, described another treatment option: chemoembolization, the process by which Dr. Matayoshi hoped they could shrink Glaser's tumor. (Id. at 393-94.) Dr. Matayoshi encouraged Glaser to meet with the Kaiser oncologist as planned on October 11, 2006. (Id.) Glaser was also given another appointment with Dr. Takamori for the same day to discuss her treatment options. (Id. at 157.)

Glaser did not keep either of her appointments with Kaiser physicians. (See Glaser's Brief at 6.) Instead, Glaser met with Dr. Lin-Hurtubise on Maui in preparation for her surgery. (Id.)

After being informed that Kaiser had denied her coverage for the liver resection, Glaser nonetheless underwent surgery with Dr. Lin-Hurtubise on October 12, 2006. (AR at 157, 131.) Dr. Lin-Hurtubise removed 75% of Glaser's liver, including the entire right lobe, medical segment of the left lobe and the caudate lobe. (Id. at 131.) Although Dr. Lin-Hurtubise contends that 100% of Glaser's tumor was removed (id.), the MMMC pathology report on surgical specimens removed during the surgery indicate that the specimens had "positive margins" within 1 mm, meaning the cancerous tissue was present on the outer edges of the specimen. (Id. at 269-70.) Dr. Matayoshi indicated that the desired minimum margin with Glaser's type of cancer would be 1 cm. (Id. at 157-58.)

Glaser remained at MMMC post-operatively from October 12, 2006 to November 3, 2006. (Id. at 158.) While at MMMC, Glaser suffered from prolonged hepatic encephalopathy, wherein her brain function was impaired as a result of certain medications and lowered liver function. (Id. at 267-68.) She was discharged from MMMC on November 4, 2006 and hospitalized again at Kaiser's Moanalua Medical Center from November 6, 2006 to November 14, 2006, for

abnormal liver function tests, increasing abdominal discomfort, urinary tract infection, and dehydration. (Id. at 226-36.) While at Moanalua Medical Center, a Kaiser oncologist assessed Glaser as having a high chance of recurrence, as well as significant morbidity due to the amount of liver removed during the resection. (Id.) Glaser continued to need bi-monthly paracentesis to remove fluid from her abdominal area to relieve pressure on her internal organs but she is otherwise in good health. (Id. at 158-59, 135.)

III. Procedural History of the Case

Kaiser issued a redetermination decision, dated January 19, 2007, in which it denied coverage for the liver resection surgery. (Id. at 191-93.) The redetermination decision stated that all of the appropriate services were available within the Kaiser plan and did not require out-of-plan referral. (Id.) Glaser appealed the redetermination decision to Maximus Federal Services, an independent review entity ("Maximus"). (Id. at 186-88.) Maximus upheld the denial of the coverage because the surgery performed was out-of-plan and had not been authorized by Kaiser. (Id.)

Glaser then requested a hearing to appeal the denial before an administrative law judge ("ALJ"). (Id. at 182-83.) A telephonic hearing was held

on June 27, 2007, before ALJ J. Gerard Lewis. (Id. at 267-90.) Glaser and Dr. Matayoshi testified at the hearing. (Id.)

On October 11, 2007, the ALJ issued his decision, which reversed the determination by Maximus. (Id. at 100-10.) The ALJ found that Kaiser had failed to make their services available or adequate. The ALJ also concluded that Glaser was subject to the "urgently needed care" exception, finding that Kaiser had offered "no other treatment options other than death." (Id. at 92.) In that sense, the ALJ concluded that Kaiser had violated its own Evidence of Coverage urgently needed care provision. Accordingly, the ALJ held that Kaiser was required to cover the procedure and related hospitalization expenses at issue. (Id.)

Kaiser requested review by the MAC. (Id. at 68-90.) The MAC concluded that the evidence in the record did not indicate that Kaiser had made its services unavailable, inaccessible, or inadequate to meet Glaser's needs. (Id. at 8.) The MAC determined that the surgery could have been performed at the Kaiser hospital, had it been medically necessary or desirable. (Id.) Because Glaser failed to obtain prior authorization for her surgery, the MAC concluded that those services were not covered by Medicare and her requested referral was appropriately denied. (Id.)

On October 6, 2008, Glaser filed her complaint in this Court, seeking review of the MAC decision. (Doc. # 1.) This Court signed a stipulation of the parties to allow Kaiser to intervene as a party in the case on December 12, 2008. (Doc. # 9.) Glaser then filed her opening brief on June 9, 2009. (Doc. # 28.) HHS and Kaiser filed their answering briefs on July 9, 2009. (Doc. ## 32 & 33, respectively.) On July 31, 2009, Glaser filed her reply brief. (Doc. # 34.)

STANDARD OF REVIEW

A party to a decision made by the MAC may seek judicial review of any final agency determination. See 42 U.S.C. § 1395ff(b)(1)(a); 42 C.F.R. § 405.1136. After consideration of the pleadings and transcript of record, the district court shall enter a judgment affirming, modifying, or reversing the agency's final decision[2], with or without remanding the cause for a rehearing. 42

[2]A MAC review of an ALJ decision becomes the "final decision" of the agency, assuming the MAC does not remand for further proceedings. Heckler v. Ringer, 466 U.S. 602, 607 (1984). The final decision is the one reviewed by a district court for error. 42 U.S.C. § 405(g). Glaser argues in her reply brief that the findings of the ALJ are to be given deference and notates that the cases cited by HHS and Kaiser command deference to an ALJ's decision. (Reply at 3-5.) In all of the cases cited by Glaser, however, the ALJ's decision was, in fact, the final decision up on review and therefore the one examined. See Edlund v. Massanari, 253 F.3d 1152, 1156 (9th Cir. 2001) (Social Security Appeals Council declined to review the ALJ's decision, "and at that point the ALJ's decision became the final decision of the [agency]"); Tackett, 180 F.3d at 1097 ("[T]he Appeals Council declined Tackett's request for review. At this point, the ALJ's ruling became the (continued...)

U.S.C. § 405(g).

The court considers the record in its entirety, "weighing both evidence that supports and evidence that detracts from the Secretary's conclusion." Tackett v. Apfel, 180 F.3d 1094, 1098 (9th Cir. 1999) (citation omitted). The Secretary's final decision will be disturbed only if the factual findings underlying the decision are not supported by substantial evidence or if the decision fails to apply the correct legal standards. Id. at 1097. The findings of the Secretary as to any fact shall be conclusive and must be upheld if supported by substantial evidence. 42 U.S.C. § 405(g); Mayes v. Massanari, 276 F.3d 453, 459 (9th Cir. 2001). "If the evidence is susceptible to more than one rational interpretation," the court may not substitute its judgment for the agency's. Bear Lake Watch, Inc. v. FEC, 324 F.3d 1071, 1086 (9th Cir. 2003). Substantial evidence is "more than a mere scintilla but less than a preponderance." Tackett, 180 F.3d at 1098 (citation omitted). It is

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[2](...continued)
final decision of the Commissioner."); Morgan v. Apfel, 169 F.3d 595, 599 (9th Cir. 1999) ("[T]he Appeals Council denied review of Morgan's claim, thereby making the ALJ's determination a final decision of the Commissioner . . ."); but see Moncada v. Chater, 60 F.3d 521, 523 (9th Cir. 1995) (procedural posture unclear as Ninth Circuit does not discuss any request for review from an agency appeal board). In this case, however, the MAC ruling, dated August 15, 2008, is the final decision of the Secretary. It is the factual and legal findings of the MAC that are therefore subject to the standard of review outlined herein, not the findings of the ALJ.

"evidence that a reasonable mind might accept as adequate to support a conclusion." Richardson v. Perales, 402 U.S. 389, 402 (1971).

A court reviews administrative questions of law, including an agency's interpretation of a statute, de novo. Reynoso-Cisneros v. Gonzales, 491 F.2d 1001, 1002 (9th Cir. 2007). Although courts give deference to the agency's interpretation of relevant Medicare statutes and regulations, if its interpretations are inconsistent with those statutes and regulations, they will not be upheld. County of Los Angeles v. Sullivan, 969 F.2d 735, 740 (9th Cir. 1992).

DISCUSSION

Glaser seeks review of the MAC decision on three[3] basic issues: (1) whether the MAC erred in finding Kaiser had "arranged appointments with plan providers to discuss treatment options" and therefore whether Kaiser "made appropriate cancer treatment available within a reasonable standard of medical care;" (2) whether the MAC erred in finding that Kaiser's refusal to conduct the resection "did not render their provider network unavailable or inaccessible;" and (3) whether the MAC erred in finding that Glaser's surgery was not an "urgently needed service." (Opening Brief at 1-2 (citations omitted).) Because the MAC

[3]Glaser actually presents four issues in her brief. (See Opening Brief at 1.) However, due to the overlapping nature of Glaser's arguments, the issues are more properly organized in the manner used by the Court.

erred on these grounds, Glaser argues, Kaiser is liable for the expenses related to her surgery with Dr. Lin-Hurtubise. (Id.)

Glaser contends that Kaiser did not provide her with any other treatment option besides death and therefore failed to make appropriate treatment options available to her. Glaser argues that Dr. Matayoshi's contention -- that the October 11, 2006 meeting with her oncologist was designed to provide her with information on a chemotherapy treatment -- are post hac rationales that the ALJ found not credible.

HHS and Kaiser, on the other hand, respond that Glaser would have been informed of alternative treatment options had she kept her scheduled appointments. Furthermore, HHS and Kaiser contend that the physicians involved properly determined resection was not medically advisable under the circumstances. As such, they argue all medically appropriate treatment options were made available to Glaser, she simply chose to self-refer to Dr. Lin-Hurtubise.

I. Whether Treatment Was Available and Accessible Under the Plan

Glaser contends that the MAC erred in determining that "[a]t no time were [Kaiser]'s providers unavailable, inaccessible, or inadequate to provide appropriate treatment" under 42 C.F.R. § 422.112(a)(3). (Id. at 10 (quoting AR at 20).) This section of the Medicare regulations, titled "Access to services," requires

that an MA organization ensure that all covered services are "available and accessible under the plan." 42 C.F.R. § 422.112(a). A further subsection mandates that an MA organization arrange for specialty care outside of the plan provider network when the in-network providers are "unavailable or inadequate to meet the enrollee's medical needs." Id. at § 422.112(a)(3).

The MAC found that the evidence in the record did not indicate that Kaiser had made its services unavailable, inaccessible, or inadequate to meet the enrollee's medical needs. (AR at 6.) The MAC determined that Kaiser had never denied Glaser medical treatment that was reasonably believed to be within the standard of appropriate medical care; instead, it simply denied her referral to an out-of-network provider for a service it believed to be inadvisable. (Id.) The MAC relied on the fact that Glaser failed to keep her appointments with her Kaiser oncologist and Dr. Takamori, where Dr. Matayoshi indicated he intended to discuss the possibility of performing the liver resection surgery after completing chemotherapy. (Id.)

The Court finds that the MAC did not err and, in fact, there is substantial evidence in the record to indicate that Kaiser made services available to Glaser that were within a reasonable medical standard of care. At the outset, the Court notes that Glaser's plan was a closed-panel HMO in which Glaser generally

agreed to pursue benefits within her network. See 42 U.S.C. § 1395w-22(d)(1). Outside of certain enumerated exceptions, therefore, Glaser was required to seek treatment from Kaiser physicians or seek referral authorization by Kaiser. Id.

Secondly, the Court accepts the fact that the Tumor Board and Dr. Lin-Hurtubise disagreed about whether it was medically sound to conduct the liver resection surgery at that time. The Court is in no position to second-guess the learned expertise of any of the medical professionals involved in this case. Nevertheless, the record indicates that the Tumor Board, consisting of 30 Kaiser and non-Kaiser physicians, recommended against the surgery and instead suggested chemotherapy. (Id. at 155.) Dr. Matayoshi explained further the reasons why such surgery was not medically advisable, including the fact that proper resection would require removal of such a substantial portion of Glaser's liver that she would likely not survive. (Id.) Simply because one physician, Dr. Lin-Hurtubise, was willing to conduct the surgery does not make the medical determination of the Tumor Board unreasonable or unsound.[4]

[4]Nor can the Court weigh the outcome of Glaser's surgery in determining whether the initial decision was either correct or in error. There remains substantial debate about whether Glaser's surgery was, in fact, a "success." Regardless, this Court may not review the benefit decision with 20-20 hindsight. Instead, the Court determines that there was sufficient medical support at the time for Kaiser's position that resection was inadvisable.

The crux of the issue raised on appeal is whether the alternative treatment options -- namely, chemotherapy or chemoembolization -- were, in fact, made available to Glaser. Glaser argues that the only option she was presented with was death within three to six months. (Opening Brief at 11.) The record indicates otherwise. In the first instance, Kaiser did make two appointments for Glaser with her oncologist and Dr. Takamori for October 11, 2006. Presumably, at these appointments, Glaser would be informed of further options available to her. In fact, Dr. Matayoshi testified that those appointments were scheduled with the intent to discuss the possibility of performing the liver resection surgery after chemotherapy had sufficiently shrunken the tumor, at which time it would be safer and more effective at completely removing the cancerous tissue. (Id. at 377-78.) Glaser, however, failed to keep both of those appointments.[5]

The Court rejects Glaser's implicit contention that she can refuse appointments with in-network providers and, at the same time, argue that alternative options were not made available to her. To accept Glaser's argument would place on physicians and HMO's an exceedingly high burden, requiring them

[5]Glaser did speak with Dr. Takamori on the phone. (AR at 224.) His clinical notes indicate that the "issues/nuances if the clinical decision making were reviewed multiple times." (Id.)

to nearly force services upon patients. Such a requirement would clearly be more burdensome than the standard outlined in 42 C.F.R. § 422.112(a)(3).

Furthermore, a careful review of the record indicates that Glaser had been informed, at least minimally, of the alternative option of chemoembolization. (AR at 393-94.) In his hearing testimony, Dr. Matayoshi testified that he specifically remembered mentioning this option to Glaser during a phone call prior to her surgery with Dr. Lin-Hurtubise. (Id.) This evidence indicates that not only would Glaser have been given a thorough explanation of her options had she kept her appointments, but she had in fact been informed of other options prior to her surgery. Glaser was not, therefore, merely given the "death-death option," she was offered, at least minimally, a chance at alternative treatment options.

As such, the Court concludes that there is substantial evidence to support the MAC's conclusions that medically-sound services were "available and accessible" to Glaser under her plan and that Kaiser's refusal to conduct the liver resection at that time "did not render their provider network unavailable or inaccessible."

II. Whether the Surgery Was an "Urgently Needed Service"

Glaser also contends that Kaiser is liable for the cost of her surgery because the resection was an "urgently needed service" under provisions of the Medicare regulations. (Opening Brief at 11-12.) Under 42 C.F.R. § 422.112(a)(9), an MA organization is required to provide coverage for certain services, including "urgently needed services." The regulations define "urgently needed services" as:

> covered services that are not emergency services as defined in this section, provided when an enrollee is temporarily absent from the MA plan's service (or, if applicable, continuation) area (or, under unusual and extraordinary circumstances, provided when the enrollee is in the service or continuation area but the organization's provider network is temporarily unavailable or inaccessible) when the services are medically necessary and immediately required –
>
> (A) As a result of unforeseen illness, injury, or condition; and
>
> (B) It was not reasonable given the circumstances to obtain the services through the organization offering the MA plan.

42 C.F.R. § 422.113(b)(iii) (emphasis added).

Glaser contends that the decision to not conduct the resection made Kaiser's provider network "temporarily unavailable or inaccessible" under the provision. (Opening Brief at 12.) Glaser's argument is without merit.

First, the plain language of the regulation indicates that an exception should be made only in "unusual or extraordinary circumstances." In promulgating the regulation, CMS identified labor strikes and earthquakes as examples of such "unusual or extraordinary circumstances." See 65 Fed. Reg. 40,170, 40,199 (June 29, 2000). Other circumstances could include "possibly some temporary physical impediment to traveling to [] plan providers that are otherwise readily accessible." 63 Fed. Reg. 34,968, 34, 973 (June 26, 1998). These examples emphasize that the exception should only be applied when there is some extraordinary circumstance preventing the provider from rendering services otherwise normally available, not merely when a provider refuses to pursue a particular treatment option.

To hold otherwise, as Glaser would have this Court do, would essentially eviscerate the general prohibition against out-of-network services when such services can be supplied in-network. Although Glaser's condition was certainly serious, nothing in the circumstances presented required invoking this exception.

Furthermore, Glaser's contention that Kaiser's refusal to perform the surgery made its provider network "inaccessible" is likewise unavailing. A decision not to pursue a medical course of treatment cannot be the same as making services "inaccessible." Again, to hold so would mean that every time an MA

organization declined a request, that patient could simply get reimbursed for treatment found elsewhere. Plainly, the regulations do not contemplate such a result.

Finally, CMS has already spoken to this issue during the notice and comment period of its regulatory rulemaking procedure. When asked whether the exception could be invoked by a beneficiary who "unilaterally obtain[s] care out-of-plan" that an MA organization has declined to cover, CMS replied that since the network is not unavailable in that scenario, the appeals procedure in the regulations is the proper mechanism through which to seek redress. 65 Fed. Reg. at 40,199.

The Court is not unsympathetic to the serious medical situation Glaser found herself in. However, the Court cannot render legal decisions based upon sympathy while ignoring the facts and law. The Court, therefore, finds that the MAC did not err in concluding the "urgently needed services" exception did not apply in this case.

CONCLUSION

For the reasons stated above, the Court AFFIRMS the decision of the MAC.

IT IS SO ORDERED.

DATED: Honolulu, Hawaii, September 9, 2009.

David Alan Ezra
United States District Judge

Glaser v. U.S. Dept. Of Health and Human Services Secretary, Civ. No. 08-00443 DAE-BMK; ORDER AFFIRMING DECISION OF MEDICARE APPEALS COUNCIL