JS-6

UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA

PRIME HEALTHCARE SERVICES - HUNTINGTON BEACH, LLC, d/b/a Huntington Beach Hospital,

Plaintiff,

v.

ERIC D. HARGAN, in his official capacity as Acting Secretary of the U.S. Department of Health and Human Services,

Defendant.

No. CV 16-8102 PA (GJSx)

FINDINGS OF FACT AND CONCLUSIONS OF LAW

Plaintiff Prime Healthcare Services - Huntington Beach LLC ("Plaintiff"), which owns and operates Huntington Beach Hospital, brought this action pursuant to the Administrative Procedure Act ("APA"), 42 U.S.C. § 1395ff(b)(1)(A) (incorporating the judicial review procedure of 42 U.S.C. § 405(g)), for judicial review of a final decision by Eric D. Hargan, in his official capacity as Acting Secretary of the U.S. Department of Health and Human Services ("Secretary" or "Defendant"),[1/] that Plaintiff received an overpayment of $5,380.30 for inpatient services that were not medically reasonable and necessary.

[1/] By operation of Federal Rule of Civil Procedure 25(d), Eric D. Hargan is automatically substituted into this action as the defendant in place of Thomas E. Price.

Following the filing, consideration, and review of the Administrative Record ("AR") (Docket No. 45), the parties' Opening and Responsive Trial Briefs, the submission of their respective Proposed Findings of Fact and Conclusions of Law, and their objections to each other's Proposed Findings of Fact and Conclusions of Law, the Court, makes the following findings of fact and conclusions of law pursuant to Federal Rule of Civil Procedure 52(a). Any finding of fact that constitutes a conclusion of law is hereby adopted as a conclusion of law, and any conclusion of law that constitutes a finding of fact is hereby adopted as a finding of fact.

I. Findings of Fact

A. Statutory and Regulatory Background

1. Medicare is a federally funded health insurance program for the elderly and disabled. See 42 U.S.C. § 1395, et seq. Medicare coverage is limited to services that are medically "reasonable and necessary." See Palomar Med. Ctr. v. Sebelius, 693 F.3d 1151, 1155 (9th Cir. 2012) (citing 42 U.S.C. § 1395y(a)(1)(A)). In the absence of a national or local coverage determination, the regional Medicare Administrative Contractor responsible for administering benefits claims generally determines whether a claim is medically reasonable and necessary. See 68 Fed. Reg. 63692, 63693 (Sept. 26, 2003) (final rule).

2. Medicare service providers submit claims for reimbursement for covered services, and Medicare Administrative Contractors make initial determinations of coverage and amount. See Palomar Med. Ctr., 693 F.3d at 1154-55 (citing 42 U.S.C. § 1395ff(a); 42 C.F.R. § 405.920). In exercising their regulatory functions, contractors conduct post-payment audits to ensure that payments are made in accordance with applicable Medicare payment criteria. When audited, a Medicare provider seeking payment must provide sufficient evidence to establish the medical reasonableness and necessity of the services billed to Medicare. See 42 U.S.C. §§ 1395g(a), 1395l(e), 1395gg; 42 C.F.R. § 411.15(k)(1).

3. Initial determinations are appealable through a four-step administrative process. First, if the claimant is dissatisfied with the initial determination, it may request

that the same contractor conduct a "redetermination." 42 U.S.C. § 1395ff(a)(3); 42 C.F.R. § 405.940. Second, if the claimant is dissatisfied with the contractor's redetermination, it may request a "reconsideration" by a "qualified independent contractor" ("QIC"). 42 U.S.C. § 1395ff(b)(1)(A) & (c)(2); 42 C.F.R. § 405.960. Third, a still dissatisfied claimant may request a hearing before an administrative law judge. 42 U.S.C. § 1395ff(b)(1)(A), (E) & (d)(1); 42 C.F.R. § 405.1002. Finally, the claimant may seek review of the ALJ's decision by the Medicare Appeals Council, Departmental Appeals Board. 42 U.S.C. § 1395ff(d)(2); 42 C.F.R. § 405.1100.

4. Once this administrative process is exhausted, the claimant may then seek judicial review, as provided in 42 U.S.C. § 405(g), of the final agency decision of the ALJ or the Medicare Appeals Council, as applicable. 42 U.S.C. § 1395ff(b)(2)(C); 42 C.F.R. § 405.1136.

5. The Medicare Act provides for a process called "escalation," whereby a service provider can bypass steps in the administrative appeals process if a decision is not issued within the statutorily set time period. If, for instance, the Medicare Appeals Council does not issue a determination within 90 days, a service provider may seek judicial review in federal court. 42 U.S.C. § 1395ff(d)(3); 42 C.F.R. § 405.1100(c).

6. The Medicare Act provides that with respect to all Medicare items or services, "no payment may be made under Part A or Part B for any expenses incurred for items or services . . . which. . . are not reasonable and necessary for the diagnosis or treatment of illness or injury. . . ." 42 U.S.C. § 1395y(a)(1)(A); 42 C.F.R. § 411.15(k)(1).

7. Congress has vested final authority in the Secretary to determine what items or services are "reasonable and necessary." 42 U.S.C. § 1395ff(a); Heckler v. Ringer, 466 U.S. 602, 617 (1984) (citing 42 U.S.C. § 1395ff(a)). Congress likewise has vested discretion in the Secretary to determine what information to require as a condition of payment. See Maximum Comfort, Inc. v. Sec'y of Health & Human Servs., 512 F.3d 1081, 1088 (9th Cir. 2007); Cmty. Hosp. v. Thompson, 323 F.3d 782, 789 (9th Cir. 2003) (noting that the Medicare statute "specifically granted the Secretary broad discretion as to what information

to require as a condition of payment to providers under the Medicare program"). Consistent with this authority, the Secretary has promulgated policies and regulations relating to the "reasonable and necessary" requirement, which place the burden of establishing the reasonableness and necessity of medical care squarely on the entity submitting the claim. 42 U.S.C. § 1395l(e); 42 C.F.R. § 424.5(a)(6).

8. The statutory provisions governing Part A do not define the term "inpatient." See 42 U.S.C. §§ 1395d(a), 1395x(b), 1395x(i). The Secretary, however, through the Centers for Medicare & Medicaid Services ("CMS"), defined the term "inpatient" in CMS's Medicare Benefits Policy Manual in effect at the time of the claim at issue as:

> [A] person who has been admitted to a hospital for bed occupancy for purposes of receiving inpatient hospital services. Generally, a patient is considered an inpatient if formally admitted as inpatient with the expectation that he or she will remain at least overnight and occupy a bed even though it later develops that the patient can be discharged or transferred to another hospital and not actually use a hospital bed overnight.

CMS, Publ'n No. 100-02, Medicare Benefits Policy Manual ("Policy Manual"), Ch. 1, § 10; Barrows v. Burwell, 777 F.3d 106, 108 & n.5 (2d Cir. 2015) (quoting the language of Ch. 1, § 10 of the Policy Manual in effect at the time of the claim). The Policy Manual states that when deciding whether to admit a patient, "[p]hysicians should use a 24 hour period as a benchmark, i.e., they should order admission for patients who are expected to need hospital care for 24 hours or more, and treat other patients on an outpatient basis." Policy Manual, Ch. 1, § 10. The Policy Manual further articulates "a number of factors" that a physician should also consider, "including the patient's medical history and current medical needs, the types of facilities available to inpatients and outpatients, the hospital's by-laws and admissions policies, and the relative appropriateness of treatment in each setting." Id. The Policy Manual, moreover, provides that whether the admission is "not covered or

non-covered" is not to be based solely on the length of time the patient actually spends in the hospital. Id.

9. As an alternative to admitting an individual as an inpatient, a hospital may instead place the patient on "observation status," in which case the services he or she receives will be considered outpatient "observation services." The Policy Manual defines "observation services" as:

> [A] well-defined set of specific, clinically appropriate services, which include ongoing short term treatment, assessment, and reassessment before a decision can be made regarding whether patients will require further treatment as hospital inpatients or if they are able to be discharged from the hospital. Observation services are commonly ordered for patients who present to the emergency department and who then require a significant period of treatment or monitoring in order to make a decision concerning their admission or discharge.
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> . . .
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> In the majority of cases, the decision whether to discharge a patient from the hospital following resolution of the reason for the observation care or to admit the patient as an inpatient can be made in less than 48 hours, usually in less than 24 hours. In only rare and exceptional cases do reasonable and necessary outpatient observation services span more than 48 hours.

Policy Manual, Ch. 6, § 20.6(A). "The purpose of observation is to determine the need for further treatment or for inpatient admission." Id. at § 20.6(B).

10. Because patients on observation status are not yet "inpatients," the services they receive while on observation status are covered under Part B as outpatient services. Id. § 20.6(B) ("When a physician orders that a patient receive observation care, the patient's status is that of an outpatient."). This distinction is significant because coverage of

outpatient services under Part B is usually reimbursed at a lower rate than the same services billed as inpatient services under Part A. See Alexander v. Cochran, No. CV11-1703, 2017 WL 522944, at *1 (D. Conn. Feb. 8, 2017).

B. Overpayment to Plaintiff for Services Provided to N.V.

11. On March 15, 2011, at approximately 8:47 p.m., N.V., a 68-year-old woman, presented at the emergency department at Huntington Beach Hospital complaining of chest pains and some mild dizziness. (AR 231-232.) N.V. reported that the chest pain lasted for about 45 minutes, was non-radiating, occurring at a level of 7/10 at rest. (Id.) N.V.'s pain was not associated with shortness of breath or palpitation. (AR 234.) An EKG showed normal sinus rhythm and no acute ST elevations or changes, with a normal rate. (AR 233.) The chest x-ray was normal, and a CT scan of the head displayed no abnormalities. (Id.) A single troponin determination was normal. (Id.) Blood pressure on admission was elevated at 184/111 with a normal pulse, respiratory rate, and oxygen saturation. (AR 232.) The remainder of the physical examination was otherwise normal. (AR 233.) The emergency department report noted N.V.'s history of a prior stroke. (Id.)

12. In the emergency department, N.V. reported that her mother had suffered a myocardial infarction, but later denied that event to the cardiologist. (AR 232, 234.)

13. N.V. was given a half-inch strip of nitroglycerin paste that resolved her chest pain, and she continued to be observed in the emergency department after evaluation and stabilization without incident. (AR 233.) The emergency department physician diagnosed N.V. with chest pain and admitted her around 9:24 p.m. as an inpatient to the telemetry unit for diagnostic testing to rule out acute coronary syndrome. (AR 229, 233, 246.) N.V. was pain-free on discharge to the telemetry unit. (AR 233.)

14. Following her inpatient admission, N.V. had a consultation with a cardiologist around 5:36 p.m. on March 16, 2011. (AR 234-236.) N.V.'s condition remained stable in the hospital setting and her blood pressure improved to 121/77. (AR 234-236, 294.) The physician ruled out myocardial infarction and diagnosed accelerated hypertension, "currently improved," and atypical chest pain. (AR 236.) The assessment also included advanced

chronic obstructive pulmonary disease, peptic ulcer disease, and hypercholesterolemia, and noted N.V.'s history of cerebrovascular accident in 1998. (AR 234-236.)

15. N.V.'s blood pressure continued to improve in the hospital. (AR 294.) She was discharged in improved condition around 12:50 p.m. on March 17, 2011. (AR 267.)

16. On or about December 13, 2011, the Medicare contractor informed Plaintiff that following a post-payment review, the inpatient medical services provided during N.V.'s hospitalization at Huntington Beach Hospital were not medically reasonable and necessary and could have been provided as outpatient services in the hospital. (AR 211-216.)

17. The Medicare contractor found that Plaintiff received an overpayment of $5,380.30 in connection with N.V.'s hospitalization. (AR 206.)

18. Plaintiff unsuccessfully appealed the overpayment decision through multiple levels of administrative appeals. First, the Medicare contractor denied Plaintiff's request for redetermination on or about April 17, 2012. (AR 164-167.) The Medicare QIC denied Plaintiff's request for reconsideration on or about January 16, 2013. (AR 143-147.) Plaintiff appealed the overpayment decision for a third time to the ALJ, and included with its appeal a report from its expert, Dr. Hassan Alkhouli. (AR 107-142.)

C. <u>Proceedings Before the Administrative Law Judge</u>

19. On May 14, 2014, Medicare ALJ Arthur Liberty conducted a telephonic hearing on Plaintiff's administrative appeal. (AR 348-361.) Plaintiff was represented by counsel and proffered expert witness testimony from Dr. Marcia McCampbell. (AR 352.)

20. At the administrative hearing, the ALJ noted that he found it significant that N.V.'s "pain was completely resolved in 45 minutes with a single half-inch strip treatment of nitropaste" and invited Plaintiff to explain the need for inpatient admission in light of this, stating that "I kind of scratch my head about an [acute coronary syndrome] argument, but I'll certainly entertain it if that's where you're going." (AR 353-355.)

21. Plaintiff's expert witness, Dr. McCampbell, after hearing the ALJ's summary of the medical record, stated: "I think you have totally summarized it. And you're absolutely right. You know exactly what is going on with this patient." (AR 355.)

Dr. McCampbell testified that the resolution of the chest pain with the nitroglycerin likely indicated that N.V.'s pain was coronary in nature, and stated: "But let's say that you're happy with that result and you're not going to follow up anymore on the possible coronary issue, you still have this malignant hypertension and a history of stroke." (AR 356.)

22. The ALJ stated that he considered the report submitted by Dr. Alkhouli, who opined that "[t]he physician suspected that the patient had chest pain probably due to acute coronary syndrome (ACS) or anxiety, along with accelerated hypertension which is a life threatening condition and warrants immediate evaluation and management." (AR 71, 81, 111, 353.)

23. On May 22, 2014, the ALJ issued a written decision affirming the initial overpayment determination. (AR 70-77.) The ALJ considered, but found unpersuasive, Plaintiff's argument that N.V.'s inpatient admission was medically necessary due to malignant hypertension. (AR 76.) Plaintiff's expert witness had opined that inpatient admission was appropriate in order to conduct serial troponins and inhalation therapy, but the ALJ noted that neither of these treatments bore on a diagnosis of malignant hypertension. (Id.) The ALJ also concluded that Plaintiff did not identify the use of any of a number of accepted therapies for malignant hypertension, nor was the ALJ able to find any indication in the medical record of any therapies that were attempted. (Id.) The ALJ concluded that Plaintiff "failed to present relevant, credible evidence which tends to show that [N.V.'s inpatient admission was medically reasonable and necessary." (AR 77.)

24. Finally, the ALJ considered Sections 1870 and 1879 of the Social Security Act and determined that Plaintiff could not avoid liability for the overpayment. (AR 77.) The ALJ therefore found that the Medicare Overpayment Statute required Plaintiff to return to Medicare the overpayment for the inpatient services provided to N.V. (Id.)

25. Thereafter, Plaintiff sought review of the ALJ decision by the Medicare Appeals Council. (AR 49-59.) On August 26, 2016, the Council granted Plaintiff's request for escalation to seek review of the ALJ's decision in federal district court. (AR 16-17.)

26. On October 31, 2016, Plaintiff filed the instant complaint, seeking judicial review of the Secretary's final decision.

II. Conclusions of Law

A. Standard of Review

1. Where, as here, the Medicare Appeals Council did not review the ALJ's decision, the ALJ's opinion stands as the final decision of the Secretary. Judicial review of such final decisions lies with this Court pursuant to 42 U.S.C. § 1395ff(b)(1)(A), which incorporates 42 U.S.C. § 405(g) and allows for judicial review of a final decision of the Secretary with respect to Medicare benefits. "The findings of the Secretary as to any fact, if supported by substantial evidence, shall be conclusive." 42 U.S.C. § 405(g), incorporated into 42 U.S.C. § 1395ff(b).

2. Judicial review of the Secretary's factual findings must be based solely on the administrative record and is limited to determining whether: (1) the record contains substantial evidence to support the ALJ's findings; and (2) whether the correct legal standards were applied. 42 U.S.C. §§ 1395ff(b), 1395w-22(g)(5); Mayes v. Massanari, 276 F.3d 453, 458-59 (9th Cir. 2001) ("A court must affirm the findings of fact if they are supported by 'substantial evidence' and if the proper legal standard was applied.").

3. The substantial evidence standard is "extremely deferential" and a reviewing court must uphold the agency's findings "unless the evidence presented would compel a reasonable factfinder to reach a contrary result." Monjaraz-Munoz v. INS, 327 F.3d 892, 895 (9th Cir. 2003), amended by 339 F.3d 1012 (9th Cir. 2003); Singh-Kaur v. INS, 183 F.3d 1147, 1149-50 (9th Cir. 1999).

4. Under the substantial evidence standard, an agency's fact-based conclusion must be sustained unless no reasonable factfinder could have reached that conclusion based on the record. See INS v. Elias-Zacarias, 502 U.S. 478, 481 (1992). "Substantial evidence" is "more than a mere scintilla but less than a preponderance; it is such relevant evidence as a reasonable mind might accept as adequate to support a conclusion." NLRB v. Int'l Bhd. of Elec. Workers, Local 48, 345 F.3d 1049, 1054 (9th Cir. 2003).

5. In reviewing the administrative record, courts must review the record as a whole, taking into account both the evidence that supports the agency's findings and the evidence that detracts from them. See Universal Camera Corp. v. NLRB, 340 U.S. 474, 488 (1951); De Gorter v. Fed. Trade Comm'n, 244 F.2d 270, 272 (9th Cir. 1957) ("The enactment of the [APA] has placed upon the courts the responsibility of reviewing the entire record with the object of determining whether, on the whole, substantial evidence sustained the action of the administrative body."). The reviewing court may not substitute its judgment for that of the agency. See U.S. Postal Serv. v. Gregory, 534 U.S. 1, 6-7 (2001); Barnes v. U.S. Dep't of Transp., 655 F.3d 1124, 1132 (9th Cir. 2011).

B. Substantial Evidence Supports the Secretary's Decision

6. The burden of establishing the necessity and reasonableness of medical care rests squarely with the entity submitting the claim. 42 U.S.C. § 1395l(e); 42 C.F.R. § 424.5(a)(6); see also Int'l Rehab. Scis., Inc. v. Sebelius, 688 F.3d 994, 997 (9th Cir. 2012) ("The burden is on the claimant to show that the [billed medical service] is reasonable and necessary."); Garcia v. Sebelius, CV10-8820-PA, 2011 WL 5434426, *7 (C.D. Cal. Nov. 8, 2011) (noting that "a Medicare provider seeking payment must provide sufficient evidence to establish the medical reasonableness and necessity of the services billed to Medicare"). CMS has explained that "a treating physician controls the documentation supporting his or her opinion as to appropriate treatment." See HCFA Ruling 93-1 (May 18, 1993). In creating the medical assessment, medical history, and discharge notes, "the physician has ample opportunity to explain in detail why the course of treatment was appropriate" for the patient's condition. Id. In addition, "the physician has the opportunity to describe and explain aspects of the patient's medical history that may not otherwise be apparent. Thus, the physician is responsible for ensuring that the patient's record includes complete medical information, and this information is the basis for determining the appropriateness of the prescribed treatment." Id. Plaintiff has failed to meet this burden.

7. Here, the administrative record contained considerable evidence that the challenged inpatient admission was not medically necessary, including but not limited to the

resolution of N.V.'s chest pain with a single half-inch strip treatment of nitropaste while she was under management and observation in the emergency department, N.V.'s pain-free status on discharge to telemetry, and the absence of any documentation or rationale in the medical record indicating that N.V.'s medical condition at the time of admission warranted an inpatient level of care rather than an outpatient level of care. (AR 71-72.)

8. At the administrative hearing, the ALJ found it significant that N.V.'s "pain was completely resolved in 45 minutes with a single half-inch strip treatment of nitropaste" and gave Plaintiff an opportunity to explain the need for inpatient admission in light of this, stating that "I kind of scratch my head about an ACS argument, but I'll certainly entertain it if that's where you're going." (AR 353-355.)

9. Plaintiff's expert witness, Dr. McCampbell, after hearing the ALJ's summary of the medical record, stated: "I think you have totally summarized it. And you're absolutely right. You know exactly what is going on with this patient." (AR 355.) Dr. McCampbell noted that the resolution of the chest pain with the nitroglycerin likely indicated that N.V.'s pain was coronary in nature. (AR 356.) According to Dr. McCampbell, even if one were to "take the coronary issue off the table" as supporting the inpatient hospitalization, the record would nevertheless support N.V.'s inpatient admission. (Id.) Specifically, Dr. McCampbell testified that N.V.'s inpatient admission was medically necessary based on the purported need to evaluate N.V. for accelerated or malignant hypertension. (AR 356.)

10. The ALJ asked Plaintiff to identify the evidence in the record that would support the Hospital's proffered reasoning that inpatient admission was necessary on account of the possibility of malignant hypertension with a history of cerebrovascular accident:

> Judge Liberty: But you're also making the argument that the accelerated malignant hypertension with the history of CVA mandated or certainly justified an inpatient admission. Where do

we find in the documentation that this was the consideration or a consideration? And is there evidence that she was aggressively treated specifically for the accelerated malignant hypertension?

Dr. McCampbell: Well, in the H&P it's noted a couple of times about her high blood pressure. It talks about her having -- noted her blood pressure was high at 200 over 100 at home. And then talks about in the ED, emergency room, it was 184 over 111. And they did treat her with anti-hypertensive medications. She was prescribed an ACE inhibitor and also monitored to make sure that the blood pressure did indeed respond to that medication.

(AR 357.) Although Dr. McCampbell suggested that inpatient admission was appropriate for serial troponins and inhalation therapy, the ALJ found that neither of these treatments bore on a diagnosis of malignant hypertension. (AR 76-77.)

11. As the ALJ noted, "the decision to admit a patient to inpatient service or to outpatient/observation service is made by consideration of only a limited data set, and that data set is comprised only of the information which is known to the admitting physician one second before he or she decides to admit the patient." (AR 76.)

12. The medical record belies Plaintiff's assertion that "accelerated or malignant hypertension should be considered and was considered by the ED physician and admitting physician." (AR 355.) The emergency department report did not contain any reference to malignant hypertension or any treatment for the condition; rather, the emergency department and admitting physicians expressly predicated their decision to admit N.V. on the need to

rule out acute coronary syndrome. (AR 233.) Specifically, the emergency department physician noted on his differential diagnosis: "The differential diagnosis includes, but not limited to acute coronary syndrome, gastritis, peptic ulcer disease, myocardial infarction, pneumonia, pneumothorax, aortic dissection." (Id.) The emergency department physician noted that he spoke to Dr. Chan, the admitting physician, "and we will admit the patient to telemetry to rule out [myocardial infarction]" and also reported a diagnosis of "[c]hest pain, rule out acute coronary syndrome." (Id.)

13. N.V.'s admission orders consisted of admission to the telemetry unit, with activity level as tolerated. (AR 246.) The admission orders likewise do not contain any reference to or evidence of treatment directed at malignant hypertension, which Dr. Alkhouli had described as a "life threatening condition" that "warrants immediate evaluation and management." (AR 111.) The ALJ found that the medical records offered no support for Plaintiff's post-hoc rationalization that N.V.'s inpatient admission was necessary to treat possible malignant hypertension. (AR 76-77.)

14. There is insufficient evidence in the record that the admitting physician found the signs and symptoms exhibited by N.V. to be severe enough to require inpatient admission. See Policy Manual, Ch. 1, § 10. Nor did Plaintiff identify "any additional necessary medical services that were not available in observation status that became available through an inpatient admission." See In re Providence Health Ctr., MAC No. M-12-809, 2012 WL 3637361, at *5 (June 29, 2012) (upholding ALJ's decision that inpatient hospitalization was not medically necessary for 67-year-old beneficiary with a history of cardiac problems who presented with chest pains where, at the time of admission, the beneficiary's vital signs were within normal limits, he was not complaining of chest pain, cardiac enzymes did not show any acute cardiac injury, and an EKG did not show acute abnormalities).

15. Moreover and in any event, even had the admitting physician documented risks to N.V.'s health and safety, that opinion alone would not be sufficient to justify inpatient care if it was not supported by other evidence in the record. As CMS has

explained, "no presumptive weight" should be assigned to a treating physician's medical opinion in determining the medical necessity of Part A inpatient services. See HCFA Ruling 93-1 (May 18, 1993). Instead, CMS provides that "[a] physician's opinion will be evaluated in the context of the evidence in the complete administrative record. Even though a physician's certification is required for payment, coverage decisions are not made based solely on this certification; they are made based on objective medical information about the patient's condition and the services received." Id. In this context, a treating physician's medical opinions are entitled to no additional weight. See Maxmed Healthcare, Inc. v. Burwell, 152 F. Supp. 3d 619, 639 (W.D. Tex. 2016) ("There is no presumption that a treating physician's determination is subject to any greater weight in the Medicare context."), aff'd sub nom. Maxmed Healthcare, Inc. v. Price, 860 F.3d 335 (5th Cir. 2017); Hospital Serv. Dist. No. 1 of Parish of Lafourche v. Thompson, 343 F. Supp. 2d 518, 523 (E.D. La. 2004) (noting that "there is no jurisprudential authority mandating the import of the treating physician rule in Medicare cases.").

16. Equally unavailing is Plaintiff's attack on the ALJ's finding that Dr. McCampbell "failed to identify the use of any of a number of accepted therapies for malignant hypertension, and my perusal of the record does not indicate that any were tried." (AR 27.) The ALJ's review of the record to determine whether the post-admission management of N.V. included any therapies for malignant hypertension does not constitute a retrospective review. Rather, the ALJ properly and logically reviewed the record for evidence to support Plaintiff's contention that the possible malignant hypertension warranted inpatient admission – indeed, it stands to reason that ALJ expected to find in the admission plan and medical records treatments directed at managing this condition.

17. Even were the ALJ's review considered retrospective, an ALJ is not prohibited from considering evidence of a patient's medical condition after an admission decision has been made. See In re Texas Health Arlington Mem. Hosp., MAC No. M-11-1345, 2013 WL 9555028, at *7 (Sept. 11, 2013) ("[I]t is appropriate to consider all of the medical evidence, including evidence that became available after admissions. But, more importantly, the

[Policy Manual], Chapter 1, Section 10 does not explicitly state that a reviewer is prohibited from considering post admission information. . . . The appellant seems to mischaracterize and misinterpret the [Policy Manual] language.").

18. In fact, Medicare's inpatient admission guidelines themselves require that medical providers consider various factors, including the severity of the signs and symptoms exhibited by the patient, the medical predictability of something adverse happening to the patient, and the types of facilities and resources available to inpatients and outpatients. See Policy Manual, Ch. 1, § 10. According to the Medicare Appeals Council, these guidelines "contemplate that the beneficiary's condition may change following admission, which may necessitate a change in the beneficiary's status from that of an inpatient to an outpatient, or vice versa. As such, consideration of the beneficiary's condition during the course of the hospital stay would be relevant." In re Providence Health Ctr., Waco, MAC No. M-11-2719, 2013 WL 8744199, at *7 (June 20, 2013); see also In re Integris Baptist Med., MAC No. M-11-1418, 2013 WL 8633102, at *6 (June 11, 2013) (holding that "the ALJ's consideration of the beneficiary's condition during the hospital course is relevant in assessing the factors listed in the coverage guidelines"); In re Texas Health Arlington Mem. Hosp., 2013 WL 9555028, at *7 (explaining that "it is appropriate [for an ALJ] to consider all of the medical evidence, including evidence that became available after admission").

19. Consistent with those guidelines, the ALJ properly considered N.V.'s medical condition from the time of her arrival to the time of discharge in assessing whether the decision to admit her as an inpatient satisfied Medicare's inpatient coverage guidelines. (AR 70-77.)

20. Plaintiff also argued that the admitting physician had documented that N.V. met Milliman and InterQual criteria for inpatient admissions. (AR 357.) Plaintiff did not, however, explain how these criteria were relevant to or otherwise informed the admitting physician's decision to admit N.V. as an inpatient. Specifically, on the Milliman guideline form, "[i]nability to perform evaluation of a patient with possible ACS (e.g., chest pain pattern, angina equivalent syndrome, or other finding suggesting ACS) in emergency

department" and "[o]ngoing ischemic pain" are circled. (AR 178.) Contrary to what is indicated on this form, the emergency department report noted that N.V. was "currently chest pain free" at the time of admission. (AR 233.)

21. The ALJ properly found that the Milliman and InterQual criteria are insufficient justification for an inpatient admission, as they are not developed by CMS and are not binding on CMS for coverage purposes. (AR 76, 166.) See In re Providence Health Ctr., 2012 WL 3637361, at *8 n.1 (noting that "[t]he InterQual criteria are not developed by CMS and are not binding on CMS for coverage purposes" and ALJs and the Council "are not bound to follow them"); In re Providence Health Ctr., MAC No. 11-1217, 2012 WL 3780378, at *4 n.4 (July 13, 2012) ("Milliman guidelines are not developed by CMS and are not binding on CMS for coverage purposes" and "ALJs and the Council are not bound to follow them").

22. Because substantial evidence in the administrative record supports the Secretary's conclusion that Plaintiff did not meet its burden of establishing the medical reasonableness and necessity of the inpatient services provided to N.V., the Secretary properly found that Plaintiff had received an overpayment of $5,380.30 in connection with N.V.'s hospitalization.

B. Plaintiff's Effort to Obtain a Waiver of Overpayment

23. Following his determination that N.V.'s inpatient services were not covered by Medicare because they were not medically reasonable and necessary, the ALJ correctly stated that sections 1870 and 1879 of the Social Security Act "must be considered." (AR 77.)

24. Section 1879 of the Act limits a provider's liability for services that are not medically reasonable and necessary when it has been determined that the provider "did not know, and could not reasonably have been expected to know, that payment would not be made for such services." 42 U.S.C. § 1395pp(a). A provider is deemed to have actual or constructive knowledge of non-coverage based upon "[i]ts receipt of CMS notices, including manual issuances, bulletins, or other written guides or directives from [a Medicare

contractor]. . . " and "[i]ts knowledge of what are considered acceptable standards of practice by the local medical community." 42 C.F.R. §§ 411.406(e)(1) & (e)(3).

25. The ALJ noted in his decision that "[p]roviders, practitioners, and other suppliers are always responsible for knowing locally acceptable standards of practice; their local licensure is premised on the assumption that they have such knowledge. Medicare payment to providers, practitioners, or other suppliers is premised on the presumption that they have such knowledge, as evidenced by their licensure." (AR 74-75.) Despite this statement, it is unclear from the ALJ's decision if this recitation in the "Principles of Law" section of the decision constituted the ALJ's determination that Plaintiff was not entitled to a waiver under sections 1870 and 1879. Specifically, the "Analysis" section of the decision does not appear to link the standard for a waiver of overpayment to the facts applicable to this claim. Instead, after acknowledging that he must consider sections 1870 and 1879, the ALJ's decision states only that "[t]here is no Advanced Beneficiary Notice in the record, so the beneficiary is not responsible for the cost of the services not covered by Medicare." (AR 77.) It is not clear what N.V.'s potential liability has to do with whether Plaintiff knew, or reasonably could have expected to know, that the inpatient services provided to N.V. would not be covered by Medicare for purposes of a section 1879 waiver.

26. Because the ALJ's decision does not clearly apply the facts of N.V.'s inpatient admission to the waiver of overpayment standard, the Court cannot determine, on this record, if the ALJ used the proper legal standard. See Mayes, 276 F.3d 453, 458-59 (9th Cir. 2001) ("A court must affirm the findings of fact if they are supported by 'substantial evidence' and if the proper legal standard was applied.").

27. "When there is a need to supplement the record to explain agency action, the preferred procedure is to remand to the agency for its amplification." Public Power Council v. Johnson, 674 F.2d 791, 794 (9th Cir. 1982). The Court therefore remands this action to the ALJ for further consideration of Plaintiff's request for a waiver of overpayment under sections 1870 and 1879. In remanding the action, the Court takes no position on the decision the ALJ should make on this issue, or whether the Administrative Record can or

should be expanded to encompass the issues raised in U.S. ex rel. Berntsen v. Prime Healthcare Services, Case No. 11-08214 PJW. The Court in no way limits the ALJ's discretion on these matters.

28. In making these Findings of Fact and Conclusions of Law, the Court does not find that Plaintiff shall be considered, at this stage, a prevailing party.

Conclusion

The Secretary's final decision in this matter that the inpatient care provided to N.V. was not medically reasonable and necessary is supported by substantial evidence, is not arbitrary or capricious, and is without legal error. The Court therefore upholds the Secretary's final decision on this issue. The Court cannot, however, determine if the ALJ considered the proper standard for Plaintiff's claim under sections 1870 and 1879 for a waiver of overpayment. The Court therefore remands this action to the ALJ for consideration of Plaintiff's request for a waiver of overpayment under sections 1870 and 1879. The Clerk is ordered to administratively close this action without prejudice to the right of either party to move, through a properly noticed motion, to have this action re-opened upon the completion of the additional administrative proceedings.

IT IS SO ORDERED.

DATED: December 13, 2017

Percy Anderson
UNITED STATES DISTRICT JUDGE