IN THE UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF TEXAS HOUSTON DIVISION

Plaintiff,

\$
VS.

Plaintiff,

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CIVIL ACTION NO. H-14-578

SYLVIA M. BURWELL, SECRETARY, \$
DEPARTMENT OF HEALTH AND \$

DEPARTMENT OF HEALTH AND \$ HUMAN SERVICES, \$

CLINIC RESOURCES MANAGEMENT,

Defendant.

MEMORANDUM AND OPINION

This case illustrates the complications that can arise when a medical-services provider's records do not meet Medicare's requirements for payment. The plaintiff, Clinic Resources Management ("Clinic Resources" or the "Clinic"), appeals the Secretary of Health and Human Services's decision that it submitted payment claims to Medicare that it knew or should have known were for services Medicare did not cover. The claims total over \$6 million. Medicare initially paid them but concluded in a postpayment audit that the documentation was inadequate to show that the services were medically reasonable and necessary. The Secretary's final decision is the Medicare Appeals Council's opinion, which found that Clinic Resources did not meet its burden of showing that the services were covered.

The parties agree that the services were provided and, if properly documented so as to show coverage, would have been paid. The issue is whether the documentation met the Clinic's burden of showing coverage. That issue is presented in cross-motions for summary judgment based on the administrative record. (Docket Entry Nos. 16, 17, 18, 24). The court held a hearing on January 23,

2015, at which counsel presented oral argument on the cross-motions. (Docket Entry No. 27).

Based on the pleadings, the motions and responses, the record, the arguments of counsel, the administrative record, and the applicable law, the court grants the Secretary's motion for summary judgment and denies Clinic Resources's cross-motion. Final judgment is separately entered.

The reasons for this ruling are explained below.

I. Background

Clinic Resources Management offers partial hospitalization program ("PHP") services. PHPs provide intensive outpatient psychiatric services, including individual or group psychotherapy, occupational therapy, family-counseling services, activity therapy, and patient education programs. PHP services are more rigorous and structured than standard outpatient psychotherapy, but less structured than the 24-hour psychiatric care provided in an inpatient setting.

Medicare Part B covers PHP services if the requirements set out in 42 U.S.C. § 1395x(ff) and its implementing regulations, 42 C.F.R. §§ 410.43 and 424.24(e), are met. The general coverage requirements are that the services be: (1) reasonable and necessary for the diagnosis or active treatment of the individual's condition; and (2) reasonably expected to improve or maintain the individual's condition and functional level and to prevent relapse or hospitalization.

The Secretary may issue national coverage determinations ("NCDs") binding throughout the Medicare system. The Center for Medicare and Medicaid Services ("CMS") administers the Medicare program and issues regulatory guidance. CMS hires private insurance carriers as contractors for claims administration, and these carriers may also issue local coverage determinations that apply on a local or carrier basis. 42 U.S.C. § 1395u(a). Local contractor TrailBlazer Health Enterprises, LLC ("TrailBlazer") issued the local coverage determination at issue

in this case.

Local coverage determination L1937 provides:

The initial psychiatric evaluation with medical history and physical examination must be performed and placed in the chart within 24 hours of admission to establish medical necessity for partial hospitalization services.

. . . .

A team approach may be used in developing the initial psychiatric evaluation, but the physician (M.D./D.O.) must document the mental status examination, physical examination, formulation, diagnosis, treatment plan, and certification.

The provider is responsible for maintaining and submitting adequate information to substantiate medical necessity and entitlement to payment. *See* 42 U.S.C. § 13951(e); 42 C.F.R. § 424.5(a)(6); *Friedman v. Sec'y of Dep't of Health and Human Servs.*, 819 F.2d 42, 45 (2d Cir. 1987). Contractors, such as Trailblazer, are responsible for initially reviewing claims and determining whether they are covered under Medicare. The claims may also be subjected to audit, and reimbursement may be demanded if the audit reveals that the coverage requirements were not met.

Clinic Resources received payments from Medicare for PHP services from January 1, 2004 to January 31, 2006. TrailBlazer initially paid the claims on Medicare's behalf. In September 2006, TriCenturion, another Medicare contractor, demanded that Clinic Resources provide documentation showing Medicare coverage for the claims. In a post-payment review of Clinic Resources's records, Health Integrity, a Medicare Zone Program Integrity Contractor, identified an overpayment of \$6,104,687 based on a random sample of the claims Clinic Resources had submitted. The sample consists of the files of 30 randomly selected beneficiaries out of 335 beneficiaries who had received Clinic PHP services that Medicare had paid for. R. 1241–43. The files included all the PHP

admissions during the period at issue.

Health Integrity found that the Clinic's claims for all but one of the sampled beneficiary files lacked information showing that the services were covered and payment was justified. Health Integrity denied the claims in a letter sent to Clinic Resources in May 2010. TrailBlazer sent Clinic Resources another letter in June 2010 stating its finding that Medicare had overpaid. R. 1245–51. Clinic Resources asked for a redetermination. TrailBlazer affirmed the finding in August 2011. R. 1257–1453; *see* 42 C.F.R. §§ 405.940, 405.942(a). Clinic Resources then asked for reconsideration from Maximus Federal Services, a Medicare-qualified independent contractor. *See* 42 C.F.R. §§ 405.960, 405.962(a). In December 2011, Maximus also affirmed the overpayment finding. R. 1088–1132.

Clinic Resources appealed to an administrative law judge in February 2012. R. 1041–72. *See* 42 C.F.R. §§ 405.1002(a)(1), 405.1006(b). The administrative law judge found that the PHP services were medically reasonable and necessary for the beneficiaries and were covered by Medicare. R. 332–488. CMS appealed to the Medicare Appeals Council in October 2013. *See* 42 C.F.R. § 1110(b). CMS's memorandum referring the appeal to the Council asserted that the record failed to show that the Clinic met two requirements imposed under local coverage determination L1937 for compensation for covered services: (1) that physicians take a medical history, do a physical examination, and perform a psychiatric evaluation, and document them; and (2) that the documents be placed in each patient file within 24 hours of PHP admission.

The Council found that the administrative law judge's decision was not supported by a preponderance of evidence. Instead, according to the Council, for all but one of the beneficiaries in the sample, Clinic Resources had failed to include documents showing that a physician performed

and documented a history, physical examination, and psychiatric evaluation, and that the documents were placed in the patients' files within 24 hours after admission. The Council found that "[n]one of the psychiatric evaluation forms has a date entered next to the physician's signature." R. 15. The Council also found no evidence in all but one of the sampled files showing that a doctor, rather than a nurse or a physician's assistant, had performed and documented the history and physical examination. R. 16–19. The Council concluded that Clinic Resources knew or should have known that the services were subject to these documentation requirements for reimbursement and would not be covered if those requirements were not met. In this lawsuit, Clinic Resources argues that the Council's decision is not supported by substantial evidence and that the Council applied an incorrect legal standard. Clinic Resources's arguments, and the Secretary's responses, are analyzed below.

II. The Applicable Legal Standards

A. Summary Judgment

"Summary judgment is required when 'the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." *Trent v. Wade*, 776 F.3d 368, 376 (5th Cir. 2015) (quoting FED. R. CIV. P. 56(a)). "A genuine dispute of material fact exists when the 'evidence is such that a reasonable jury could return a verdict for the nonmoving party." *Nola Spice Designs, LLC v. Haydel Enterprises, Inc.*, — F.3d —, 2015 WL 1600689, at *2 (5th Cir. Apr. 8, 2015) (quoting *Anderson v. Liberty Lobby*, 477 U.S. 242, 248 (1986)). "The moving party 'bears the initial responsibility of informing the district court of the basis for its motion, and identifying those portions of [the record] which it believes demonstrate the absence of a genuine issue of material fact." *Id.* at *2 (quoting *EEOC v. LHC Grp., Inc.*, 773 F.3d 688, 694 (5th Cir. 2014)); *see also Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986).

"Where the non-movant bears the burden of proof at trial, the movant may merely point to the absence of evidence and thereby shift to the non-movant the burden of demonstrating by competent summary judgment proof that there is an issue of material fact warranting trial." *Id.* (quotations omitted); *see also Celotex*, 477 U.S. at 325. Although the party moving for summary judgment must demonstrate the absence of a genuine issue of material fact, it does not need to negate the elements of the nonmovant's case. *Boudreaux v. Swift Transp. Co.*, 402 F.3d 536, 540 (5th Cir. 2005). "A fact is 'material' if its resolution in favor of one party might affect the outcome of the lawsuit under governing law." *Sossamon v. Lone Star State of Texas*, 560 F.3d 316, 326 (5th Cir. 2009) (quotation omitted). "If the moving party fails to meet [its] initial burden, the motion [for summary judgment] must be denied, regardless of the nonmovant's response." *United States v.* \$92,203.00 in U.S. Currency, 537 F.3d 504, 507 (5th Cir. 2008) (quoting *Little v. Liquid Air Corp.*, 37 F.3d 1069, 1075 (5th Cir. 1994) (en banc)).

"Once the moving party [meets its initial burden], the non-moving party must 'go beyond the pleadings and by her own affidavits, or by the depositions, answers to interrogatories, and admissions on file, designate specific facts showing that there is a genuine issue for trial." *Nola Spice*, 2015 WL 1600689, at *2 (quoting *EEOC*, 773 F.3d at 694). The nonmovant must identify specific evidence in the record and articulate how that evidence supports that party's claim. *Baranowski v. Hart*, 486 F.3d 112, 119 (5th Cir. 2007). "This burden will not be satisfied by 'some metaphysical doubt as to the material facts, by conclusory allegations, by unsubstantiated assertions, or by only a scintilla of evidence." *Boudreaux*, 402 F.3d at 540 (quoting *Little*, 37 F.3d at 1075). In deciding a summary judgment motion, the court draws all reasonable inferences in the light most favorable to the nonmoving party. *Connors v. Graves*, 538 F.3d 373, 376 (5th Cir. 2008); *see also*

Nola Spice, 2015 WL 1600689, at *2.

When the parties cross-move for summary judgment, the court must review "each motion independently, viewing the evidence and inferences in the light most favorable to the nonmoving party." *Mid-Continent Cas. Co. v. Bay Rock Operating Co.*, 614 F.3d 105, 110 (5th Cir. 2010) (internal quotation marks and alteration omitted). Nevertheless, "[i]f a party fails to properly support an assertion of fact or fails to properly address another party's assertion of fact as required by Rule 56(c), the court may . . . consider the fact undisputed for purposes of the motion." FED. R. CIV. P. 56(e)(2).

B. The Legal Standard for Reviewing the Council's Decision

The "sole avenue for judicial review for 'all claims arising under' the Medicare Act" is 42 U.S.C. § 405(g). *Heckler v. Ringer*, 466 U.S. 602, 615 (1984). A court has jurisdiction under 42 U.S.C. § 1395ff(b), which allows providers to seek judicial review of the Secretary's final decision. The court's review is limited to whether the Council's decision is supported by substantial evidence and correctly applies the law. *Morris v. Shalala*, 207 F.3d 744, 745 (5th Cir. 2000) (citing *Anthony v. Sullivan*, 954 F.2d 289, 292 (5th Cir. 1992)). "Substantial evidence is 'more than a mere scintilla. It means such relevant evidence as a reasonable mind might accept as adequate to support a conclusion." *Girling Health Care, Inc. v. Shalala*, 85 F.3d 211, 215 (5th Cir. 1996) (footnotes omitted) (quoting *Richardson v. Perales*, 402 U.S. 389, 401 (1971)); *see also Harris v. Apfel*, 209 F.3d 413, 417 (substantial evidence "is more than a mere scintilla and less than a preponderance"). "The possibility of drawing two inconsistent conclusions from the evidence does not prevent an agency's findings from being supported by substantial evidence." *Corrosion Proof Fittings v. EPS*, 947 F.2d 1201, 1213 (5th Cir. 1991) (quoting *Consolo v. Fed. Mar. Comm'n*, 383 U.S. 607, 620

(1966)). "A finding of no substantial evidence is appropriate only if no credible evidentiary choices or medical findings support the decision." *Harris*, 209 F.3d at 417. In applying the substantial evidence standard, the district court must "scrutinize the record to determine whether such evidence is present." The court reviews the record as a whole but "may not reweigh the evidence, try the issues de novo, or substitute [its] judgment for that of the Secretary." *Greenspan v. Shalala*, 38 F.3d 232, 236 (5th Cir. 1994). "If supported by substantial evidence, the decision of the Secretary is conclusive and must be affirmed." *Sid Peterson Mem'l Hosp. v. Thompson*, 274 F.3d 301, 311 (5th Cir. 2001) (quoting *Richardson*, 402 U.S. at 390).

The court applies *de novo* review to the Secretary's determinations of questions of law, while deferring "to the Secretary's interpretation [of the agency's regulation] unless an alternative reading is compelled by the regulation's plain language or by other indications of the Secretary's intent at the time of the regulation's promulgation." *Elgin Nursing and Rehab. Ctr. v. U.S. Dep't of Health and Human Servs.*, 718 F.3d 488, 491 (5th Cir. 2013) (alterations in original) (quoting *Thomas Jefferson Univ. v. Shalala*, 512 U.S. 504, 512 (1994)); *Alwan v. Ashcroft*, 388 F.3d 507, 510 (5th Cir. 2004). Deference is not warranted when an agency is interpreting its own interpretation of a regulation. *Elgin Nursing*, 718 F.3d at 493.

These standards of review are applied to the administrative record the parties submitted.

III. Analysis

Medicare providers, such as the Clinic, have the burden of maintaining and producing the records required to support their payment claims. 42 U.S.C. § 13951; 42 C.F.R. § 424.5(a)(6). The Council found that Clinic Resources failed to meet this burden for all but one of the claims examined in the sample of 30 patients out of 335 patients the Clinic treated during the relevant period. Clinic

Resources argues that the Council based its decision on requirements not properly considered and that the documents submitted complied with the requirements that are properly considered.

A. The Scope of the Council's Review

The Council found that the documents Clinic Resources submitted for payment did not meet the local coverage determination L1937 requirements because the documents did not show that: (1) a history and physical examination, as well as a psychiatric evaluation, were completed for each patient and placed in the patient's file within 24 hours of admission; or that (2) a physician (meaning a person with an M.D. or a D.O. degree) had performed and documented those examinations and evaluations. Although the Council and the administrative law judge are not bound by local coverage determinations, both give substantial deference to them. 42 C.F.R. § 405.1062.

Clinic Resources argues that the Council should not have examined whether a physician, as opposed to a nurse or physician's assistant, performed and documented the evaluations, because CMS did not raise that issue in its referral memorandum appealing the administrative law judge's decision.

When CMS refers an administrative law judge's decision to Council for review, the Council is limited to the issues CMS raises in its referral. *See* 42 C.F.R. § 405.1110(c)(2). CMS's referral memorandum asserted that Clinic Resources's patient records did not comply with local coverage determination L1937's requirement that the initial history, examination, and evaluation be timely performed and documented by a physician. The referral memorandum stated as follows:

PHP services must be furnished "under the supervision of a physician."... For almost [all] dates of admission, documentation in the record does not show that an initial evaluation and history and physical were performed and placed in the record within 24 hours of admission, as required by the applicable local medical review policy

(LMRP) and local coverage determination (LCD) L1937.

R. 43–44.

CMS's referral memorandum requesting Council review argued that the patient "admission criteria were not met" because "documentation did not support that the services were performed by qualified individuals, for instance because services were furnished by interns or temporary licensed personnel without the requisite level of supervision." R. 52–53. The referral memorandum stated that for Clinic Resources to show "that services were furnished 'under the supervision of a physician pursuant to an individualized, written plan of treatment established . . . by a physician' who is knowledgeable about the patient and certifies the need for partial hospitalization, the record *must* contain evidence that the physician examined the patient, certified the need for partial hospitalization, and developed the written plan of treatment at the outset." R. 53–54 (omission and emphasis in original).

In the referral memorandum, CMS argued that "this documentation is critical because the initial evaluation serves as the cornerstone for admission, the plan of treatment, certification of the patient's need for services, and all subsequent treatment." R. 44. CMS argued that the record-keeping requirements set out in the local coverage determination that the "medical history and physical examination were performed and placed in the chart within 24 hours of admission" were "essential to show the medical necessity for partial hospitalization services." R. 54. CMS asserted that requiring this documentation for each beneficiary's visit to a PHP showed that a physician took a medical history, performed the physical examination, certified the need for partial hospitalization, and developed the written treatment plan, at the outset. CMS argued that the records the Clinic submitted did not show that a "physician evaluated or treated the patient upon admission," did not

show that the PHP services were furnished under "the supervision of a physician pursuant to an individualized, written plan of treatment established . . . by a physician," and therefore did not show that the services were medically reasonable and necessary to meet the conditions for Medicare payment. R. 54.

CMS's referral memorandum to the Council did question whether a physician or a physician's assistant had performed the intake histories, examinations, and evaluations, and whether the documents had been timely completed by a physician and placed in the patient files. The Council did not err in considering these issues.

B. Whether the Evaluations and Examinations Complied with Local Coverage Determination L1937

The Council considered a random sample of 30 Medicare beneficiary files with reimbursement claims for 60 PHP admissions. For some of the visits, required documents are missing. The documents included in the submitted files include some that are typed, either all or in part, and some that are mostly handwritten. Most of the documents are signed, but not all. The Council found that some of the signatures did not show that a physician performed and documented the examinations and evaluations. Some of the documents are dated, either handwritten or in a typewritten header, and other documents contain no date. R. 15, 17 n.17. The issues raised in the referral memorandum and the Council's decision, and addressed by the parties, as well as the records, support grouping the patient files into the following categories:

- (1) fully supported files;
- (2) files that are missing required documents;
- (3) files with signed and dated documents showing the medical histories and physical examinations;

- (4) files with unsigned psychiatric evaluation documents;
- (5) files with psychiatric evaluation documents that are signed but not dated;
- (6) files with psychiatric evaluation documents that are signed and have dates in the headers; and
- (7) files with undated psychiatric evaluation documents but with information making it difficult or impossible to infer when the evaluations were performed and documented.

 Each category is examined below.

1. The Fully Supported Files

The Council found that Clinic Resources met its burden of showing that the services provided to a Medicare beneficiary referred to as E.M.1 from December 9, 2004 to May 27, 2005 were medically necessary and that Clinic Resources was entitled to payment for them. R. 13–14. E.M.1's psychiatric evaluation document includes a date on the second and third pages. The document includes language stating that it was dictated on December 8, 2004 and transcribed on December 9. The document is signed by Dr. H.D. There is no date next to the physician's signature. R. 15045–47.

E.M.1's file also contains a medical history and physical examination document dated December 6, 2004 and signed by Dr. H.D. R. 15039–41. The Council found that these documents met Clinic Resources's burden of proving that a medical history and physical examination and a psychiatric evaluation, were performed and documented by a physician and placed in E.M.1's file within 24 hours of admission. R. 13. The court agrees. The record shows that the Council applied the proper legal standard and that substantial evidence supports the Council's decision that the documents seeking reimbursement for the medical services provided to E.M.1 for the December 9,

2004 admission complied with the Medicare coverage requirements.

2. The Files That Are Missing Required Documentation

Clinic Resources admits that for "12 or 13 admissions," the documents it provided were deficient and did not comply with the local coverage determination requirements. (Docket Entry No. 28, Transcript at p. 6). The files for the following beneficiaries and visits do not contain the required medical history and physical examination documents:

- F.A., for admissions on January 19, 2004 and May 10, 2004;
- E.B., for an August 26, 2004 admission;
- M.D., for admissions on May 24, 2004 and September 13, 2004;
- S.H., for admissions on May 10, 2004 and September 7, 2004;
- J.H., for a June 17, 2004 admission;
- G.H., for a February 2, 2004 admission;
- I.K., for a December 14, 2005 admission;
- E.M.2, for a January 2, 2004 admission; and
- L.M., for a January 27, 2006 admission.

R. 17.

In its response to CMS's motion for summary judgment, Clinic Resources also admits that the necessary history and physical examination documents are not present for beneficiary M.C. for a December 29, 2003 admission, and for beneficiary C.H. for a June 14, 2005 admission.¹ (Docket Entry No. 24 at p. 7 n.9). The file for C.H.'s June 14, 2005 admission does not contain a document

 $^{^{1}}$ Clinic Resources's response states that there is not an appropriate history and physical examination document for C.H.'s "6/14/2004" admission. (Docket Entry No. 24, p. 7 n.9). The only admission date for C.H. is June 14, 2005.

showing the required treatment plan.

Local coverage determination L1937 requires that a history and physical examination be conducted by a physician and placed in the patient's file no later than 24 hours after the patient's admission. L1937 also requires a physician to create a treatment plan at the outset. The court finds that the Council's decision that Clinic Resources did not show compliance with local coverage determination L1937 is supported by substantial evidence as to these beneficiaries for the admissions at issue and that the Council applied the proper legal standards in reaching that conclusion.

3. The Examination Documents That Are Signed and Dated

The Council found that for the "majority" of the files with medical history and physical examination documents signed by a physician, the documents did not show that examinations were performed within 24 hours of admission or that they were performed by a physician. R. 16. For the following beneficiaries and admissions, the Council found that the files contained history and physical examination documents that a physician completed and signed, but that had dates more than 24 hours after the beneficiary was admitted to the PHP:

- F.A., for an August 30, 2004 admission (R. 2128–30);
- M.C., for an April 26, 2004 admission (R. 3061–63);
- M.D., for a February 9, 2004 admission (R. 5799, 5815–16);
- S.H., for a January 26, 2004 admission (R. 9929–31);
- P.K., for a January 13, 2004 admission (R. 12185–87);
- E.M.1, for a September 7, 2005 admission (R. 1401–03);
- L.N., for a March 22, 2005 admission (R. 16829–31); and
- D.S., for a January 19, 2004 admission (R. 17100–02).

R. 17 at n.17.

Clinic Resources has not explained or pointed to record evidence showing that the Council erred in finding that these histories and examinations were performed and documented after the regulatory deadline. Substantial evidence and the applicable law support the Council's finding that these documents did not meet the requirements for reimbursement.

The Council also found that for the following beneficiaries and admissions, the history and examination documents were dated less than 24 hours after the patient's admission, but they did not show that a physician, rather than a physician's assistant, had conducted and documented the examinations:

- R.B., for an April 21, 2004admission (R. 2770–72);
- R.D., for a November 13, 2005admission (R. 4105–07);
- T.E., for a November 22, 2004admission (R. 6170–72);
- I.K., for a December 22, 2004admission (R. 13667–68);
- S.L., for a January 6, 2004admission (R. 14343–45);
- E.M.1, for a January 9, 2006admission (R. 14426–28);
- L.N., for a March 22, 2005admission (R. 16829–31); and
- D.S., for a January 19, 2004admission (R. 17100–02).

R. 17.²

² The Council stated that for these eight documents, the signatures were dated but the examination documents failed to meet the local coverage determination requirements because the handwriting of the person filling out the documents did not match the handwriting of the person who signed them and, as explained below, did not match the handwriting of other physicians on staff, but did match the handwriting of a physician's assistant. The Council's finding on mismatches between the handwriting of the person signing and the person completing the documents applies to all the examination documents "to the extent that the signatures are dated." R. 17. This finding also applies to the following beneficiaries and admissions:

[•] F.A., for an August 30, 2004 admission (R. 2128–30);

Local coverage determination L1937 requires a physician to conduct and document the history, physical examination, and psychiatric evaluation of each admitted patient. The Council found that the handwriting of the person filling out these documents did not match the handwriting of the physicians who signed them or of any of the physicians on the Clinic staff, but did match the handwriting of a staff physician's assistant. R. 17.

Clinic Resources does not dispute that the handwriting used to fill out the documents does not match the handwriting of the physicians who signed them. The Clinic argues that the Council should have inferred that the physicians who signed the documents took the history and performed the examination, despite the mismatched handwriting, because "there would be no reason for the physicians to sign the forms if they had not been involved in and personally conducted the examinations." (Docket Entry No. 16-1 at p. 13).

The Clinic's argument at first appears to address the substantive medical requirement that a physician perform the examination, as opposed to the local coverage determination's seemingly formal record-keeping requirement that a physician "document" the examination within a specific time after admission. At first, the Council determination and CMS's position in this court appear to elevate form over substance. That appearance is, however, misleading. The local coverage determination, L1937, does not directly address who performs the examination. Instead, the

[•] M.C., for an April 26, 2004 admission (R. 3061–63);

[•] M.D., for a February 29, 2004 admission (R. 5799, 5815–16);

[•] S.H., for a January 26, 2004 admission (R. 9929–31);

[•] P.K., for a January 13, 2004 admission (R. 12185–87);

[•] E.M.1, for a September 9, 2005 admission (R. 1401–03);

[•] L.N., for a March 22, 2005 admission (R. 16829–31); and

[•] D.S., for a January 19, 2004 admission (R. 17100-02).

R. 17. These documents appear to have been prepared by a physician's assistant, not by the physician whose signature is on the documents.

determination requires a physician to prepare the documents recording the examination and the results, and requires that the documents be placed in the patient file within 24 hours after admission.

Demanding compliance with these requirements does not improperly elevate form over substance.

The local coverage determination requirements rely on the physician documenting the examination within 24 hours after the patient is admitted, and placing the documents in the patient's file within that period, as the clearest and most direct evidence of compliance with the substantive requirement that the physician examine the patient and, with that knowledge, certify the need for the PHP services and develop a treatment plan at the outset.

The documentation requirements avoid the need to rely on inferences from indirect evidence about who actually did the physical examinations, as opposed to merely signing the documents. The documentation requirements avoid the need to rely on inferring whether the person signing the documents had the required knowledge about the patient to certify the need for the services and develop a treatment plan. As the Council stated, "[t]he documentation requirements for medical records set forth in the LCD are an integral part of demonstrating medical necessity." R. 11. Other than the signatures on the documents, the Clinic does not identify evidence in the administrative record showing that the physicians conducted the examinations, as opposed to merely signing documents written by other people who did the examinations.

Clinic Resources alternatively argues that even if a physician did not complete the examination documents, the physician's signature supports an inference that he or she reviewed, ratified, and approved the examinations others—such as physician's assistants—performed. Clinic Resources relies on Chapter 3, § 3.3.2.4(A) of the Medicare Program Integrity Manual, which states that a handwritten signature is a mark "signifying knowledge approval, acceptance, or obligation."

Clinic Resources also argues that a physician is not required to personally perform or document the examinations because "generally accepted standards of practice for medicine," including the Agency for Healthcare Research and Quality's guidelines, allow physician's assistants to perform physical examinations. (Docket Entry No. 16-1 at p. 17). This argument does not account for the clear requirement in local coverage determination L1937 that the physician personally "document" the examinations. Inferring that a physician ratified or approved an examination that someone else performed and documented is far different from the physician doing the examination himself or herself and documenting the results.

Again, what appears to be an argument of substance over form is not. Substantial evidence and the applicable law both support the Council's finding, as to this category of files, that Clinic Resources did not meet its burden of showing that a physician performed the required examinations, documented them, and placed them in the patients' files no later than 24 hours after each patient's admission.

4. The Unsigned Psychiatric Evaluation Documents

The psychiatric evaluation document for beneficiary S.H. for a visit on June 13, 2005 (R. 8783–84) is not signed. The Council found that Clinic Resources had not met its burden of showing that a physician performed this evaluation. Clinic Resources has not identified evidence in the record providing a basis for this court to conclude otherwise. Both substantial evidence and the applicable law support the Council's decision that this patient file did not meet the requirements for Medicare reimbursement.

5. The Psychiatric Evaluation Documents That Are Signed But Not Dated

The Council found that for all but one of the sampled beneficiaries, Clinic Resources had not

shown that an evaluation was performed, documented, and placed within the patient's file within 24 hours of admission. The Council found that "[n]one of the psychiatric evaluation forms has a date entered next to the physician's signature," and that there was no way to tell when the evaluations were performed. R. 15.

The Council's decision did not state which psychiatric evaluations this finding applied to.

The court has reviewed each patient file in the administrative record. The psychiatric evaluation documents for the following beneficiaries and visits do not include any evaluation date:

- F.A., for an August 30, 2004 admission (R. 2125–27);
- M.C., for an August 16, 2004 admission (R. 2931–33);
- R.D., for admissions on November 13, 2004 (R. 4108–10), July 14, 2005
 (R. 3753–54), and November 8, 2005 (R. 3468–69);
- T.E., for admissions on January5, 2004 (R. 6767–69), April 14, 2004 (R. 6581–83), and November 22, 2004 (R. 6176–78);
- R.F., for a May 6, 2004 admission (R. 7213–15);
- L.F., for a March 4, 2005 admission (R. 7369–70);
- R.G., for admissions on December 17, 2004 (R. 7946–47), July 12, 2005 (R. 7741–42), and November 16, 2005 (R. 7448–49);
- S.H., for a February 18, 2005 admission (R. 9048–49);
- C.J., for a January 3, 2006 admission (R. 10958–59);
- B.K., for admissions on April 27, 2005 (R. 11255–56), May 31, 2005 (R. 11379–80),
 and September 15, 2005 (R. 11043–45);
- P.K., for a May 3, 2004 admission (R. 11964–66);

- I.K., for admissions on December 22, 2004 (R. 13672–73), April 19, 2005 (R. 13450–51), and August 15, 2005 (R. 12803–04);
- L.K., for a March 9, 2005 admission (R. 14266–67);
- S.L., for a January 6, 2004 admission (R. 14355–57);
- E.M.1, for admissions on January 2, 2004 (R. 15887–89), March 23, 2004 (R. 15711–13), July 19, 2004 (R. 15510–12), June 8, 2005 (R. 14862–63), September 7, 2005 (R. 14707–08), and January 9, 2006 (R. 14433–34);
- L.N., for admissions on February 14, 2005 (R. 16961–62) and March 22, 2005 (R. 16832–33);
- D.S., for a January 19, 2004 admission (R. 17109–11);
- W.S., for admissions on November10, 2005 (R. 17558–59) and December 30, 2005
 (R. 17294–95);
- A.S., for admissions on September 6, 2005 (R. 17893–94) and December 1, 2005
 (R. 17690–91);
- W.W., for a July 20, 2004 admission (R. 18129–31); and
- W.Y., for a September 20, 2005 admission (R. 18418–19).
- R. 17. The Council also found that for beneficiary W.W., the medical history and physical examination documents contained an admission date but no information about when the history was taken and the examination was conducted. R. 17 at n.17. The Council found that for files with undated histories, physical examinations, and psychiatric evaluations, Clinic Resources could not prove when the histories, examinations, and evaluations were completed and documented, and therefore failed to meet its burden of showing that they were performed no later than 24 hours after

admission.

Clinic Resources contends that the Council interpreted the local coverage determination to require that physicians date their signatures on the history, examination, and evaluation documents to establish when they were conducted and documented. Clinic Resources objects that requiring the signatures to be dated creates an additional requirement not contained in the local coverage determination. Clinic Resources points out that unlike other Medicare rules and regulations that explicitly require a physician to date his or her signature, *see*, *e.g.*, 42 C.F.R. § 424.22(a)(2), the local coverage determination (L1937), the statute (42 U.S.C. § 1395x(ff)), and the regulation (42 C.F.R. § 410.43) at issue here do not.

The Secretary responds that the Council did not create a new requirement that the physicians date their signatures on the medical history, physical examination, and psychiatric evaluation documents. Instead, the Council required Clinic Resources to meet the existing requirement of showing that the services were covered because a physician took the histories and performed the examinations and evaluations needed to certify the need for PHP services and developed a treatment plan at the outset. The Secretary argues that "the Council did not require physicians to date their signatures on the psychiatric evaluation [Clinic Resources] could have established other methods of documenting that the required examinations were conducted within 24 hours of admission." (Docket Entry No. 18 at p. 16). The Secretary's argument is consistent with the Council's finding that no evidence in the record made it "possible to verify that the physicians examined the beneficiaries and completed initial psychiatric examinations (including physical examinations) and placed them in the medical records within 24 hours." R. 18. The Council's opinion did not rely solely on the absence of a dated signature or impose a dated-signature

requirement. Instead, the Council found that the patient files without dates did not show when the physician did the examinations and evaluations needed to certify the patient's need for PHP services and to develop the treatment plan.

Clinic Resources's argument that the Council created and imposed a new dated-signature requirement is also contradicted by the record. The Council found that the psychiatric evaluation for beneficiary E.M.1 for an admission on December 9, 2004 (R. 15045–47) was sufficiently documented, even though that evaluation document did not have a dated signature. R. 13–14. The Council found that for that patient file, it was possible to determine when the evaluation was performed, based on the typewritten dates of transcription and evaluation shown in the evaluation document. The record does not support the conclusion that the Council imposed a dated-signature requirement not contained in the statute, regulation, or local coverage determination.

Substantial evidence and the correct legal standard support the Council's decision that the examination and evaluation documents signed by a physician but with no examination or evaluation date, either typed or handwritten, and no other basis to determine when the examination or evaluation was performed, do not show that the documents were completed and placed in the patients' files no later than 24 hours after admission.

6. The Psychiatric Evaluation Documents with a Date in the Header

The Council found that "[n]one of the psychiatric evaluation forms has a date entered next to the physician's signature." R. 15. "Instead, the evaluations record the 'Date of Admission' either in typescript or handwriting in the heading of each document." *Id*.

For some of the beneficiaries' visits, the psychiatric evaluation documents are typed and signed by a physician. While the signatures on these documents are not dated, each contains a

header with the words "psychiatric evaluation," followed by a date. Each date is no later than one day after the patient's admission. The documents in this category are for the following beneficiaries and admissions:

- F.A., for a January 19, 2004 admission (R. 2371–73);
- R.B., for an April 21, 2004 admission (R. 2773–75);
- M.C., for admissions on December 29, 2003 (R. 3175–77), and April 26, 2004
 (R. 3067–69);
- M.D., for a February 9, 2004 admission (R. 5803–05);
- S.H., for a January 26, 2004 admission (R. 9926–28);
- G.H., for a February 2, 2004 admission (R. 10706–08); and
- P.K., for a January 13, 2004 admission (R. 12191–93).

The Secretary argues, and the Council found, that these documents "merely reflect the date of admission [in the header,] which is not proof of when the psychiatric or physical evaluation was performed." (Docket Entry No. 18 at p. 18). The Council reviewed the typewritten psychiatric evaluation documents and found that their content was "remarkably consistent across multiple dates of service." R. 14 at n.12. The Council concluded that these similarities "suggest the possibility [that] a non-M.D. staff person may have created subsequent evaluations from an earlier model and submitted the forms to the physician for signature." R. 14 at n.12. Clinic Resources contends that the date in the header is the date of the evaluation and that shows that each evaluation was timely performed and documented by a physician.

The court need not decide this issue because, as discussed in detail above, each of the patient files in this category contains other deficiencies. Substantial evidence and the correct legal

standards support the Council's decision that these other deficiencies preclude finding that Clinic Resources met its burden of showing compliance with local coverage determination L1937 and the applicable statute and regulations, and therefore of showing that the submitted claims were for services that were medically reasonable and necessary and met the requirements for payment.

7. Whether the Council Should Have Inferred When the Examinations and Evaluations Were Conducted

Clinic Resources argues that for patient files with documents that do not state when the physical examinations or psychiatric evaluations were performed, the Council should have made inferences in its favor, such as assuming that the date in the header or the date of admission is the date of examination and evaluation. The Clinic argues that it would not have prepared treatment plans without first having a physician perform the physical examination and psychiatric evaluation. The Council based its finding on the fact that there were examination and evaluation documents missing from some patient files and other examination and evaluation documents lacked information clearly showing when they were prepared. R. 15–16.

The Council was not required to infer from the incomplete information in the physical examination and psychiatric evaluation documents, or from missing documents, that Clinic Resources had met its burden of showing that the PHP services it claimed were medically reasonable and necessary, were covered services, and therefore met the requirements for payment. *See* 42 U.S.C. § 13951; 42 C.F.R. § 424.5(a)(6); *Maximum Comfort, Inc. v. Sec'y of Health and Human Servs.*, 512 F.3d 1081, 1086–88 (9th Cir. 2007). Clinic Resources's argument that the Council should have filled in the evidentiary gaps to resolve these questions in its favor is inconsistent with the Clinic's burden.

Clinic Resources also argues that the Council should have inferred, based on other

documents and information in the record, that the examinations and evaluations were conducted within 24 hours of the patients' admission. (Docket Entry No. 16, Ex. 1 at p. 15). Clinic Resources relies on Chapter 3, § 3.3.2.4(H) of the Medicare Payment Integrity Manual, which instructs zone program integrity contractors to "ensure that the documentation contains enough information for the reviewer to determine the date on which the service was performed / ordered." Medicare Payment Integrity Manual, Ch. 3, § 3.3.2.4(H). The Manual gives the following example:

The claim selected for review is for a hospital visit on October 4. The [additional documentation request] response is one page from the hospital medical record containing three (3) entries. The first entry is dated October 4 and is a physical therapy note. The second entry is a physician visit note that is undated. The third entry is a nursing note dated October 4. The reviewer should conclude that the physician visit was conducted on October 4.

Id.

The Council considered this Manual language but found it an insufficient basis to support Clinic Resources's argument. The Manual describes a "single page record" with both the preceding and subsequent entries prepared by different people on the same date. Clinic Resources asked the Council to infer that the examination and evaluation documents were completed on the same date as other, separate documents. The Council found that the dates of those other documents did not show when the histories and physical examinations or psychiatric evaluations were performed. *Id.* The cited Manual provision did not require the Council to find, or provide a sufficient basis for the Council to infer, that these other documents, on different pages, showed services performed on the same date. Substantial evidence and the applicable law support the Council's decision that preceding and subsequent dated documents in the record did not show when the undated examinations and evaluations were performed or documented.

Clinic Resources argues more specifically that it is possible to infer when the undated

psychiatric evaluation for E.M.1's January 9, 2006 admission was performed. Dr. H.D. signed the psychiatric evaluation document for E.M.1 but did not date it. Clinic Resources argues that this evaluation was completed on January 10, 2006 because the document refers to E.M.1's history and physical examination and psychosocial assessment documents, which were dated January 10, 2006, and because it identifies the same five "multiaxial diagnoses" that are set out in E.M.1's January 10, 2006 Master Treatment Plan. Clinic Resources argues that the Council should have concluded that the psychiatric evaluation was completed before the Master Treatment Plan because "it would have been impossible to formulate a treatment plan without an initial psychiatric evaluation, let alone a treatment plan reflecting identical diagnoses across five axes." (Docket Entry No. 16, Ex. 1, at p. 17).

The Council found that this undated psychiatric evaluation document, like the others, did not demonstrate when it was completed or the evaluation was conducted. R. 16. Clinic Resources asks this court to reweigh the evidence and make a *de novo* factual determination. Clinic Resources does not point to new or additional evidence providing information that strips the Council's determination of any "credible evidentiary" basis. *Harris*, 209 F.3d at 417. The records make it equally plausible for the Council to have reached the factual conclusion that Clinic Resources prepared the psychiatric evaluation afterwards to be consistent with the Master Treatment Plan. Given the limits on judicial review of the Council's decision, because Clinic Resources had the burden to prove its entitlement to payment and failed to do so, there is no basis to disturb the Council's conclusion.

C. Whether Remand Is Appropriate

Clinic Resources asks the court to vacate the Council's decision and remand the case to an administrative law judge instead of granting the Secretary's motion for summary judgment. *See* 42 C.F.R. § 405.1138 (authorizing remand). Clinic Resources argues that remand is necessary so that

the Clinic can submit additional evidence on local coverage determination L1937's 24-hour rule, including "sworn testimony from the treating physicians and clinicians describing [Clinic Resources's] patient intake process, its multidisciplinary approach to patient care, and its overall documentation practices." (Docket Entry No. 16, Ex. 1 at pp. 22–23).

Clinic Resources argues that this evidence is necessary because the Council was the first administrative body to "notice" the issues on which it based its decision. Clinic Resources contends that it did not have an opportunity to submit evidence on local coverage determination L1937 because the issue had not been raised before.

Clinic Resources relies on 42 C.F.R. § 405.1122, which allows the Council to request evidence from the parties in its review.³ But this provision does not require the Council to request additional evidence from a provider even if it decides a new issue, unless the party had no opportunity to present evidence. The requirements of local coverage determination L1937, including its requirement for physicians to perform and document examinations and evaluations no later than 24 hours after admission, clearly applied and were raised in the referral memorandum. Clinic Resources had the burden throughout the audit and administrative proceedings to demonstrate its compliance with this and other requirements and its entitlement to reimbursement. Remand is inappropriate.

³ That regulation states: "(1) If the MAC is reviewing an ALJ's decision, the MAC limits its review of the evidence to the evidence contained in the record of the proceedings before the ALJ. However, if the hearing decision decides a new issue that the parties were not afforded an opportunity to address at the ALJ level, the MAC considers any evidence related to that issue that is submitted with the request for review. (2) If the MAC determines that additional evidence is needed to resolve the issues in the case and the hearing record indicates that the previous decision-makers have not attempted to obtain the evidence, the MAC may remand the case to an ALJ to obtain the evidence and issue a new decision." 42 C.F.R. § 405.1122.

D. Limitation on Liability and Presumption of No Fault

Section 1879 of the Social Security Act, 42 U.S.C. § 1395pp, limits a provider's liability for overpayment when the provider did not know, and could not reasonably have been expected to know, that the services under review would be denied. The implementing regulations, including 42 C.F.R. § 411.406(e), state that this exception does not apply when it is clear that the provider was expected to know that the services were excluded from coverage on the basis of written guidelines. When overpayment is discovered more than three years after a claim was paid, there is a presumption that the provider was without fault in causing the overpayment. 42 U.S.C. § 1395gg(b).

The Council found that Clinic Resources could not benefit from the presumption or the limitation because it either knew or should have known that the services it claimed were not covered. R. 20. Clinic Resources argues that the Council's findings on recoupment are not supported by substantial evidence because the Clinic could not have been reasonably expected to know that the Council would interpret local coverage determination L1937 to create a new documentation requirement that physicians date their signatures. The record shows that the Council did not create a new dated-signature requirement. To the contrary, as noted, the Council found that one patient file was fully supported even though the psychiatric evaluation for that file had an undated signature. R. 13–14.

Clinic Resources's patient files lacked required documents and contained documents that were unsigned or undated (either in typed or handwritten text), or were prepared by a physician's assistant rather than by the physician who signed them. Clinic Resources should have known, based on the language of local coverage determination L1937—not on an administrative interpretation of that local coverage determination—that claims based on incomplete, missing, ambiguous, or

misleading documents were not covered. Substantial evidence supports the Council's decision that Clinic Resources is not entitled to a no-fault presumption or a limitation of liability.

IV. Conclusion

The Secretary's motion for summary judgment, (Docket Entry No. 17), is granted. Clinic Resources's motion for summary judgment, (Docket Entry No. 16), is denied. Final judgment is separately entered.

SIGNED on June 26, 2015, at Houston, Texas.

Lee H. Rosenthal

United States District Judge