

UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF INDIANA  
INDIANAPOLIS DIVISION

STRAND ANALYTICAL LABORATORIES, )  
LLC, )

Plaintiff, )

vs. )

SYLVIA MATHEWS BURWELL, )  
Secretary United States Department of )  
Health & Human Services, )

Defendant. )

No. 1:13-cv-00645-LJM-DKL

No. 1:14-cv-00015-LJM-DKL

No. 1:14-cv-00427-LJM-DKL

**ORDER ON CROSS MOTIONS FOR SUMMARY JUDGMENT**

In these three cases, Plaintiff Strand Analytical Laboratories, Inc. (“Strand”), seeks judicial review of the decision by Defendant Sylvia Mathews Burwell, Secretary of the United States Department of Health & Human Services (the “Secretary”), to deny Medicare coverage for Strand’s DNA Specimen Provenance Assay (“DSPA”) test. The parties agree on the factual record in this case and both have moved for summary judgment in their favor. On April 22, 2015, the Court held a hearing on the motions primarily to clarify the proper statutory and analytical framework for the Court’s decision.

Strand asserts three legal errors by the Medicare Appeals Counsel (the “MAC”), whose decisions became those of the Secretary: (1) the MAC contradicted a key provision of Medicare when it concluded that the DSPA test was excluded from coverage because it was not reasonable and necessary for the diagnosis or treatment of an illness; (2) the MAC’s interpretation of its own regulation improperly nullifies the effective intent of the controlling statute; and (3) the MAC improperly imported a stringent requirement

into the controlling statute and regulation that is not required. Strand also asserts that the MAC's decision is unsupported by substantial evidence in the record. The Secretary asserts that the MAC properly interpreted and applied the relevant statutory and regulatory provisions to conclude that Strand's DSPA test is not covered by Medicare and that substantial evidence supports its conclusion.

The Court has carefully considered the parties' arguments and concludes that summary judgment in favor of the Secretary is appropriate because the Secretary's interpretation of the controlling statutes and regulations are reasonable and substantial evidence supports the MAC's conclusions.

### **I. STATUTORY & REGULATORY FRAMEWORK**

Judicial review of a final decision by the Secretary is guided by 42 U.S.C. § 405(g). See 42 U.S.C. § 1395ff(b)(1)(A); *Wood v. Thompson*, 246 F.3d 1026, 1029 (7<sup>th</sup> Cir. 2001). The standard under § 405(g) is a deferential one: factual "findings of the Secretary . . . if supported by substantial evidence, shall be conclusive, and where a claim has been denied by the Secretary . . . the [C]ourt shall review only the question of conformity with [the Secretary's] regulations and the validity of such regulations." *Id.* (quoting 42 U.S.C. § 405(g)).

In addition, the Secretary's decision may be set aside if the denial of coverage was based on legal error. *Id.* When reviewing such a question, the Court must follow the guidelines in *Chevron, U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984). See *Wood*, 246 F.3d at 1029. Under *Chevron*, first the Court must determine whether or not the intent of Congress is ambiguous. *Id.* (citing *Chevron*, 467 U.S. at 842). Next, "[i]f the meaning of the statute is clear, no deference is due an agency's

interpretation. If the meaning of the statute is ambiguous, an agency's interpretation will be deferred to if it is reasonable." *Id.* (citing *Chevron*, 467 U.S. at 844).

Medicare, established under Title XVIII of the Social Security Act, 42 U.S.C. § 1395, *et seq.*, is a federally funded and administered health insurance program for the elderly and disabled. See 42 U.S.C. § 1395c. Although the Medicare program is divided into three components, the component at issue here is Part B, which, among other things, provides coverage for outpatient physician services like diagnostic testing. See 42 U.S.C. §§ 1395j-1395w-5; 42 C.F.R. Pt. 410. The Secretary administers the program through agreements with private contractors to administer funds to providers on behalf of eligible beneficiaries. See 42 U.S.C. §§ 1395u(a), 1395kk-1. The contractors perform a variety of functions to ensure the accuracy of claim payments, which includes processing claims, making payments, and conducting post-payment reviews. See 42 U.S.C. § 1395kk-1(a)(4); 42 C.F.R. Pt. 421.

Medicare Part B covers "medical and other health services" only as generally outlined in the Medicare Act. See 42 U.S.C. § 1395k. The burden is on the beneficiary to show that an item is covered under Medicare. See 42 U.S.C. § 1395l(e); 42 C.F.R. § 424.5(a)(6). All Medicare coverage determinations are made in light of the section that excludes certain items from coverage, 42 U.S.C. § 1395y(a)(1)(A). This section provides, in pertinent part: "Notwithstanding any other provision of this subchapter, no payment may be made under . . . part B of this subchapter for any expenses incurred for items or services—(1)(A) which . . . are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member . . ." 42 U.S.C. § 1395y(a)(1)(A).

Coverage determinations may be made in several ways. First, the Secretary may issue binding guidance, such as a National Coverage Determination (“NCD”). See 42 U.S.C. §§ 1395y(l)(6)(A), 1395ff(a), 1395ff(f)(1)(B). Second, a Medicare contractor may issue its own guidance, which is known as a Local Coverage Determination or “LCD;” an LCD applies to a specific geographic region only. See 42 U.S.C. §§ 1395y(l)(6)(B), 1395ff(f)(2)(B). Third, if neither an NCD nor an LCD exists, a Medicare contractor makes an individual determination on whether the service is covered by deciding whether it falls within a Medicare benefit category and is “reasonable and necessary for the diagnosis or treatment of illness or injury . . . .” 42 U.S.C. §§ 1395(u), 1395ff(a)(1)(A).

A Medicare contractor may use Medicare manuals for guidance to make a coverage determination. Although an ALJ and the MAC are not bound by these manuals, they must give “substantial deference” to them “if they are applicable to a particular case.” 42 C.F.R. § 405.1062(a). The manual at issue in this case is the Medicare Program Integrity Manual (“MPIM”), which provides guidance on how to determine whether items or services are “reasonable and necessary for the diagnosis or treatment of illness.” MPIM, CMS Pub. No. 100-08, Ch.13, *available at* <http://www.cms.gov/Regualtions-and-Guidance/Manuals/Internet-Only-Manuals-IOMs.html>. For individual claims, like the ones at issue here, the MPIM provides, “An item or service may be covered . . . if it meets all of the conditions listed in § 13.5.1, Reasonable and Necessary Provisions in LCDs.” MPIM § 13.3. The MPIM also reminds the contractor and subsequent reviewers that an item or service is covered by Medicare only if it comports with the statutory requirements of 42 U.S.C. § 1395y(a)(1)(A). MPIM § 13.5.1. Specifically, the MPIM instructs:

. . . Contractors shall consider a service to be reasonable and necessary if the contractor determines that the service is:

- Safe and effective;
- Not experimental or investigational . . .; and
- Appropriate, including the duration and frequency that is considered appropriate for the service, in terms of whether it is:
  - Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition or to improve the function of a malformed body member;
  - Furnished in a setting appropriate to the patient's medical needs and condition;
  - Ordered and furnished by qualified personnel;
  - One that meets, but does not exceed, the patient's medical need; and
  - At least as beneficial as an existing and available medically appropriate alternative.

MPIM § 13.5.1.

The MPIM also instructs contractors to use the strongest evidence available and provides a list of evidence in order of preference:

- Published authoritative evidence derived from definitive randomized clinical trials or other definitive studies, and
- General acceptance by the medical community (standard of practice), as supported by sound medical evidence based on:
  - Scientific data or research studies published in peer-reviewed medical journals;
  - Consensus of expert medical opinion (i.e., recognized authorities in the field); or
  - Medical opinion derived from consultations with medical associations or other health care experts.

MPIM § 13.7.1. The MPIM further provides:

Acceptance by individual health care providers, or even a limited group of health care providers, normally does not indicate general acceptance by the medical community. Testimonials indicating such limited acceptance, and limited case studies distributed by sponsors with financial interest in the outcome, are not sufficient evidence of general acceptance by the medical community. The broad range of available evidence must be considered and its quality shall be evaluated before a conclusion is reached.

*Id.* The MPIM cautions that determinations that “challenge the standard of practice in a community and specify that an item or service is never reasonable and necessary shall

be based on sufficient evidence to convincingly refute evidence presented in support of coverage.” *Id.* “Less stringent evidence is needed when allowing for individual consideration.” *Id.*

Diagnostic laboratory tests that are reasonable and necessary are covered under Medicare Part B. 42 U.S.C. §§ 1395k(a), 1395x(s)(3), 1395y(a)(1)(A); 42 C.F.R. §§ 410.32(a) & (d). The regulation regarding diagnostic tests provides, in relevant part:

All . . . diagnostic laboratory tests, and other diagnostic tests must be ordered by the physician who is treating the beneficiary, that is, the physician who furnishes a consultation or treats a beneficiary for a specific medical problem and who uses the results in the management of the beneficiary’s specific medical problem.

42 C.F.R. § 410.32(a). Further, “[t]he physician . . . who orders the service must maintain documentation of medical necessity in the beneficiary’s medical record.” 42 C.F.R. § 410.32(d)(2)(i). If documentation provided to CMS for the beneficiary’s claim does not demonstrate that the service is reasonable and necessary, CMS reviews the claim and will request additional information regarding medical necessity. 42 C.F.R. § 410.32(d)(3)(ii).

The Medicare Benefit Policy Manual (“MBPM”), which is available at <http://www.cms.gov/Regulations-and-Guidance/Duidance/Manuals/Internet-Only-Manuals-IOMs.html>, also provides coverage guidance at the various levels of review of a Medicare claim. With respect to clinical laboratory services, the MBPM provides the following definition of services: “the biological, microbiological, serological, chemical, immuno-hematological, hematological, biophysical, cytological, pathological, or other examination of materials derived from the human body for the diagnosis, prevention, or treatment of a disease or assessment of a medical condition.” MBPM Ch.15, § 80.1.

In the ordinary course of processing a claim, a Medicare contractor is the first level of review and it must determine whether the claim is covered under the statutes discussed above. See 42 U.S.C. §§ 1395l, 1395u, 1395y(a)(1)(A); 42 C.F.R. Pt. 424. If the Medicare contractor denies the claim, the supplier can challenge the denial through the Medicare appeals process. 42 U.S.C. §§ 405(g), (h); 1395ff; 1395ii. The first level of appeal is a request for redetermination by the Part B Medicare contractor. 42 U.S.C. § 1395ff(a)(3); 42 C.F.R. § 405.940. The redetermination is performed by a different individual than the one who performed the initial review. 42 C.F.R. § 405.948.

If the redetermination is unsatisfactory to the supplier, it may seek reconsideration by a qualified independent contractor (“QIC”). 42 U.S.C. § 1395f(c); 42 C.F.R. §§ 405.960, 405.962. The QIC independently reviews the evidence from the initial determination and redetermination as well as any other evidence provided by the supplier or the contractor or that the QIC obtains on its own. 42 C.F.R. § 405.968(a). The panel members at the QIC level must have “sufficient medical, legal and other expertise, including knowledge of the Medicare program.” 42 C.F.R. § 405.968(c)(1). Pursuant to statute, the QIC review must “be based on applicable information, including clinical experience (including the medical records of the individual involved) and medical, technical, and scientific evidence.” 42 U.S.C. § 1395ff(c)(3)(B)(i). If there is no Medicare coverage policy, the statutes require the QIC to render its decision “based on applicable information, including clinical experience and medical, technical, and scientific evidence.” 42 U.S.C. § 1395ff(c)(3)(B)(ii)(III).

If the QIC determination is adverse, the supplier may request a hearing before an administrative law judge (“ALJ”), who is independent from CMS. 42 U.S.C. § 1395ff(d);

42 C.F.R. §§ 405.1000-54. CMS may, but need not, participate or become a party at the hearing stage; the ALJ is not allowed to draw an adverse inference if CMS fails to appear. 42 C.F.R. §§ 405.1010, 405.1028(a). The ALJ conducts a *de novo* review and considers “all the issues brought out in the initial determination, redetermination, or reconsideration that were not decided entirely in a party’s favor” and may consider other issues without notice to the parties. 42 C.F.R. §§ 405.1000(d), 405.1032.

A supplier that receives an unfavorable decision may seek review with the Medicare Appeals Council (the “MAC”). 42 U.S.C. § 1395ff(d)(2); 42 C.F.R. § 405.1100-30. Further, even if CMS did not participate in the hearing before an ALJ, CMS may refer a case to the MAC so that the MAC can consider whether or not to review the ALJ decision on its own motion. 42 C.F.R. §§ 1110(a) & (b). Specifically, “CMS . . . may refer a case to the MAC if, in their view, the decision . . . contains an error of law material to the outcome of the claim or presents a broad policy or procedural issue that may affect the public interest.” 42 C.F.R. § 1110(b)(1). CMS may also make a referral if, “[i]n CMS’ view, the ALJ’s decision . . . is not supported by the preponderance of evidence in the record or the ALJ abused his or her discretion.” *Id.*

Upon referral, in cases like these where CMS did not participate,

[t]he MAC will accept review if the decision or dismissal contains an error of law material to the outcome of the case or represents a broad policy or procedural issue that may affect the general public interest. In deciding whether to accept review, the MAC will limit its consideration of the ALJ’s action to those exceptions raised by CMS.

42 C.F.R. § 405.1110(c)(2). According to statute, however, once the MAC accepts review, the standard is *de novo*. 42 U.S.C. § 1395ff(d)(2)(B). The MAC decision is the final decision of the Secretary.



## **II. FACTUAL & PROCEDURAL BACKGROUND**

The factual and procedural background in these cases is largely uncontested; therefore, the Court has drawn much of the background directly from the parties' briefs. Citations to the record in Cause No. 1:13-cv-00645-LJM-DKL will be "Strand 1, R(page number);" in Cause No. 1:14-cv-00015-LJM-DKL, "Strand 2, R(page number);" and in Cause No. 1:14-cv-00427-LJM-DKL, "Strand 3, R(page number)."

Under conventional treatment, a treating physician who suspects a patient may have prostate cancer will order a prostate biopsy to identify suspected cancerous cells within the prostate. Strand 1, R2155-58. To perform the biopsy, a urologist will remove multiple "cores" of prostate tissue to "map" different sections of the prostate gland. *Id.* Each core is tested and assigned a "Gleason" score. *Id.* A higher Gleason score represents a more aggressive and advanced cancer. *Id.* Based on the Gleason scores of each core and the distribution of those scores through the prostate, the urologist will render a diagnosis and develop a treatment plan for the patient. Strand 1, R2158. Treatment may range from surveillance of the patient to more radical measures, such as radiation or surgery. Strand 1, R2158-59.

The testing cycle for prostate cancer inherently involves the risk of specimen transposition and contamination. Strand 1, R2147. Published studies have calculated that up to 2% of all prostate biopsies contain such errors. *Id.* Strand's DSPA test eliminates this error and confirms that the cores that were tested belong to a particular patient. Strand 1, R2145.

The MAC summarized how Strand's test is used:

DSPA testing involves swabbing of the cheek of a patient to obtain a DNA sample which is sent to a DNA-testing laboratory. At approximately the

same time, a biopsy or other specimen is removed from the patient and sent to a diagnostic laboratory to determine if the patient has cancer. If a positive result of malignancy is obtained from the diagnostic laboratory specimen, then pursuant to a physician's order the DNA laboratory will then perform DSPA testing of the swab of the same patient to confirm that the cancer-positive specimen belongs to the particular individual and was not erroneously identified with an incorrect patient.

Strand 1, R11.

#### **A. STRAND 1**

In Strand 1, based on physician orders, Strand performed DSPA testing for 27 Medicare beneficiaries on various dates of service. Strand 1, R5. Strand subsequently filed claims for reimbursement with National Government Services, Inc. ("NGS"), the Medicare contractor for its region. *Id.* NGS initially paid the claims. *Id.* However, on September 15, 2010, NGS notified Strand that it had performed a post-pay review of the patients' records and identified a potential overpayment. Strand 1, R1619-34; *id.* R761-74. NGS requested that Strand submit documentation to support the medical necessity of the DSPA testing. *Id.*

On October 11, 2010, Strand timely responded to NGS' request for documentation. Strand 1, R1615-18. Included in its response was a copy of Strand's test reports, documentation from treating physicians' orders for the test performed showing a putative finding of cancer, and pertinent patient medical records. Strand 1, R1650-2117.

In November 2010, NGS notified Strand that it had reopened the claims at issue, informed Strand that the claims error rate was 100%, and the anticipated overpayment amount. Strand 1, R761-73. Strand timely appealed NGS' initial determination.<sup>1</sup> Strand

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<sup>1</sup> As the Court previously outline, when a claim has been denied, the supplier is entitled to appeal under a five-part appeals process: (1) redetermination; (2) reconsideration; (3)

1, R1563-600. On April 7, 2011, NGS issued an unfavorable redetermination decision for all the claims. Strand 1, R338-55.

On September 20, 2011, Strand filed a request for reconsideration of NGS' redetermination decision with the QIC, C2C Solutions, Inc. ("C2C"). Strand 1, R678-1539. On November 19, 2011, C2C issued an unfavorable decision, which was reopened on December 30, 2011. Strand 1, R393-95; 656-69. On February 24, 2012, C2C issued a reopened, unfavorable decision. Strand 1, R400-526. In its decision, C2C determined that the DSPA test "was rendered as a confirmation of specimen handling, not to provide a diagnosis or treatment of the beneficiary's condition," and "did not meet the criteria to be considered medically reasonable and necessary . . . ." Strand 1, R523-24.

On August 14, 2012, a telephonic administrative hearing was held before ALJ William W. Cowan ("ALJ 1"). Strand 1, R2118-71. Strand had two expert witnesses testify on its behalf and submitted a pre-hearing brief that appended journal articles and studies to illustrate the medical necessity of DSPA testing, as well as written statements from treating physicians who opined that DSPA testing is an integral component in the diagnostic testing cycle for prostate cancer, and thus, directly impacts treatment options for patients. Strand 1, R106-21; 123-367. Notably, Strand submitted evidence that approximately 6% of all prostate biopsies nationally include Strand's DSPA test as an integral part of the biopsy test cycle. Strand 1, R13. CMS did not appear. Strand 1, R87-94.

On September 20, 2012, ALJ 1 issued a decision reversing C2C and finding that

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ALJ hearing; (4) MAC review; and (5) appeal to a Federal District Court. *See, generally*, 42 C.F.R. § 405.900.

Strand's DSPA tests were covered under Medicare. Strand 1, R84-104. ALJ 1 concluded that "the testimony, studies and journal articles submitted by [Strand] demonstrate that the DSPA testing fits the definition of diagnostic testing, as defined by Medicare." Strand 1, R93. ALJ 1 further opined that the DSPA tests were "used by the physician to aid in the assessment of a medical condition or the identification of a disease." *Id.* In large part, ALJ 1 adopted Strand's argument that the DSPA tests "provide concordance that the [beneficiaries'] specific cancer has been accurately characterized." Strand 1, R92. Again, adopting Strand's argument, ALJ 1 analogized the DSPA tests to a "second opinion, consultation, or special histopathology stain, all of which are covered by Medicare." Strand 1, R93. ALJ 1 concluded his opinion with the following:

[T]here is a fine line between diagnostic testing and quality control in the context of an individual patient's tissue samples. Here, I find that [Strand] . . . demonstrated the diagnostic value of a test that seeks to confirm the accuracy and correct identification of the sampling in individual cases, and thus aids in the identification of treatment options. . . . [T]he record establishes that the test was medically necessary for the individual patients.

Strand 1, R93-94.

On November 16, 2012, the Administrative Qualified Independent Contractor ("AdQIC") informed Strand that it intended to refer ALJ 1's decision to the MAC for possible review on the MAC's own motion. Strand 1, R83.

On February 15, 2013, the MAC issued its decision, which reversed ALJ 1. Strand 1, R1-21. In its decision, the MAC explained that it "decided, on its own motion, to review [ALJ 1's] decision . . . because there is an error of law material to the outcome of the claim." Strand 1, R4 (citing 42 C.F.R. § 405.1110). After a *de novo* review of the record evidence, the MAC concluded "that the DSPA tests at issue are not diagnostic laboratory tests, do not otherwise fall within a Medicare benefit category, and are not covered by

Medicare.” Strand 1, R4. The MAC explained, “[W]hile DSPA testing is very useful as a tool for avoiding error and misidentification of a patient with cancer, these tests are not a Medicare-covered service as they are not used directly for the diagnosis or treatment of an illness or injury or for the assessment of a medical condition.” Strand 1, R11.

To make its decision, the MAC used the Medicare regulations for diagnostic test coverage under Part B, 42 C.F.R. §§ 410.32; the MBPM; the statutory language for exclusions, 42 U.S.C. § 1395y(a)(1)(A); and, in the absence of an LCD, the MPIM, Ch. 13, § 13.5.1 & 13.7.1. The MAC considered the physician testimony presented by Strand at the ALJ hearing and noted that “the testimony regarding the usefulness of the testing -- a point not disputed by the Council --- is not the sole determinative factor in whether it is covered by Medicare.” Strand 1, R14. It further stated that “such individual physician opinions do not establish acceptance by the general medical community.” *Id.* With respect to journal articles presented by Strand, the MAC rejected two of them outright because they were unpublished. Strand 1, R14-15. The MAC reviewed the remaining five articles and summarized them as presenting “the problem of misdiagnosis and offer DSPA testing as a useful tool to prevent laboratory error.” Strand 1, R15-16. The MAC acknowledged the truth of those statements, but stated that “there is no support that DSPA testing is used to diagnose the beneficiary’s illness or injury or to determine the ‘Gleason scale,’ [the location and presence of cancer in a core sample that indicates the severity of a beneficiary’s cancer], which dictates treatment options.” Strand 1, R15. In other words, the MAC concluded there was no proof of “published authoritative evidence derived from randomized clinical trials or other definitive studies . . . .” *Id.* It repeated that it “did not find that DSPA testing directly diagnoses illness or injury; rather it confirms the

identity of the individual who has already been diagnosed through other (generally Medicare-covered) diagnostic testing.” *Id.*

The MAC reviewed the remainder of Strand's evidence and rejected it because none of it showed that the DSPA test was used “to directly diagnose the presence of cancer,” or “to diagnose the presence of cancer itself,” or “to diagnose or treat a beneficiary,” or “for the diagnosis, prevention, or treatment of a disease or assessment of a medical condition.” Strand 1, R16-17. Rather, the MAC opined that the evidence showed that the test was used “to verify that a cancer diagnosis was assigned to the correct beneficiary,” or as “a valuable tool in preventing misdiagnosis and subsequent unnecessary treatment when used to accompany subjective histopathology,” or “to prevent laboratory identification error.” Strand 1, R17.

## **B. STRAND 2**

In Strand 2, based on physician orders, Strand performed DSPA testing for 19 Medicare beneficiaries on various dates of service between October 4, 2011, and March 1, 2012. Strand 2, R98. Subsequently, Strand filed claims for reimbursement with NGS; instead of reimbursement, Strand received Additional Document Request (“ADR”) letters from NGS. Strand 2, R2258-76, 2290-305, 2319-48, 2362-77, 2391-465, 2480-95, 2510-30, 2546-61, 2575-90, 2605-20, 2636-56, 2671-700, 2714-34, 2748-63, 2777-92, 2806-21, 2835-50, 2867-909, 2929-54. By letters dated May 21, 22, 24, and 29, 2012, NGS notified Strand that it had reopened the claims for the 19 beneficiaries and that it had denied the claims. Strand 2, R988-97, 1298-307, 1634-44, 1947-55.

Strand sought redetermination of these claims, which the NGS denied in decisions dated July 13 and 14, 2012. Strand 2, R979-1288, 1289-623, 1624-938, 1939-2245, 644-

801, 2247-55, 2279-87, 2308-16, 2351-59, 2380-88, 2469-77, 2498-506, 2534-42, 2564-72, 2593-601, 2625-33, 2660-68, 2703-11, 2737-45, 2766-74, 2795-803, 2824-32, 2853-64, 2912-20. In each decision NGS concluded that no diagnostic service was provided and that DSPA testing was a “quality assurance” activity; therefore, it is not separately reimbursable. *Id.*

On September 6, 2012, Strand submitted a request for reconsideration with C2C, the QIC. Strand 2, R636-967. On November 9, 2012, C2C issued an unfavorable decision. Strand 2, R553-609. C2C determined that the DSPA test “was rendered as a confirmation of specimen handling, not to provide a diagnosis or treatment of the beneficiary’s condition;” therefore, it was not medically reasonable and necessary as required. Strand 2, R557.

Strand appealed C2C’s decision by requesting an ALJ hearing. Strand 2, R202-551. On June 6, 2013, a hearing was held before ALJ James O’Leary (“ALJ 2”). Strand 2, R2957-3008. Like it had in Strand 1, Strand presented testimony from its Chief Financial Officer regarding billing and utilization of DSPA testing and two expert witnesses. Strand 2, R2957-3008. Strand also submitted a pre-hearing brief with journal articles and studies regarding the necessity for DSPA testing, and written statements from physicians that opined that DSPA testing was an integral component in the diagnostic testing cycle for prostate cancer. Strand 2, R202-551. Neither NGS nor CMS appeared as a party or participated in the hearing. *Id.*

On June 18, 2013, ALJ 2 issued his decision in which he reversed C2C and concluded that the DSPA tests at issue were fully reimbursable. Strand 2, R110-47. Like ALJ 1, ALJ 2 adopted Strand’s argument that “DSPA testing is similar to a second opinion

and is medically reasonable and necessary for the diagnosis and treatment of the 19 Beneficiaries, because it ensures that the treatment undertaken by the treating physician is not more invasive than needed.” Strand 2, R138. ALJ 2 also concluded that based on the expert testimony, it is the “standard of practice for urologists to get the results of DSPA testing . . . before discussing prostate cancer management, including various treatment options, with a patient . . . .” *Id.*

The AdQIC filed a Referral for Own Motion Review with the MAC. Strand 2, R96-109. The AdQIC asserted that ALJ 2’s decision contained three errors of law material to the outcome of the claims: (a) ALJ 2 erred in finding that the DSPA test is a separately reimbursable diagnostic test; (b) the DSPA test did not diagnose or treat an illness or injury, nor could its results be used to manage a specific medical problem; and (c) Strand’s documentation did not support the conclusion that the services were reasonable and necessary for each patient. Strand 2, R97.

Strand filed exceptions to the AdQIC memorandum arguing that ALJ 2’s decision was consistent with the unchallenged record developed at the hearing, as well as all applicable Medicare rules and regulations. Strand 2, R24-59, 60-95. Strand argued that the AdQIC misinterpreted the Medicare and Clinical Lab Improvement Amendments (“CLIA”) statutes and regulations when it claimed that DSPA testing was not reimbursable as quality assurance activity. Strand 2, R28-35, 65-72. Strand also argued that the administrative record demonstrated that DSPA testing is medically necessary, reasonable and payable by Medicare because it aids in the diagnosis and treatment of patients on an individual basis. Strand 2, R35-46, 72-83. Strand further asserted that the claims were properly documented; it also objected to additional documents presented by



the AdQIC that were not presented to ALJ 2. Strand 2, R46-52, 83-89.

On January 16, 2014, the MAC issued its decision, which reversed ALJ 2. Strand 2, R1-22. Similarly to Strand 1, in Strand 2, the MAC decided to review ALJ 2's decision on its own motion "because there is an error of law material to the outcome of the claim." Strand 2, R5.

After setting forth the regulations applicable to its decision, Strand 2, R8-11, the MAC addressed evidentiary issues. Strand 2, R11-12. The MAC then evaluated whether or not the evidence Strand had admitted was sufficient to establish that the DSPA tests were reasonable and necessary. Strand 2, R12. The MAC concluded

that while DSPA testing is very useful as a tool for avoiding error and misidentification of a patient with cancer, these tests are not a Medicare-covered service as they are not used directly for the diagnosis or treatment of an illness or injury or for the assessment of a medical condition.

*Id.* First, the MAC noted that DSPA tests are not statutorily excluded; however, the MAC stated that the Medicare statutes gave the Secretary the authority to make coverage decisions. Strand 2, R14.

Second, the MAC evaluated Strand's testimonial and evidentiary submissions. Strand 2, R14-18. With respect to acceptance in the medical community, the MAC reviewed the written correspondence from five oncology physicians and the two expert witnesses who testified at the ALJ hearing. Strand 2, R14-15. However, it concluded that the testimonials showed "that DSPA testing plays a useful role by ensuring that the sample tested is associated with the correct beneficiary." Strand 2, R15. The MAC stated further that "individual opinions do not establish acceptance by the general medical community." Strand 2, R15-16 (quoting MPIM, Ch. 13, § 13.7.1). With respect to Strand's journal articles, the MAC considered seven articles that all, in the MAC's words,

“consider[] the problem of misidentification and/or contamination of pathology specimens and supports the use of DSPA testing to prevent such errors.” Strand 2, R17. The MAC concluded that “the articles do not support a conclusion that DSPA testing is used to diagnose the beneficiary’s illness or injury or to determine the ‘Gleason scale,’ [the location and presence of core sample that indicates the severity of a beneficiary’s cancer], which dictates treatment options.” *Id.* Ultimately, like in Strand 1, the MAC rejected the articles because they did not “support a conclusion that DSPA testing directly diagnoses illness or injury; rather, it confirms the identity of the individual who has already been diagnosed through other (generally Medicare-covered) diagnostic testing.” Strand 2, R18.

The MAC then turned to objective evidence to support a conclusion that DSPA testing is used to treat cancer. Strand 2, R18-19. It concluded:

[T]here is no objective evidence in the record that DSPA testing is used to directly diagnose the presence of cancer. Instead, the record evidence establishes that DSPA testing is used in conjunction with subjective histopathology (e.g. the initial diagnostic test) to *confirm* that the specimen is indeed that of the beneficiary tested.

Strand 2, R18. The MAC relied in part on Strand’s own description of DSPA testing as a mere identifying test to conclude “that the testing is not used to diagnose the presence of cancer itself, but to verify that a cancer diagnosis was assigned to the correct beneficiary.” *Id.* Similarly, the MAC rejected Strand’s argument that DSPA results are used to direct treatment options stating that Strand offered evidence that treatment options were based on the Gleason scale, not DSPA test results. *Id.* Moreover, the MAC

acknowledge[d] that the physicians find DSPA testing to be a valuable tool in preventing misdiagnosis and subsequent unnecessary treatment when used to accompany subjective histopathology. However, the Council [found] that the treating physicians and medical experts confirmed that

DSPA testing is used not to diagnose or treat a beneficiary but to verify that the specimen used to diagnose the beneficiary originated with the identified beneficiary.

Strand 2, R18-19.

Based on these findings, the MAC concluded that DSPA tests did not meet the definition of diagnostic laboratory tests for coverage under Medicare. Strand 2, R19.

Finally, the MAC addressed whether or not DSPA testing was a separately payable diagnostic test under CLIA. Strand 2, R19-20. Similarly to its conclusion in Strand 1, the MAC decided that it was unclear as to whether or not DSPA testing would be classified as quality assurance and found merit to both Strand's and CMS' arguments. Strand 2, R20. However, based on its prior analysis, the MAC concluded

that DSPA testing is not covered because it does not directly diagnose or treat an illness or injury, nor does it assess a medical condition. . . . It is simply not covered by Medicare under the limited definition of a medically reasonable and necessary laboratory test for the diagnosis, treatment or assessment of an illness or injury.

*Id.*

The MAC summarized its decision as follows:

[T]he DSPA tests at issue are not for the diagnosis or treatment of a disease or for the assessment of a medical condition, and thus do not meet the definition of a diagnostic laboratory test for Medicare coverage purposes. . . . Similarly, had the tests been part of the diagnostic laboratory test Medicare benefit, the tests are neither medically reasonable nor necessary because they are not for the diagnosis and treatment of illness or injury or to improve the functioning of a malformed body member, but to prevent laboratory identification error.

Strand 2, R21 (citations omitted).

### **C. STRAND 3**

Strand 3 involves a single beneficiary. Strand 3, R5. On December 14, 2011, Strand submitted a claim for payment for a DSPA test to NGS. *Id.* On January 2012,

Strand received an ADR letter from NGS for the claim, to which Strand timely responded. Strand 3, R576-605, 608-09, 638-71. NGS denied payment of the claim because it determined that the services provided were not medically necessary. Strand 3, R612.

On March 23, 2012, NGS denied Strand's request for redetermination. Strand 3, R617-37. Specifically, NGS found that "[t]he routine use of [the] DNA Specimen Provenance Assignment test indicates a concern with the quality of the personnel obtaining and labeling biopsy specimens and the laboratory performing the pathology results" and that "[r]outine DSPA testing would not be medically necessary." Strand 3, R611. *See also id.* at 610-16.

On April 16, 2012, the beneficiary submitted a request for reconsideration to C2C. Strand, R565-68. On June 13, 2012, C2C issued an unfavorable decision. Strand 3, R552-60.

On July 26, 2012, Strand requested a hearing before an ALJ. Strand 3, R533-51. ALJ Tony Smith ("ALJ 3") held a telephonic hearing on August 14, 2013. Strand 3, R942-94. Strand had the same witnesses testify and offered the same evidence to ALJ 3 as it did in the Strand 2 hearing. Strand 3, R375-522. Neither C2C nor anyone from CMS appeared or participated in the Strand 3 hearing. Strand 3, R942-94.

On August 22, 2013, ALJ 3 issued a decision in Strand's favor. Strand 3, R351-57. Based on the testimony of Strand's experts, ALJ 3 determined that Strand's DSPA testing "is provided not as routine testing, but for proper diagnosis. The testing provides the aggressiveness of the tumor and determines type of treatment, as well as helps lessen occult errors." Strand 3, R.352. He also concluded that, with respect to this beneficiary, "the tests performed were necessary to establish the proper diagnosis and treatment for

the [b]eneficiary” and, therefore, were “medically reasonable and necessary according to the Medicare regulations.” Strand 3, R356. ALJ 3 further stated that the DSPA test was medically reasonable and necessary as a matter of law and concluded that Medicare coverage was proper. *Id.*

On October 18, 2013, the AdQIC, Q2Administrators, LLC (the “AdQIC”), filed a Referral for Own Motion Review with the MAC. Strand 3, R125-45. The AdQIC asserted that ALJ 3’s decision contained an error of law material to the outcome of the claim. Strand 3, R126. Specifically, the AdQIC argued that ALJ 3 erred when he: (a) determined that the DSPA test is a separately reimbursable diagnostic test; (b) determined that the DSPA test was reasonable and necessary because it diagnosed and/or treated an illness or injury; and (c) concluded that Strand had provided enough supporting documentation from the treating physician to support the medical necessity of the test. *Id.*

On November 5, 2013, Strand filed an exception to the AdQIC’s memorandum arguing, as it had in Strand 1 and Strand 2, that ALJ 3’s decision was consistent with the testimony and evidence presented at the hearing. Strand 3, R147-317, 318-50. Strand also noted that the AdQIC had misinterpreted CLIA. Strand 3, R151-58. Further, Strand asserted that the record demonstrated that DSPA testing is medically necessary and reasonable because it aids in the diagnosis and treatment of individual patients with a positive diagnosis of cancer. Strand 3, R158-70. Strand also argued that the documentation was adequate. Strand 3, R170-77.

On January 16, 2014, the MAC issued its decision reversing ALJ 3. Strand 2, R4-23. Similarly to its decision in Strand 1, in Strand 3 the MAC decided, on its own motion, to review ALJ 3’s decision “because there are errors of law . . . material to the outcome

of the claim at issue . . . .” Strand 3, R4. The MAC concluded:

[T]he ALJ erred as a matter of law in his decision by ordering reimbursement for the DSPA test as a diagnostic test without fully applying the coverage criteria for diagnostic testing. The ALJ also did not consider other relevant criteria for assessing the medical reasonableness and necessity of the DSPA test. We conclude that the criteria for coverage has not been satisfied and, as such, Medicare does not cover the test.

Strand 3, R5.

To make its decision, the MAC used the same sources as it did in Strand 1: the Medicare regulations for diagnostic test coverage under Part B, 42 C.F.R. § 410.32; the MBPM; the statutory language for exclusions, 42 U.S.C. § 1395y(a)(1)(A); and, in the absence of an LCD, the MPIM, Ch.13, §§ 13.5.1 & 13.7.1. Strand 3, R8-11. The MAC first noted that answering the legal question of whether the tests were covered involved mixed issues of law and fact that were inextricably intertwined. Strand 3, R13. It then turned to the question of whether or not the DSPA test qualified as a diagnostic test, stating that ALJ 3 had not addressed the issue. Strand 3, R14. The MAC concluded “that the purpose of DSPA testing is for it to be used in conjunction with an initial diagnostic test for cancer, in order to confirm that the specimen tested is indeed that of the patient (preventing misdiagnosis and subsequent unnecessary treatment).” *Id.* The MAC reasoned that the DSPA testing is not used to diagnose, assess or treat the cancer itself and there was no medical documentation that the physicians who ordered the tests used the results for that purpose. *Id.* It further concluded that “while DSPA testing may be a useful tool for avoiding error and misidentification of a patient with cancer, these tests are not a Medicare-covered service as they are not used directly for the diagnosis or treatment of an illness or injury or for the assessment of a medical condition.” *Id.*

The MAC also assessed Strand’s evidence that treating physicians testified or

opined that the test was medically necessary. Strand 3, R16-17. However, the MAC stated “that there is no objective evidence in the record that DSPA testing is used to directly diagnose the presence of cancer . . . .” Strand 3, R16. Rather, the MAC concluded that “the record evidence establishes that DSPA testing is used in conjunction with subjective histopathology (e.g. the initial diagnostic test) to *confirm* that the specimen is indeed that of the beneficiary tested.” *Id.* This conclusion, the MAC stated, was supported by the physicians and medical experts that provided testimony and/or statements on behalf of Strand. Strand 3, R16-17. For these reasons, the MAC stated that the DSPA tests did “not meet the definition of diagnostic tests for Medicare coverage purposes.” Strand 3, R17.

The MAC then assessed whether or not the DSPA test met the criteria in the MPIM to be “medically reasonable and necessary under § 1395y(a)(1)(A).” *Id.* Again, the MAC concluded that there was insufficient evidence to support Strand’s assertion that “DSPA testing is safe and effective, not experimental or investigational, and appropriate for diagnosis and treatment of cancer . . . .” *Id.* The MAC considered seven journal articles submitted by Strand, but rejected them because they did not support the notion that “DSPA testing is used specifically to diagnose cancer or that it directly dictates treatment (or determines a Gleason score).” Strand 3, R17-18. The MAC also considered and rejected written submissions and expert statements from physicians because they did not constitute “published authoritative evidence.” Strand 3, R18. Applying the rule in MPIM, ch.13, § 13.7.1, the MAC concluded that these “individual opinions do not establish acceptance by, or the opinion of, the general medical community.” Strand 3, R18. The MAC emphasized that the DSPA test was used by the physicians and/or experts “to

confirm that the sample was obtained from the correct patient . . . [it] was not otherwise used in any manner to diagnose or treat the underlying disease process.” Strand 3, R18-19.

The MAC also concluded that the ALJ had erred because “he did not address, explicitly, whether the submitted documentation showed that the results were used by the ordering physician.” Strand 3, R19. The record only established that the physician ordered the tests and received the results, but it did “not indicate how [the physician] used the test results or how they otherwise affected his treatment of the beneficiary’s condition.” *Id.*

The MAC further addressed whether or not DSPA testing is a separately payable diagnostic test as a quality assurance program. Strand 3, R19-20. Although the MAC found merit to both CMS’s and Strand’s arguments on the subject, it was not convinced that DSPA testing would be classified as quality assurance under CLIA. Strand 3, R20. It concluded that it was not necessary to address the issue because the DSPA test is “not covered because it does not directly diagnose or treat an illness or injury, nor does it assess a medical condition.” *Id.*

Moreover, the MAC rejected Strand’s assertion that the ALJ did not err because there are other favorable decisions issued in other cases. Strand 3, R20-21.

The MAC summarized its conclusions as follows:

[T]he DSPA tests at issue are not for the diagnosis or treatment of a disease or for the assessment of a medical condition, and thus do not meet the definition of a diagnostic laboratory test for Medicare coverage purposes. . . . Similarly, had the tests been part of the diagnostic laboratory test Medicare benefit, the tests are neither medically reasonable nor necessary because they are not for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member, but to prevent or avert laboratory identification error.



Strand 3, R22 (citations omitted).

### **III. ANALYSIS**

#### **A. STANDARDS OF REVIEW**

In Strand 1, Strand argued that both § 405(g) and the Administrative Procedures Act (the “APA”), 5 U.S.C. §§ 701, *et seq.*, provides the proper procedure for review in this Court. Dkt. No. 39 at 15-16. At the hearing, Strand appeared to concede that § 405(g) provided the proper standard, but even if it did not, the Court concludes that § 405(g) applies. Section 1395ff of Title 42, United States Code, provides the scheme under which the Secretary makes decisions under Medicare Part B. See 42 U.S.C. §§ 1395ff(a)(1) & (b)(1)(A). Section 1395ff(b)(1)(A) specifically delineates that judicial review of the Secretary’s decision “is provided in section 405(g) of this title.”

In addition, also in Strand 1, Strand argued that the MAC erred when it conducted a *de novo* review of the evidence when it made its determination because CMS had not participated in the hearing. Dkt. No. 39 at 16-17. Again, at the hearing, Strand appeared to concede that *de novo* review was proper and focused on errors of law made by the MAC. Regardless of whether or not Strand made such an acknowledgement at the hearing, the Court concludes that, once it accepts review of a case on its own motion, the statutory scheme requires the MAC to conduct a *de novo* review of the issues. 42 U.S.C. § 1395ff(d)(2)(B).

Further, to the extent that Strand also argues that the MAC erred when it made its determination to review the cases on its own motion, the Court disagrees. In each case, the MAC specifically stated that it decided to perform a review because each ALJ had made an error of law material to the outcome of the case, which was the reason in each

case that CMS sought review. Strand 1, R4; Strand 2, R5; Strand 3, R4. Once it made that decision in each case, the Medicare statutes required the MAC to make a *de novo* coverage decision. 42 U.S.C. § 1395ff(d)(2)(B). On a *de novo* review, the MAC was entitled to consider additional evidence and the Court sees no error in the MAC's determinations in this regard in any of the three cases. In addition, the MAC's reliance on new evidence to make its determinations is minimal compared to its substantial treatment and discussion of the evidence Strand presented to the ALJ and to the MAC itself.

For these reasons, the Court will apply the standard in § 405(g) to analyze Strand's claims and the Court disagrees with Strand that the MAC used the wrong standard of review once it decided to take the review on its own motion.

## **B. STRAND'S SUBSTANTIVE ARGUMENTS**

Strand's first argument is that the MAC contradicted the key statutory provision, 42 U.S.C. § 1395y(a)(1)(A), when it ruled that the DSPA test is not reasonable and necessary for the diagnosis or treatment of illness. Strand asserts that the MAC improperly required the test to "directly" diagnose an illness, but Congress intended for the statute to have a broader meaning. Strand alleged at the hearing that the MAC improperly stated this requirement ten times in the three decisions at issue here. For example, in Strand 2, the MAC said, "We conclude that while DSPA testing is very useful as a tool for avoiding error and misidentification of a patient with cancer, these tests are not a Medicare-covered service, as they are not used directly for the diagnosis or treatment of an illness." Strand 2, R12.

Further, Strand asserts that the plain language of the statute does not require that

the test “directly” diagnose or treat an illness. It argues that the legislative history supports a broader interpretation for the statute. The Senate report issued at the time the statute was passed explained that items and services “would only be covered where they contribute meaningfully to the treatment of an illness.” S. Rep. No. 89-404 (1965), *reprinted in* 1965 U.S.C.C.A.N. 1943, 1990. In other words, so long as the service contributes meaningfully to the diagnosis or treatment of an illness, it is reasonable and necessary. Strand 2, Dkt. No. 41 at 31 (citing MBPM Ch. 15, § 80.1). Strand asserts that the “uncontroverted evidence” is that the DSPA test impacts treatment options and assists the staging of a specific prostate cancer; therefore, it meets the “contributes meaningfully” intention of the statute.

The Secretary argues that 42 U.S.C. § 1395y(a)(1)(A) has gone for fifty years without a statutory or regulatory definition for “the diagnosis or treatment of an illness,” therefore, it must have a plain meaning. According to the Secretary, the dictionary, as a source for the plain meaning, provides an amalgamated definition of “for the diagnosis or treatment” as follows: “the purpose of either identifying a disease from its signs and symptoms or treating a patient medically or surgically.” Strand 2, Dkt. No. 46 at 4. The Secretary asserts that the DSPA test, a forensic DNA test, does not identify a disease or treat a patient; it matches samples to patients.

Further, the Secretary avers that § 1395y(a)(1)(A) is an exclusionary provision and that Strand’s interpretation would read that function out of the statute. Strand 2, Dkt. No. 46, at 5. At the hearing, the Secretary stated that the provision cannot be interpreted broadly because when Congress intends for Medicare to cover something that would be excluded under § 1395y(a)(1)(A), such as screening tests, inoculations or vaccines, it

must expressly make an exception to the exclusionary rule. Moreover, the Secretary claims that the legislative history makes clear what Congress meant: if it does not diagnose or treat an illness, Medicare does not pay. Strand 2, Dkt. No. 46, at 5-6 (citing, *inter alia*, S. Rep. No. 89-404 (1965), *reprinted in* 1965 U.S.C.C.A.N. 1943, 1990).

The Court agrees with the Secretary that the plain meaning of the “for the diagnosis or treatment of a disease” language of § 1395y(a)(1)(A) requires that the service either diagnose or treat an illness or disease; the “contribute meaningfully” language is outside the scope of the plain meaning. According to Stedman’s Medical Dictionary (“Stedman’s”), “diagnosis” means, “[t]he determination of the nature of a disease, injury, or congenital defect.” Thomas Lanthrop Stedman, *STEDMAN’S MED. DICTIONARY* 531 (Lippincott Williams & Wilkins eds., 28<sup>th</sup> ed. 2006) (hereinafter, “STEDMAN’S”). See also *DORLAND’S MED. DICTIONARY*, [www.dorlands.com](http://www.dorlands.com), Word Search “diagnosis,” <http://dorlands.com/index.jsp> (last visited July 22, 2015) (hereinafter, “DORLAND’S”) (defining “diagnosis” as “the determination of the nature of a case of disease” or “the art of distinguishing one disease from another”). Therefore, under § 1395y(a)(1)(A), a service is for “the diagnosis . . . of an illness” if it determines the nature of it.

Also according to Stedman’s, “treatment” means “[m]edical or surgical management of a patient.” *STEDMAN’S*, at 2022. See also *DORLAND’S*, Word Search “treatment” (defining “treatment” as “the management and care of a patient for the purpose of combating disease or disorder”). Therefore, under § 1395y(a)(1)(A), a service is for “the . . . treatment of an illness” when it is for the medical or surgical management of a patient. There is nothing in the plain meaning of the statute that allows for something that “contributes meaningfully to the medical . . . management of a patient” to be included.

As suggested by the Secretary, such a broad interpretation is against the whole purpose of § 1395y(a)(1)(A) as an exclusionary measure that limits Medicare coverage.

Turning to Strand's second legal argument, even if the Court considered the "diagnosis or treatment" language of § 1395y(a)(1)(A) to be ambiguous, the MAC did not err when it required the DSPA test to either diagnose prostate cancer or be used to direct treatment options for the patient. Strand contends that, if the statute is ambiguous, the MAC interpreted its own regulation governing diagnostic tests to nullify its intent. Section 410.32(a) of the Medicare regulations provides, in part, that the treating physician must "use[] the results in the management of the beneficiary's specific medical problem." 42 C.F.R. § 410.32(a). Strand argues that the MAC's decisions improperly contradict this regulation because they fail to consider the evidence that doctors use the results of the DSPA test to help determine treatment options for patients who have been diagnosed with prostate cancer. Strand 2, Dkt. No. 41, at 2-3. In other words, the MAC contradicted the Secretary's own regulation when it concluded that the DSPA, which assists in the management of prostate cancer, is not for the diagnosis or treatment of a disease.

The Secretary asserts that 42 C.F.R. § 410.32(a) is not definitional, rather, it imposes additional restrictions on coverage of tests that have already been deemed a diagnostic test. Strand 2, Dkt. No. 43 at 32. Further, the Secretary argues, the regulation includes the stipulation that laboratory services be reasonable and necessary for the diagnosis or treatment of an illness, which necessarily defines the scope of coverage under the controlling statute, § 1395y(a)(1)(A). *Id.* at 32-33 (citing, *inter alia*, 42 C.F.R. § 410.32(d)).

The Court concludes that the Secretary applied the correct standard to Strand's

DSPA test, which is the standard in both the regulation and the statute – the test must be for the diagnosis or treatment of an illness. The Court agrees with the Secretary that 42 C.F.R. § 410.32(a) is not definitional, rather it sets additional conditions for coverage for services that have already been deemed a diagnostic test. In addition, another subsection of this regulation specifically alerts a provider that a service must be “reasonable and necessary” or CMS will review it to make a coverage determination. 42 C.F.R. § 410.32(d). Further, 42 C.F.R. § 410.32(a) explicitly incorporates by reference the standard in 42 C.F.R. § 411.15(k), which is another exclusionary provision that expressly excludes services that are not reasonable and necessary for “the diagnosis or treatment of an illness . . . .” See 42 C.F.R. §§ 410.32(a) & 411.15(k)(1).

In addition, the Secretary may not construe regulations more broadly than the statute and the Secretary has considered her own language and that of the statute to be narrower. The plain meaning of the words diagnose and treat do not include the broader concept of “contribute meaningfully.” Rather, the terms “diagnose” or “treat” convey that the service must determine a disease or illness, which the DSPA test admittedly does not; or medically or surgically manage an illness, which the Secretary concluded the DSPA test did not do. The latter conclusion is supported by substantial evidence in the record because the doctors’ testimony and/or letters as well as the studies reflect that the DSPA test is used to confirm that a biopsy sample belongs to a particular patient (a fact that Strand does not contest), it does not medically or surgically manage a disease. See Strand 1, R13; Strand 2, R14-15; Strand 3, R16-17. Strand’s expert Dr. Kapoor conceded that Gleason scores determine treatment, and the DSPA test is used to confirm that the core samples belong to a particular patient. See, e.g., Strand 1, R 16 (citing, *inter*

*alia*, Dr. Kapoor’s hearing testimony); Strand 2, R2995. Moreover, Strand’s own statements reflect that the test is not used to determine if a patient has prostate cancer; rather it is used to connect a positive biopsy to a particular beneficiary. See Strand 3, R16 (citing, “Process Overview for the Laboratory,” at <http://knowerror.com/process-overview/for-the-laboratory>). Strand’s evidence at the Strand 3 hearing also confirmed that treatment options are based on the Gleason scores and their distribution within the core samples, not on DSPA testing. See Strand 3, at 16 (citing Hr’g CD at 2:21-2:24).

Strand’s reliance on the MBPM ch. 6, § 20.4.1 is also unavailing. That section advises that a diagnostic test is one performed to “obtain information to aid in the assessment of a medical condition or the identification of a disease.” MBPM ch. 6, § 20.4.1. The DSPA test does neither: the DSPA test confirms that tissue samples belong to a particular person, it does not “aid in the assessment of a medical condition,” such as determine a Gleason score distribution of a core sample; or identify a disease, such as determine the Gleason score itself. The Court cannot conclude that the Secretary’s construction of the statute or its own guidelines is unreasonable or that her decision was unsupported by the evidence in the record. The DSPA test matches patients to tissue samples and thus aids in the identification of samples, not the identification of a disease or illness.

Strand’s third legal argument, that the MAC’s flawed analysis of the diagnosis or treatment element fatally flawed its decision that the DSPA test is not reasonable and necessary, is equally unavailing. Strand 2, Dkt. No. 44 at 17-18. As discussed at length above, the Court cannot agree that the Secretary erred in her decision that the DSPA test is not for the diagnosis or treatment of an illness. Therefore, Strand’s argument that the

Secretary's reliance on that finding to support her conclusion that the DSPA test is not reasonable or necessary cannot stand.

Further, the Secretary's decisions also conclude that the tests are not reasonable or necessary because they are not generally accepted in the medical community. See, e.g., Strand 2, R15-16 (discussing the requirements in MPIM § 13.7.1). The MAC provided multiple legitimate reasons for this conclusion including the lack of significant use in the relevant medical community and Strand's reliance on individual physician opinions, which the MAC is not required to accept as definitive evidence. See *id.*; see also Strand 1, R13-14 (discussing acceptance in the legal community including correspondence and expert testimony about estimate error rates in sample identification); Strand 3, R17-19 (discussing journal articles, written submissions, and expert testimony as well as the requirements of MPIM § 13.7.1). The MAC also assessed the articles Strand presented and reasonably concluded that they did not support Strand's assertion that the DSPA test is generally accepted in the medical community as a tool for the diagnosis or treatment of prostate cancer; however, the tool is used to prevent mis-identification of a tissue samples. See Strand 1, R14-16; Strand 2, R16-18; Strand 3, R17-18.

For these reasons, the Secretary's decision is consistent with the law and supported by substantial evidence in the record.

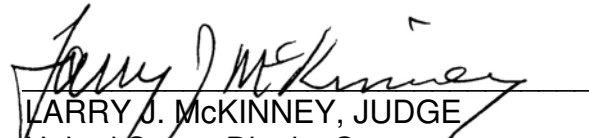
#### **IV. CONCLUSION**

For the reasons stated herein, the Court **GRANTS** summary judgment in favor of Defendant Sylvia Mathews Burwell, Secretary of the U.S. Department of Health & Human Services on all of Plaintiff Strand Analytical Laboratories, LLC's, claims against her; and



**DENIES** Plaintiff Strand Analytical Laboratories, LLC's, cross-motion for summary judgment. The Court will enter judgment accordingly.

IT IS SO ORDERED this 30<sup>th</sup> day of July, 2015.

  
LARRY J. MCKINNEY, JUDGE  
United States District Court  
Southern District of Indiana

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