DEPARTMENT OF HEALTH AND HUMAN SERVICES
DEPARTMENTAL APPEALS BOARD

DECISION OF MEDICARE APPEALS COUNCIL
Docket Number: M-13-160

In the case of	**Claim for**
Strand Analytical Labs (Appellant)	Supplementary Medical Insurance Benefits (Part B)
(Beneficiaries)	(HIC Numbers)
National Government Services (Contractor)	1-921456878 (ALJ Appeal Number)

The Medicare Appeals Council has decided, on its own motion, to review the Administrative Law Judge's (ALJ's) decision dated September 20, 2012, because there is an error of law material to the outcome of the claim. *See* 42 C.F.R. § 405.1110. In that decision, the ALJ found that the DNA Specimen Provenance Assignment (DSPA) testing fit the definition of diagnostic testing and was covered as medically necessary for each of the beneficiaries whose claim is at issue in the present case.

By memorandum dated November 16, 2012, Q^2Administrators, acting on behalf of the Centers for Medicare & Medicaid Services (CMS) asked the Council to take own-motion review of the ALJ's decision. The Council admits CMS's referral memorandum, with attachments, into the record as exhibit (Exh.) MAC-1. The appellant, represented by legal counsel, filed a response to the CMS Referral Memorandum, dated December 20, 2012, which the Council enters into the record as Exh. MAC-2. *See* 42 C.F.R. § 405.1110(b)(2).

For the reasons explained below, the Council reverses the ALJ's decision and finds 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.

BACKGROUND

The appellant provided DSPA testing to the 28 beneficiaries subject to this action on dates spanning from November 2, 2009, through April 28, 2010.[1] The HCPCS/CPT codes[2] at issue were defined on the dates of service as follows[3]:

- 83890: mitochondrial DNA mutations/deletions analysis
- 83900: molecule nucleic ampli 2 seq
- 83901: molecule nucleic ampli addon
- 83907: lyse cell for nucleic ext
- 83909: nucleic acid high resolute
- 83912: genetic examination

Id.; see also Exh. 22 at 106. The claims were initially paid; however, National Government Services (NGS) determined an overpayment was made for the DSPA services and issued a demand for repayment. Exhibit (Exh.) 12 at 56. The appellant requested review of the overpayment determination and, upon redetermination, NGS upheld its overpayment decision finding that the services were quality assurance actions taken by the appellant and thus not covered within a Medicare benefit category. Exh. 14.

The appellant then appealed to the Qualified Independent Contractor (QIC), and the QIC subsequently issued an unfavorable reconsideration decision, concurring with NGS that the items at issue were not covered by Medicare. *See* Exh. 18.[4]

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[1] *See* Appendix A for a full list of beneficiaries, HICNs, and dates of service at issue.

[2] CMS has developed the Healthcare Common Procedure Coding System (HCPCS) to establish uniform national definitions of services, codes to represent services, and payment modifiers to the codes. *See* 42 C.F.R. § 414.2. In order to receive Medicare reimbursement, suppliers utilize the HCPCS in filing claims for services. The Current Procedure Terminology (CPT) is an American Medical Association publication of billing codes for medical services. The HCPCS incorporates the CPT coding system and includes additional coding references.

[3] The Council notes that as of the date of this decision, some of the codes at issue have been deleted from the HCPCS system.

[4] The QIC initially issued its reconsideration on November 22, 2011, finding that the services at issue were not covered by Medicare. *See* Exh. 17. The QIC revised its decision to correct typographical errors and issued a new reconsideration decision, also unfavorable to the appellant, on February 24, 2012. *See* Exh. 18.

Upon further appeal, the ALJ determined that the items at issue were covered by Medicare. Dec. at 6-8. Specifically, the ALJ found the appellant's testimony compelling regarding its classification of the DSPA tests as tools to "provide concordance that the [beneficiary's] specific cancer has been accurately characterized". *Id.* at 6; *reference also* Hearing CD at 10:56:57-11:13:27 (Dr. J.P.) and 11:13:52-11:40:08 (Dr. D.K.). Thus, in finding coverage for DSPA testing, the ALJ adopted the appellant's argument and determined that the DSPA testing was analogous to a "second opinion, consultation or special histopathology stain, all of which are covered by Medicare". *Id.* at 7.

In its memorandum for the Council to take own motion review, CMS argues that the ALJ committed errors of law material to the outcome of the claim in finding that the DSPA testing is a separately payable diagnostic test. Specifically, CMS argues that:

- It is the responsibility of the entity to ensure positive identification and optimum integrity of the beneficiary's specimen from the time of collection or receipt of the specimen through completion of testing and reporting of results;
- DSPA testing is not covered by Medicare because it does not diagnose or treat an injury; thus, it is not medically reasonable and necessary pursuant to Section 1862(a)(1)(A) of the Social Security Act (Act); and
- DSPA testing was not ordered by the treating physician who "uses the results in management of the beneficiary's specific medical problem."

Exh. MAC-1 at 9. In response, the appellant argues that the ALJ did not engage in a material error of law and thus the Council should decline to take own motion review of the ALJ's decision. Specifically, the appellant argues:

- CMS inaccurately interprets Clinical Lab Improvement Amendments (CLIA) requirements in arguing that DSPA testing is not separately reimbursable because it is "covered by CLIA requirements [and] that DSPA testing is routine quality assurance." Exh. MAC-2 at 4, 13-15.
- DSPA testing was ordered by the treating physician and was used to aid in the treating physician's assessment of a beneficiary's medical condition and is therefore medically reasonable and necessary. *Id* at 5, 16-20.

- Expert testimony offered at the ALJ hearing by two physicians support that DSPA testing is "to assist in the diagnosis and treatment of patients" because it "is an indispensable part of a physician's duty to obtain an accurate diagnosis and craft an appropriate treatment regimen." *Id.* at 6-10.
- Numerous publications support the medical necessity of DSPA testing and that it is critical to the diagnosis and treatment of cancer. *Id* at 10.

PROCEDURAL ISSUES

Oral Argument

The appellant requested an opportunity to present oral argument before the Medicare Appeals Council pursuant to 42 C.F.R. § 405.1124. The Council has discretion with respect to granting oral argument; there is no right to appear before the Council. *Id.; see also* 42 C.F.R. § 405.1108(a). In accordance with the factors enumerated in 42 C.F.R. § 405.1124(a), the Council finds that the present case before the Council does not warrant oral argument because it does not raise an important question of law, policy, or fact that cannot be readily decided based on written submissions alone. *Id.*

Evidentiary Submissions

The appellant challenges the admissibility of what it classifies as impermissible new evidence provided with and/or cited to in CMS' referral for own motion review. Exh. MAC-2 at 23-26 *citing* Exh. MAC-1 at 9-13. Specifically, the appellant objects to the inclusion of correspondence between CMS' Acting Administrator and a U.S. Congressman regarding CMS' position on DSPA testing and Medicare coverage. Exh. MAC-1 at 13 (identified for reference purposes only). The appellant also objects to CMS citation and arguments regarding "Coding and Billing Guidelines Updates" issued by a different Medicare Administrative Contractor regarding coverage of DSPA testing in a different geographic area of the country. *Id.* at 10.

The Council acknowledges that guidance from an alternative contractor that lacks jurisdiction over the present matter is not determinative. Further, the correspondence between the Acting CMS Administrator and a U.S. Congressman references CMS' position after the dates of service at issue and is therefore likewise not determinative of the matter at hand. Thus, these

documents are of limited probative value.[5] However, the Council has admitted these documents into the record as part of Exh. MAC-1.

APPLICABLE LEGAL AUTHORITIES

Diagnostic Laboratory Tests

Medicare regulations at 42 C.F.R. section 410.32 set out the conditions for coverage of diagnostic tests under Part B. The regulations provide, in relevant part: "All . . . 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). Medicare Part B pays for covered diagnostic laboratory tests that are furnished by a laboratory. 42 C.F.R. § 410.32(d)(v), *see also* Section 1833 of the Social Security Act (the Act). Specifically, clinical laboratory services involve the biological, microbiological, serological, chemical, immunohematological, 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. Medicare Benefit Policy Manual (MBPM), (Pub. 100-02), Ch. 15, § 80.1.[6] Laboratory services must meet all applicable requirements of the Clinical Laboratory Improvement Amendments of 1988 (CLIA), as set forth at 42 CFR part 493. *Id.*

Medically Reasonable and Necessary

Section 1862 of the Act provides that:

> (a) Notwithstanding any other provision of this title, no payment may be made under part A or part B for any expenses incurred for items and services –
>
> > (1)(A) which . . . are not reasonable and necessary for the diagnosis and treatment of illness or injury or to improve the functioning of a malformed body member.

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[5] While these documents are of limited probative value, they are fully admissible. The regulations restricting the submission of new evidence to the Council apply to requests for review, but do not, based on the language of the regulations, apply to agency referral actions initiated by CMS. *See generally* 42 C.F.R. §§ 405.1110 and 405.1122.

[6] Manuals issued by CMS can be found at http://www.cms.hhs.gov/manuals.

Historically, in making coverage determinations, CMS has interpreted the terms reasonable and necessary to mean that the item or service in question is safe and effective and not experimental. CMS has further determined that the relevant tests for applying these terms are whether the item or service has been proven safe and effective based on authoritative evidence, or, alternatively, whether the item or service is generally accepted in the medical community as safe and effective for the condition for which it is used. 54 Fed. Reg. 4304 (Jan. 30, 1989); 60 Fed Reg. 48417 (Sept. 19, 1995). *See also* 52 Fed. Reg. 15560 (Apr. 29, 1987).

The Act vests in the Secretary the authority to make coverage decisions. Under that authority, CMS issues National Coverage Determinations (NCDs) that state whether specific medical items, services, treatment procedures, or technologies may be paid for by Medicare. In the absence of a specific NCD, the Medicare contractor is responsible for determining whether an item or service is reasonable and necessary. *See* Preface to Coverage Issues Manual (reprinted at 54 Fed. Reg. 34555 (Aug. 21, 1989)). The Medicare contractor has not issued any Local Coverage Determinations (LCDs) concerning the diagnostic laboratory tests at issue. However, in determining whether the diagnostic laboratory tests were medically reasonable and necessary, individual adjudicators, including ALJs and the Council, take into account the same issues that CMS and its contractors consider when they make coverage determinations, including, when appropriate, factors that contractors use when they develop LCDs.

CMS has provided guidance in the Medicare Program Integrity Manual (MPIM), (CMS Pub. 100-08) to assist contractors in developing LCDs. The MPIM instructs contractors that, "[i]n order to be covered under Medicare, a service shall be reasonable and necessary." MPIM Ch. 13, § 13.5.1. The MPIM contemplates that, in making a determination as to whether an item or service is reasonable and necessary, contractors will analyze whether the item or service is safe and effective, and not experimental or investigational:

> 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 . . . .

Id. The MPIM further instructs contractors to base LCDs on the strongest evidence available at the time the determination is issued. In order of preference, this includes:

- Published authoritative evidence derived from definitive randomized clinical trials or other definitive studies, and
- General acceptance by the medical community (standards of practice), 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 manual further explains:

> 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.

DISCUSSION

The burden is on the appellant to establish that the diagnostic laboratory tests were medically reasonable and necessary when provided to the beneficiaries. Accordingly, the Council has considered whether the evidence the appellant has submitted in its reply to CMS' request for the Council to take own motion review and at previous levels, including at the hearing, is sufficient to establish that the DSPA tests were medically reasonable and necessary when they were provided to the beneficiaries. 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 or injury or for the assessment of a medical condition. Thus, they do not fit within the definition of a covered laboratory service nor are they medically reasonable and necessary within Medicare's limited definition of such terms.

According to the claim file, 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.

Throughout the record, the purpose of the collection of procedures defined as DSPA testing has been described in a number of ways. The first description provided by the appellant to NGS as "general background [information to] facilitate your understanding of the reason treating physicians ordered [the appellant] to perform the test" is as follows:

> DSPA testing, when paired with histopathology increases the sensitivity of the testing overall, and therefore, the diagnostic accuracy, minimizing the likelihood of inappropriate or unnecessary medical treatment which can result from undetected specimen provenance complications such as specimen contamination or misidentification.

Id. The appellant's second description suggests that the medical benefit of DSPA testing is that --

> DSPA testing provides an objective, measureable assessment to accompany subjective histopathology, and improves quality of care, patient outcomes, and patient safety by enabling the physician to recommend the treatment that is most appropriate for a particular identified patient.

Id. In its reply to CMS' request for own motion review, the appellant disagrees with CMS' inclusion of the description of DSPA testing taken from its webpage. Exh. MAC-2 at 26-27 *referencing* Exh. MAC-1 at 8-10. Specifically, the appellant states that CMS' quotes "are misleading and taken out of context" because the "website is designed to educate the general public about DSPA testing, and thus, does not explain in the same scientific detail the diagnostic purposes of DSPA testing." *Id.* at 26. Nonetheless, the Council notes that the appellant has used the website language to describe its product. *See e.g.* Exh. 11 at 549. In any event, the Council must determine if the tests fall within a Medicare benefit category and whether the tests are medically reasonable and necessary. The appellant argues that DSPA tests are not statutorily excluded. Exh. MAC-2 at 15-16. The Council agrees and notes that, as stated above, the Act vests in the Secretary the authority to make coverage decisions. *See* preface to Coverage Issues Manual (reprinted at 54 Fed. Reg. 34555 (Aug. 21, 1989)). Absent the issuance of an NCD or LCD, the Council follows the guidance set forth in the MPIM regarding the development of a LCD to determine Medicare coverage for DSPA testing.

Appellant's Evidentiary Submissions

In its request for the Council to take own motion review, CMS argues that DSPA testing "does not diagnose or treat an illness or injury, nor can the results be used to manage a specific medical problem." Exh. MAC-1 at 9. The appellant responds that the testimony of its medical experts, written submission from treating physicians, and medical articles support that DSPA is used to aid in the treatment of cancer and is thus medically reasonable and necessary. Exh. MAC-2. The Council addresses these assertions here.

a. Acceptance in the Medical Community

The appellant submitted correspondence from five oncology physicians to CMS concerning the physicians' usage of DSPA testing in their practices. Exh. 22 at 279-286. Each physician expressed an opinion that a "small but ever-present problem with diagnosing cancer patients has been laboratory error in identification of biopsy samples," and that DSPA testing "confirms that a cancer diagnosis made by analyzing a patient's biopsy actually relates to the patient (*i.e.* that there is no mismatch)," *Id.* at 281, 282. The physicians attest that DSPA testing has been useful in their practice to "be certain that the cancer diagnosis is as accurate as possible and that the right treatment regimen is utilized." *Id.* at 284. Likewise, all of the physicians attest that DSPA was integral to "best practices" in oncology care, stating that DSPA testing "has proven its worth in preventing the misdiagnosis of [cancer], and has thus prevented unnecessary treatments. . . ." *Id.* at 279-280. One physician stated that "[i]t would not be good medical practice to prescribe treatment without the highest level of confidence, both that the diagnosis is correct and that the treatment is appropriate." *Id.* at 285.

During the hearing, the ALJ questioned the appellant's expert, surgical pathologist Dr. J.P., "other than the identification of the correct patient to the sample, what else does [DSPA testing] tell you to help in the clinical diagnosis, the treatment or the diagnosis?" *Reference* Hearing CD 11:04:31-11:05:34. Dr. J.P., responded "that is in essence what it tells you." *Id.* at 11:05:35-11:07:45. Further, the ALJ confirmed with the appellant's urology expert, Dr. D.K., that DSPA testing does not confirm the presence of cancer, but whether the laboratory has a correct, non-contaminated sample. *Id.* at 11:30:05-11:30:49. Dr. D.K. added that "knowing that [the sample specimen] belongs to the identified patient has a significant impact on what we do." *Id.* at 11:30:50-11:32:53. Both physicians attest that they believe the error rate in all samples in diagnostic laboratory testing to be between 0.8% and 2%, that DSPA testing is used in approximately 6% of all prostate cancer diagnoses, and used at 25% of all the larger laboratories. *Id.* at 11:08:21-11:09:35, 11:35:09-11:35:51, 11:40-09-11:44:14.

In its response to CMS' memorandum for own motion review, the appellant claims that CMS "ignored the uncontroverted expert

testimony presented at the ALJ hearing". Exh. MAC-2. The Council notes that expert testimony is only one aspect of determining Medicare coverage and is weighed against the evidence of record. *See* MPIM § 13.7.1. In any event, 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.

Moreover, to the extent that the appellant produced testimonials from prescribing physicians asserting that DSPA testing is effective for their patients, or that one or more independent medical experts may have opined in proceedings before this and other ALJs that the diagnostic testing was medically reasonable and necessary, such individual opinions do not establish acceptance by the general medical community. *Id.*

As stated above, the MPIM 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 . . . are not sufficient evidence of general acceptance by the medical community.

MPIM Ch. 13, § 13.7.1.

For these reasons, the Council concludes that the appellant has not established that DSPA testing is covered based on testimony and the written submission of other physicians.

b. Journal Articles

The MPIM instructs contractors to base coverage determinations on the strongest evidence available at the time the determination is issued. In order of preference, this includes published authoritative evidence derived from definitive randomized clinical trials or other definitive studies. The appellant submitted seven journal articles, two unpublished, regarding studies that it asserts demonstrate the diagnostic and treatment properties of DSPA testing:

- "Extraneous Tissue in Surgical Pathology," *Archives of Pathology and Laboratory*, Volume 120, November 1996; (Exh. 22 at 111-117)

- "Surgical specimen identification errors: A new measure of quality in surgical care," Volume 141, *Journal of Surgery*; (*id.* at 118-124)
- "The Changing Spectrum of DNA-Based Specimen Provenance Testing in Surgical Pathology," Volume 135, *American Journal of Clinical Pathology*; (*id.* at 125-132)
- "Little of no Residual Prostate Cancer at Radical Prostatectomy: Vanishing Cancer of Switched Specimen?," *American Journal of Surgical Pathology*; (*id.* at 133-140)
- "Rate of Occult Specimen Provenance Complications in Routine Clinical Practice", unpublished article submitted (*id.* at 141-162)
- "Patient Identification Error Among Prostate Needle Core Biopsy Specimens—Are we ready for a DNA Time-out?," Volume 178, October 2007, The Journal of Urology; (*id.* at 163-168)
- "Development of a decision-analytic model for the application of STR-based provenance testing of transrectal prostate biopsy specimens," unpublished article submitted (*id.* at 201-233).

The appellant argues that each article supports the medical necessity of DSPA testing. Exh. MAC-2 at 10. The Council first notes that two articles, "Development of a decision-analytic model for the application of STR-based provenance testing of transrectal prostate biopsy specimens," and "Rate of Occult Specimen Provenance Complications in Routine Clinical Practice" were submitted into evidence as unpublished articles and are thus not accorded significant weight in our present review. As stated above, the articles must include "*published* authoritative evidence derived from definitive randomized clinical trials or other definitive studies;" thus, the Council declines to rely on the aforementioned articles in the present case.

The authors of "Extraneous Tissue in Surgical Pathology" documents the "frequency, type, origin, source and diagnostic difficulty of extraneous tissue" in surgical pathology. Exh. 22 at 111. Likewise the authors of "Surgical specimen identification errors: A new measure of quality in surgical care," conclude that "surgical specimen identification errors are common and pose important risks to all patients". *Id.* at 118. In "The Changing Spectrum of DNA-Based Specimen Provenance Testing in Surgical Pathology," the article supports that short tandem repeat analysis, [DSPA testing,] "has emerged as the method of choice for testing to resolve specimen source contamination and identify problems that arise in surgical pathology." *Id.* at 125. The appellant presents case studies

regarding the usefulness of DSPA testing which suggests "vanishing cancer" patients should be tested using DSPA testing methods for identification errors. *Id.* at 133. Similarly, "Patient Identification Error Among Prostate Needle Core Biopsy Specimens—Are we ready for a DNA Time-out?" suggests [DSPA testing] "may eliminate patient identification errors among needed biopsies." *Id.* at 163.

CMS argues that "DSPA confirms that the biopsy sample belongs to the patient being diagnosed . . . . Procedures confirming a biopsy specimen belongs to the correct patient do not diagnose or identify a disease and do not constitute a Medicare covered benefit." Exh. MAC-1 at 11. The articles in evidence each present the problem of misdiagnosis and offer DSPA testing as a useful tool to prevent laboratory error. Again, the Council does not dispute its usefulness for this purpose. However, 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. *See* Exh. MAC-2 at 7; *reference also* Hearing CD at 11:22:31-11:30:05. DSPA testing, as described by the appellant's medical expert, Dr. D.K., gives a treating physician confidence that the diagnosis and treatment plan is appropriate for an identified beneficiary only in that it confirms that the diagnosis of cancer is valid for that particular patient.

Accordingly, the Council concludes that the appellant has not proven that there is published authoritative evidence derived from definitive randomized clinical trials or other definitive studies for Medicare coverage of DSPA testing. The Council does 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.

DSPA and the Treatment of Cancer

Having reviewed the appellant's evidentiary submissions, CMS' arguments and the appellant's brief in response, the Council finds that there is no objective evidence in the record that DSPA testing is used to directly diagnose the presence of cancer. Instead there are many evidentiary examples provided by the appellant where DSPA testing is described as being used in

conjunction with subjective histopathology (*e.g.* the initial diagnostic test) to *confirm* that the specimen is indeed that of the beneficiary tested. *See e.g.* Exh. 11 at 549. In describing its own process, the appellant explains that once a beneficiary is diagnosed with cancer, a secondary test identified as the DSPA process, is performed to verify that the specimen that indicated cancer was biopsied from the identified beneficiary. *See* "Process Overview, For the Laboratory" at http://knowerror.com/process-overview/for-the-laboratory. Thus, the Council finds 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.

Finally, the appellant argues that DSPA testing results *themselves* are used to direct treatment options, *i.e.*, that the DSPA tests are medically reasonable and necessary diagnostic tests. However, the appellant has offered evidence that the treatment options are based on the "Gleason scale," *e.g.* the location of cancer in cone samples, not from the DSPA testing. *Reference* Hearing CD at 11:22:31 - 11:22:30.

The Council acknowledges 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 finds 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.

Therefore, the DSPA tests were not for the diagnosis, prevention, or treatment of a disease or assessment of a medical condition, and thus do not meet the definition of diagnostic laboratory tests for Medicare coverage purposes. MBPM Ch. 15, § 80.1. 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. § 1861(a)(1)(A) of the Act.

Other Reasonableness Arguments

In its request for the Council to take own motion review, CMS also argues that the ALJ erred in finding DSPA testing is a separately payable diagnostic test. Exh. MAC-1 at 9.

Specifically, CMS states the DSPA testing falls under CLIA requirements for quality assurance of non-waived testing. *Id.* at 9-10. In response, the appellant argues that CMS improperly interpreted the CLIA regulations at 42 C.F.R. § 493.1232 by arguing that "every test that may incidentally help to ensure 'positive identification' or 'optimum integrity' must be defined as quality assurance". Exh. MAC-2 at 13-15. The appellant further maintains that DSPA testing is not routine, *e.g.* that it is provided for select beneficiaries upon positive diagnosis of cancer. Exh. MAC-2 at 16-21 citing the *College of American Pathologists v. Heckler (Heckler); reference also* Hearing CD at 11:05:35-11:07:45. The appellant further asserts that the use of DSPA testing prevents misdiagnosis and unnecessary, potentially life-threatening treatment. Exh. MAC-2 at 22.

CLIA provides that each laboratory must establish and maintain policies and procedures that implement and monitor a quality system for all phases of the testing process. 42 C.F.R. § 493.1200. Further, the laboratory must have a system in place to ensure positive identification and optimum integrity of a patient's specimen from the time of collection or receipt of the specimen through completion of testing and reporting of results. 42 C.F.R. § 493.1232. As stated above, laboratory services must meet all applicable requirements of the Clinical Laboratory Improvement Amendments of 1988 (CLIA), as set forth at 42 CFR part 493. MBPM Ch. 15, § 80.1.

The Council finds that CLIA does not speak to whether a laboratory's quality assurance program requires testing on every specimen or a select few that meet certain criteria (*e.g.* positive cancer diagnoses). Nor is it clear to the Council whether DSPA testing would be classified as quality assurance. The Council finds merit to the arguments made by both CMS and the appellant on this point. In any event, the Council finds, as discussed above, 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. Thus, it is not necessary for the Council to determine whether DSPA is a quality assurance test under CLIA, another type of test individualized to a beneficiary which is in a separate or unique category, or both. 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.

LIABILITY

The ALJ determined that the claims at issue were covered by Medicare and thus did not discuss financial liability. CMS argues that for the purposes of determining liability, DSPA tests are not separately billable. Exh. MAC-1 at 10.

Section 1879 of the Act provides that a beneficiary or supplier may be liable for the cost of an item or service that is not "reasonable and necessary" based upon prior knowledge of noncoverage. Act at § 1879(a); 42 C.F.R. §§ 411.400, 411.404, 411.406; Medicare Claims Processing Manual (MCPM), Pub. 100-04, Ch. 30 at § 40. A beneficiary is deemed to have knowledge of noncoverage if the supplier provides written notice to the beneficiary explaining why it believes that Medicare will not cover the item or service. 42 C.F.R. § 411.404(b). A supplier has actual or constructive knowledge of noncoverage based upon "[i]ts receipt of CMS notices, including manual issuances, bulletins, or other written guides or directives from [Medicare contractors]" and "[i]ts knowledge of what are considered acceptable standards of practice by the local medical community." 42 C.F.R. §§ 411.406(e)(1),(3).

Congress enacted, and CMS issued, respectively, among other provisions, Section 1833 of the Act and 42 C.F.R. §§ 410.32(a) and 42 C.F.R. § 410.32(d)(v). All detail the Medicare coverage requirements for diagnostic laboratory tests that are furnished by a laboratory. Thus, the appellant could reasonably have been expected to know that Medicare would not pay for the services at issue. Further, the record lacks evidence that the appellant notified the beneficiaries that Medicare would not likely cover the services at issue.

Section 1870 of the Act allows for a waiver of recoupment of an overpayment to a supplier if it is without fault in incurring the overpayment. The Medicare Financial Management Manual (MFMM) (Pub. 100-06) states that a supplier is without fault if it exercised reasonable care in billing and accepting Medicare payment. MFMM Ch. 3, § 90. The MFMM further explains that the supplier should have known about a policy or rule if the policy or rule is in the provider manual or in the regulations. *Id.* at § 90.1.

Accordingly, the appellant could reasonably have been expected to know Medicare would not pay for services at issue and no waiver of recovery of the overpayments is warranted.

CONCLUSION

The DSPA tests at issue were 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. MBPM Ch. 15, § 80.1. 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. Section 1861(a)(1)(A) of the Act. Accordingly, the DSPA test are not covered by Medicare. The appellant is financially liable for the costs of the noncovered tests at issue.

MEDICARE APPEALS COUNCIL

[redacted]

Date: FEB 15 2013