UNITED STATES DISTRICT COURT
DISTRICT OF CONNECTICUT

Henry Lodge, *Plaintiff*, *v.* Sylvia Mathews Burwell, *Defendant*.	Civil No. 3:15-cv-390 (JBA) December 30, 2016

RULING ON CROSS-MOTIONS FOR SUMMARY JUDGMENT

Plaintiff-Appellant Henry Lodge ("Plaintiff" or "Mr. Lodge") moves for an entry of summary judgment reversing a determination of the Medicare Appeals Council ("MAC") that denied Medicare Part B coverage for dental extractions and implants performed in connection with particularly devastating side-effects of radiation therapy for squamous cell cancer in Mr. Lodge's mouth. Defendant-Appellee Sylvia Mathews Burwell, Secretary of Health & Human Services ("Defendant" or "Secretary") cross-moves for an entry of summary judgment affirming the MAC's decision as supported by substantial evidence and comporting with the Medicare statute, regulations and applicable policies.

For the reasons set forth below, the Court GRANTS Defendant's Motion for Summary Judgment and DENIES Plaintiff's Motion for Summary Judgment.

I. Factual Background

Plaintiff Henry Lodge is a 71-year-old cancer survivor who lives in Bristol, Connecticut. At all relevant times, he was a Medicare beneficiary enrolled in Medicare Part A and Part B. In 1996, Mr. Lodge was diagnosed with cancer in his mouth and subsequently treated by a team of doctors at the Head and Neck Cancer Oral Oncology Program at the Neag Comprehensive Health Center at the University of Connecticut Health Center. (Def.'s Loc. R. 56a(2) Statement. ¶¶ 4 – 5, 7.)

("Def.'s 56a(2) Stmt.")[1] The treatment for his condition included removal of a tumor at the base of Mr. Lodge's tongue, removal of his lymph nodes, removal of the mastoid muscle in his neck, radiation seed implants at the base of the back of his tongue, and radiation treatment in the head and neck area. (*Id.* at ¶¶ 8 – 13). After this surgery and radiotherapy, the cancer has not returned.[2] Administrative Record ("AR") at 415-416.

This treatment, while successfully combatting the cancer, had severe side-effects, including the loss of the ability to produce saliva which can lead to cavities and tooth decay. As one of his treating physicians, Dr. Spiro, noted, "[i]t is well known that such treatments cause significant ongoing issues in regards to dental and oral cavity health in general. . . . Treatment such as dental extractions, hyperbaric oxygen therapy, and dental implants are medically necessary to help manage the after effects of this patient's cancer treatment."[3] AR at 123. *See also* Letter from Dr. Eric Ruiz, AR at 131.

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[1] The team of doctors included Dr. Jeffrey Spiro and Dr. Robert Dowsett, who provided cancer treatment, as well as Dr. Upendra Hegde, who provided an evaluation of a recurrence of cancer. Mr. Lodge received treatment from Dr. Easwar Natarajan and Dr. Ellen Eisenberg, specialists in oral and maxillofacial pathology. He also received treatment from Dr. Eric Ruiz, a dental surgeon specializing in head and neck cancer and oral oncology, and Dr. David M. Schafer, an oral and maxillofacial surgeon. Defendant emphasizes that the treatment received from Drs. Eisenberg, Natarajan, Ruiz, and Schafer was not cancer treatment "because Plaintiff's cancer had been treated without recurrence before he presented to them." Def.'s Loc. R. 56a(2) Stmt. ¶ 7.

[2] In September, 2011, Mr. Lodge was tested for a recurrence of cancer. In addition to noting that the mouth cancer had not returned, his oncologist noted that there were no signs of cancer elsewhere in his body. AR 99, 415-516.

[3] The full text of Dr. Spiro's letter reads:

> Please be advised that Mr. Henry Lodge has been under my care for cancer of the base of the tongue. His treatments included high-dose radiation therapy treatments. It is well known that such treatments cause significant ongoing issues in regards to dental and oral cavity health in general. It is my opinion that all the dental care

Some fourteen years after conclusion of his cancer treatment, in September 2010, Mr. Lodge visited Easwar Natarajan, D.D.S., a member of Mr. Lodge's original treating team, with complaints of oral ulcers, a dry mouth, and candidiasis. (Def.'s 56a(2) Stmt. ¶ 15; AR 90.) Mr. Lodge stated that he was unable to eat comfortably and had suffered weight loss as a result. (Def.'s 56a(2) Stmt. ¶ 16; AR 90.) Over the course of the next year, Mr. Lodge lost another 40 lbs. due to discomfort while eating, and during visits to various doctors was diagnosed with dry mouth and severe cavities. (Def.'s 56a(2) Stmt. ¶¶ 18 – 21; AR 94-96.) During these visits, Mr. Lodge saw Dr. Ellen Eisenberg, D.M.D., David M. Schafer, D.M.D. and Eric Ruiz, D.D.S. (AR 94.)

Based on this diagnosis, Dr. Shafer extracted six of Mr. Lodge's teeth on or about January 10, 2012 and performed dental implant surgery on April 3, 2012. (Def.'s 56a(2) Stmt. ¶¶ 26-27.) Prior to the extraction, Dr. Shafer ordered 20 days of hyperbaric oxygen chamber treatment and ten days of hyperbaric treatment post-extraction. (Def.'s 56a(2) Stmt. ¶ 28). Mr. Lodge requested Medicare coverage for the extractions and the implant surgery which were initially denied (AR 221) and then denied at both the redetermination and the reconsideration levels of appeal. (Def.'s 56a(2) Stmt. ¶ 35; AR 213-216, 236)

> rendered in recent years for Mr. Lodge has been incident to, and an integral part of, care for his head and neck cancer and the after effects of the treatment he received for his head and neck cancer. This treatment is not routine and is specialized because issues related to dental sequelae of head and neck cancer treatment are not frequently seen by dentists in community practice and are therefore best managed in a University dental setting. Treatment such as dental extractions, hyperbaric oxygen therapy, and dental implants are medically necessary to help manage the after effects of this patient's cancer treatment. In particular, such efforts to help improve his nutritional intake and avoid serious bone infections of the upper and lower jaw are clearly medically necessary and are related to his previous cancer treatment.

AR 123.

II. Procedural Posture

Mr. Lodge appealed from a decision of the MAC—deemed the final decision of the Secretary of Health and Human Services (the "Secretary") pursuant to 42 C.F.R. 405.1130—denying coverage under Medicare part B, 42 U.S.C. §§ 1395 *et seq* ("Medicare" or the "Act") for dental services Mr. Lodge received.[4] Prior to the MAC's decision, Mr. Lodge's case moved through a series of determinations in which coverage was initially denied, denied on redetermination by a Medicare contractor, denied on reconsideration by a qualified independent contractor, and then granted by Administrative Law Judge Takos (the "ALJ"). (Def.'s Loc. R. 56a(2) Stmt. ¶¶ 41 – 43). The Center for Medicare & Medicaid Services (the "CMS"), through which the Secretary administers Medicare, appealed the ALJ's decision to the MAC on "own motion review" because it believed the ALJ had made an error of law in concluding that Mr. Lodge's dental services were covered under Medicare as "non-routine" dental services.

III. Statutory and Regulatory Framework

Plaintiff moves for summary judgment on his first cause of action, arguing that the statutory language unambiguously provides for coverage of the services he received. Pl.'s Mem. Supp. at 12. In the alternative, Plaintiff claims the services he received fall into the so-called "incident-and-integral" exception that appears in a Medicare manual interpreting the statutory

[4] The MAC's decision is deemed the final decision of the Secretary pursuant to 42 C.F.R. § 405.1130, "Effect of the MAC's Decision:" "The MAC's decision is final and binding on all parties unless a Federal district court issues a decision modifying the MAC's decision or the decision is revised as the result of a reopening in accordance with § 405.980. A party may file an action in a Federal district court within 60 calendar days after the date it receives notice of the MAC's decision."

language. *Id.* at 14. To set the legal context for these two arguments, the Court will briefly canvass the relevant statutes, regulations, and interpretive rules.

Plaintiff moves for summary judgment on his second cause of action which contends that the amended regulation under which the Secretary denied coverage to the Plaintiff was promulgated without giving fair notice of the proposed amendment in violation of the Administrative Procedure Act (the "APA").

A. Medicare Statute and Implementing Regulations

Medicare, Title XVIII of the Social Security Act ("Medicare" or the "Act"), is a program that provides medical insurance for, inter alia, persons age 65 or older. It originally consisted of two parts: part A and part B.[5] Part A, 42 U.S.C. §§ 1395c *et seq*, pays for inpatient hospital and related post-hospital benefits on behalf of eligible individuals. Part B, 42 U.S.C. § 1395j *et seq*, provides a voluntary supplemental insurance program for payment of various other health services. Mr. Lodge applied for coverage under Part B.

1. The Statutory Language

As enacted in 1965, the Act entitled persons enrolled in Part B to have payment made for "medical and other health services," so long as they did not fall under two coverage exclusions: any service that was "not reasonable and necessary for the treatment of illness or injury or to improve the functioning of a malformed body member. . . " was not covered (42 U.S.C. 1395y(a)(1)(A)), and, even if services were reasonable and necessary, a person was not entitled to payment if the services were explicitly excluded by any other provision of the Act. *Id.*

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[5] *See* CMS Program History, https://www.cms.gov/About-CMS/Agency-Information/History/index.html?redirect=/history/ (last visited November 21, 2016).

The statutory definition of "medical and other health services" included both "physicians' services" and "services and supplies . . . furnished as an incident to a physician's professional service, of kinds which are commonly furnished in physicians' offices and are commonly rendered without charge or included in the physicians' bills . . . ." 42 U.S.C. § 1395x(s)(1); (2)(A). To specify whose services would be covered under "physician's services," the Act then defined 'physician' to include "a doctor of dentistry or of dental or oral surgery," but "only with respect to (A) surgery related to the jaw or any structure contiguous to the jaw, or (B) the reduction of any fracture of the jaw or facial bone." Pub. L. No. 89-97, § 1861(r)(2), 79 Stat. 286, 321 (1965). However, this narrow definition has since been amended, and at all times relevant to the dispute, the Act defined 'physician' to include "a doctor of dental surgery or of dental medicine who is legally authorized to practice dentistry by the state in which he performs such function and who is acting within the scope of his license when he performs such functions." 42 U.S.C. § 1395x(r).

Notwithstanding this apparent inclusion of dental services within the definition of "physician," the 1965 Act and all subsequent iterations contained a dental services exclusion:

> Notwithstanding any other provision of this title, no payment may be made under part A or part B for any expenses incurred for items or services . . .
> (12) where such expenses are for services in connection with the care, treatment, filling, removal or replacement of teeth or structures directly supporting teeth.

Pub. L. 89-97, § 1862(a) 79 Stat. 286, 325 (1965).

In the 1970s, Congress amended the dental services exclusion to introduce an exception "under part A in the case of inpatient hospital services in connection with a dental procedure." The parties dispute whether this amendment covers only inpatient hospital costs associated with dental services, or whether it covers the dental services themselves, but they agree that since Mr. Lodge

did not seek coverage under Part A, this Amendment does not apply to his situation. The full text of the Act in 1972, after Congress passed the amendment, reads:

> Notwithstanding any other provision of this subchapter, no payment may be made under part A or part B of this subchapter for any expenses incurred for items or services . . .
> (12) where such expenses are for services in connection with the care, treatment, filling, removal or replacement of teeth or structures directly supporting teeth,[6] except that payment may be made under part A in the case of inpatient hospital services in connection with a dental procedure where the individual suffers from impairments of such severity as to require hospitalization.

Pub. L. No. 92-603, § 256(c). In 1973, this passage was further amended to allow coverage only if the beneficiary's "underlying medical condition and clinical status require hospitalization in connection with the provision of such services." Although this statutory amendment touches only on part A and therefore does not affect coverage of the services Mr. Lodge received, it was this statutory amendment that triggered changes to the regulations that Plaintiff contends violated the notice-and-comment requirements of the APA.

The Senate committee report on the original Medicare bill, which recommended that the full Senate pass the Act, stated that the "committee bill provides a specific exclusion of routine dental care to make clear that the services of dental surgeons covered under the bill are restricted to complex surgical procedures." The committee report explained that similar to the exclusion of payment for routine eye examinations and charges for eyeglasses, "routine dental treatment—

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[6] The statute does not clarify what "structures directly supporting teeth" means and it does not specify what "in connection with" means. The Secretary does set forth what this phrase means in a handbook. There, she states that "'[s]tructures directly supporting the teeth' means the periodontium, which includes the gingivae, dentogingival junction, periodontal membrane, cementum of the teeth, and alveolar process." Centers for Medicare & Medicate Servs., Publ'n No. 100-02, *Medicare Benefit Policy Manual*, ch. 15, § 150, at 134.

filling, removal, or replacement of teeth or structures directly supporting the teeth—would not be covered." S. Rep. 89-404, at 49, *reprinted in* 1965 U.S.C.C.A.N. 1943, 1989-1990.

2. Implementing Regulations

Congress authorized the Secretary (acting through the CMS), to "prescribe such regulations as may be necessary to carry out the administration of the insurance programs" under Medicare (42 U.S.C. 1395hh(a)(1)) and to "make initial determinations with respect to benefits under part A of this subchapter or part B of this subchapter in accordance with those regulations . . . ." 42 U.S.C. § 1395ff(a)(1).

Pursuant to this statutory grant of power, the Secretary promulgated an initial set of implementing regulations shortly after passage of the Act. With respect to the dental exclusion, these regulations parroted the Act with slightly simplified language and structure, but they introduced the word "routine" to describe excluded services, declaring that Medicare would not cover ". . . *routine* dental services in connection with the care, treatment, filling, removal, or replacement of teeth, or structures directly supporting the teeth." 20 C.F.R. § 405.310(i), added by 31 Fed. Reg. 13534, 13535 (Oct. 20, 1966).

After the 1972 and 1973 amendments to the Act, the Secretary proposed to amend the implementing regulations and gave notice of the proposed amendment in the Federal Register. In the notice, the Secretary explained that the "purpose of these revisions is to reflect the changes made" to the Act. Ex. J to Pl.'s Mem. Supp., 38 F.R. 17246 (June 29, 1973) at 17247, [Doc. # 39-11].

Accordingly, the final regulation, announced on August 9, 1974, did indeed reflect the hospital services exception, but it also incorporated one additional change: the word "routine" was deleted. In announcing the final regulations, the Secretary explained that the purpose of the

amendments was to "conform the regulatory language regarding hospital admissions for excluded dental services with the statutory language in" the amended Act.

The current version of the regulation states that

> The following services are excluded from coverage: . . . Dental services in connection with the care, treatment, filling, removal, or replacement of teeth, or structures directly supporting the teeth, except for inpatient hospital services in connection with such dental procedures when hospitalization is required because of (1) the individual's underlying medical condition and clinical status; or (2) the severity of the dental procedures.

42 C.F.R. 411.15(i).

3. The Secretary's Interpretive Guidance

In addition to the regulations, the Secretary has issued interpretive guidance in several different manuals. First, in a coverage manual, the Secretary defines the term "dentist" and the last sentence sheds light on her understanding of the dental services exclusion.

> A dentist qualifies as a physician if he/she is a doctor of dental surgery or of dental medicine who is legally authorized to practice dentistry by the State in which he/she performs such functions and who is acting within the scope of his/her license when he/she performs such functions. Such services include any otherwise covered service that may legally and alternatively be performed by doctors of medicine, osteopathy and dentistry; e.g., dental examinations to detect infections prior to certain surgical procedures, treatment of oral infections and interpretations of diagnostic X-ray examinations in connection with covered services. **Because the general exclusion of payment for dental services has not been withdrawn, payment for the services of dentists is also limited to those procedures which are not primarily provided for the care, treatment, removal, or replacement of teeth or structures directly supporting the teeth**. . . .

Medicare General Information, Eligibility and Entitlement Manual, Pub. 100-01, Ch. 5, § 70.2, Ex. A to Pl.'s Mot. Summ. J. [Doc. # 39-2] (emphasis added).

Second, in the Medicare Benefit Policy Manual (the "MBPM"), the Secretary has articulated an exception, commonly referred to as the "incident-and-integral" exception or the "same physician rule" to the general dental services exclusion contained in the Act.[7] After noting that "under the general exclusions from coverage, items and services in connection with the care, treatment, filling, removal, or replacement of teeth or structures directly supporting the teeth are not covered," the Secretary then explains her exception:

> if an otherwise noncovered procedure or service is performed by a dentist as incident to and as an integral part of a covered procedure or service performed by the dentist, the total service performed by the dentist on such an occasion would be covered.

U.S. Dep't. of Health & Human Servs., Ctr. For Medicare & Medicaid Serv. Pub. 100-02, MBPM, Ch. 15, § 150 at 134-35 and Ch. 16, § 140 at 32. Under this regulation, an otherwise non-covered procedure would have to satisfy three requirements to be covered: it would have to be performed (1) as incident to and an integral part of a covered procedure, (2) it would have to be performed by the same person who performed the covered procedure, and (3) it would have to be performed on the same occasion as the covered procedure.

The MBPM then provides examples that illustrate the application of this rule to particular fact situations. For example, it clarifies that a dental service like the reconstruction of a ridge "performed as a result of and at the same time as the surgical removal of a tumor" would be

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[7] The MBPM does not make clear which passages in the Act are synthesized into the incident-and-integral exception. As noted above, the definition of "medical and other services" in the act allows for payment for non-covered services if they are "furnished as an incident to a physician's professional service, of kinds which are commonly furnished in physicians' offices and are commonly rendered without charge or included in the physicians' bills . . . ." 42 U.S.C. § 1395x(s)(2)(A).

covered, but the reconstruction of a ridge to prepare the mouth for dentures would not be covered. Likewise, the wiring of teeth when done in connection with the reduction of a jaw fracture would be covered. Finally, the preparation of the jaw for radiation treatment of neoplastic disease would also be covered. *See id.* The MBPM notes that if an excluded service (e.g. elective cosmetic surgery) is the primary procedure, any dental service is not covered, "regardless of its complexity or difficulty." *Id.*

B. The Administrative Procedure Act

The APA establishes procedures that agencies must use to promulgate legislative rules. 5 U.S.C. § 551(5). Under the APA, agencies must ensure that individuals subject to their rule-making authority receive due process; the APA guarantees this by requiring that agencies first issue a notice of proposed rule-making, respond to comments on the proposed rule, and, when issuing a final rule, include a general statement of the rule's basis and purpose.

Final rules need not be identical to the proposed rule, but must be a "logical outgrowth" of the proposed rule. *Long Island Care at Home, Ltd. v. Coke*, 551 U.S. 158, 174 (2007).

> While a final rule need not be an exact replica of the rule proposed in the Notice, the final rule must be a logical outgrowth of the rule proposed. Clearly, if the final rule deviates too sharply from the proposal, affected parties will be deprived of notice and an opportunity to respond to the proposal. The test that has been set forth is whether the agency's notice would fairly apprise interested persons of the subjects and issues' [of the rulemaking.

Nat'l Black Media Coal. v. F.C.C., 791 F.2d 1016, 1022 (2d Cir. 1986) (interior citations omitted). The purpose of the notice-and-comment rulemaking and the logical outgrowth test is "fair notice" to interested parties potentially subject to the regulation. *Time Warner Cable, Inc. v. F.C.C.*, 729 F.3d 137, 170 (2d Cir. 2013).

IV. The Decision Below

After Mr. Lodge received a fully favorable decision from ALJ Takos, the Secretary requested that the MAC review his decision and on January 20, 2015, the MAC reversed that decision, concluding that "1862(a)(12) of the Act excludes the services from Medicare coverage." AR at 14.

The MAC reasoned that:

> The appellant's arguments before both the ALJ and the Council seek to expand the limited exceptions to the exclusion provided for in the Act, the regulations, the MBPM and the NCD to all instances where dental services are non-routine, or furnished as part of a broader medical treatment and where such services are incident to and integral to treatment of a medical condition. Such an expansion would result in "the exceptions swallowing the rule," as many dental conditions are directly related to medical conditions and treatments thereof. Contrary to the appellant's assertion, 45 [sic] U.S.C. § 1395y(a)(12) does not allow for coverage of non-routine dental services. . . . The exceptions to the dental exclusion are very limited and are governed by their precise language. . . .The first exception provided in the MBPM relating to services incident to and an integral part of a covered medical service require that both the medical and dental services be performed *by the dentist* and *on the same date of service*. . . . [T]he record does not show that both the cancer treatment and the dental services were provided by the dentist. And further the appellant received his cancer treatment in 1996, and the services at issue were provided in 2012 . . . .

MAC Decision, AR 11-14 (internal citations omitted). This decision begins by tacitly assuming that Mr. Lodge's dental services were reasonable and necessary and then works systematically through the various levels of guidance. It concludes that the services were properly excluded from coverage because they are excluded by the Act's general dental services exclusion and do not fall into any of the exceptions created by the Act or by the regulations. The MAC then observes that the Agency's manuals, including the MBPM, also exclude the services because the incident-and-integral exception does not apply where the cancer treatment and dental services occurred 14 years apart and were performed by different doctors.

V. The Parties' Positions

Plaintiff moves for summary judgment on his two causes of action. Pl.'s Mem. Supp. at 1. Under the first cause of action, he claims that the decision below should be reversed because the services Mr. Lodge received were not excluded under the Act's dental services exclusion. To support this position, Plaintiff argues that the Act unambiguously excludes only "routine" dental services and does not exclude non-routine dental services. *Id.* at 12. To support his interpretation, he relies on the legislative history contained in the Senate report and the close textual proximity of the dental services exclusion to exclusions of other routine services in the structure of the Act. Plaintiff then argues in the alternative that the dental services that Mr. Lodge received fall into the "incident-and-integral" exception articulated in the MBPM as part of his ongoing treatment for cancer and its side effects. *Id.* at 14.

Under his second cause of action, Plaintiff claims that the decision below should be reversed, and the prior, fully favorable decision of the ALJ reinstated, because the Secretary promulgated the 1973 amendment to the implementing regulations without giving fair notice of the proposed amendment in violation of the Administrative Procedure Act.

Defendant cross-moves for summary judgment, maintaining that the Court should affirm the decision of the MAC because the Secretary's interpretation of the Act is entitled to *Chevron* deference and the Secretary's findings of fact are supported by substantial evidence.

VI. Standard of Review and Appropriate Level of Deference

Pursuant to 42 U.S.C. § 1395ff(b)(1)(A), which incorporates the substantive standards of 42 U.S.C. § 405(g), this Court is empowered to affirm, modify, or reverse the Secretary's final decision with or without remand. The Act dictates that the Secretary's factual findings shall be

deemed conclusive if supported by "substantial evidence,"[8] (*see* 42 U.S.C. 405(g)), but the reviewing court "is not bound by the Secretary's conclusions or interpretations of law, or an application of an incorrect legal standard. Where an error of law has been made that might have affected the disposition of the case, this court cannot fulfill its statutory and constitutional duty to review the decision of the administrative agency by simply deferring to the factual findings of the ALJ." *Anghel v. Sebelius*, 912 F. Supp. 2d 4, 14 (E.D.N.Y. 2012) (*citing Townley v. Heckler,* 748 F.2d 109, 112 (2d Cir.1984)).

Plaintiff does not raise the issue of deference in his motion for summary judgment, but Defendant argues that *Chevron* deference is appropriate and outcome-determinative. Because ascribing *Chevron* deference to the Secretary's interpretation of the Act would affect how the Court evaluates the decision below, the Court must first determine whether and to what extent it will defer to MAC's decision or, alternatively, to the rules and guidance issued by the agency.

As the Supreme Court has pointed out, there is no need to defer to an agency interpretation if Congress has "directly spoken to the precise question at issue," because where a statute is clear "that is the end of the matter, for the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress." *Chevron U.S.A. Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837, 842 (1984). Only where an express delegation of power or an ambiguity or gap in the statute leaves room for discretion on the part of the agency does the question of deference arise.

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[8] "If substantial evidence supports the Secretary's decision, the decision must be upheld, even if there is also substantial evidence for the plaintiff's position. The court may not substitute its own judgment for that of the Secretary, even if it might justifiably have reached a different result upon a *de novo* review." *Anghel*, 912 F. Supp. 2d at 14 (E.D.N.Y. 2012) (*citing Jones v. Sullivan*, 949 F. 2d 57, 59 (2d Cir. 1991)).

The Supreme Court has clarified that *Chevron* deference is appropriate in two situations: first, "when Congress has explicitly left a gap for an agency to fill, there is an express delegation of authority to the agency to elucidate a specific provision of the statute by regulation . . . ." *United States v. Mead Corp.*, 533 U.S. 218, 227 (2001) (*citing Chevron*). Second, "sometimes the legislative delegation to an agency on a particular question is implicit," as when it is apparent "from the agency's generally conferred authority and other statutory circumstances that Congress would expect the agency to be able to speak with the force of law when it addresses ambiguity in the statute or fills a space in the enacted law." *Id.* at 229. However, "[i]nterpretations such as those in opinion letters—like interpretations contained in policy statements, agency manuals, and enforcement guidelines, all of which lack the force of law—do not warrant *Chevron*-style deference." *Christensen v. Harris Cty.*, 529 U.S. 576, 587 (2000). Crucially, where an Agency has chosen to parrot ambiguous statutory language in its regulation, and then to interpret that parroted language by means of interpretive letters and the like, deference is inappropriate because

> the existence of a parroting regulation does not change the fact that the question here is not the meaning of the regulation but the meaning of the statute. An agency does not acquire special authority to interpret its own words when, instead of using its expertise and experience to formulate a regulation, it has elected merely to paraphrase the statutory language.

Gonzales v. Oregon, 546 U.S. 243, 257 (2006). Agencies cannot do an end-run around notice-and-comment rulemaking by promulgating ambiguous regulations that simply parrot ambiguous statutory language, setting forth interpretive guidance to those ambiguous regulations, and then demanding deference over those agency interpretations.

Even where *Chevron* deference is inappropriate, an agency's interpretation "is still entitled to respect according to its persuasiveness, as evidenced by the thoroughness evident in the agency's

consideration, the validity of its reasoning, its consistency with earlier and later pronouncements, and all those factors which give it power to persuade" under the doctrine of *Skidmore* weight. *Estate of Landers v. Leavitt*, 545 F.3d 98, 107 (2d Cir. 2008), *as revised* (Jan. 15, 2009) (*citing United States v. Mead*, 553 U.S. 218, 222 (2001)). Factors a court should consider in assigning weight to an agency's opinion include whether or not there are gaps in the statute, the complexity of the statute, the expertise of the agency in making policy decisions, the importance of the agency's decisions to the administration of the statute, and the degree of consideration the agency has given to the relevant issues over time. *See Barnhart v. Walton*, 535 U.S. 212 (2002).

With respect to the narrow question of whether *Chevron* deference is appropriate in reviewing decisions of the MAC, the Second Circuit has not yet spoken and courts in this and other circuits have divergent views. Recently, in *Albert v. Burwell*, 118 F. Supp. 3d 505 (E.D.N.Y. 2015) the district court concluded that *Skidmore* weight, rather than *Chevron* deference, was the appropriate weight to ascribe to the MAC's decision regarding reimbursement for chiropractic services. That court followed the Second Circuit's lead in *Estate of Landers* and reasoned that *Chevron* deference was inappropriate where the MAC had to interpret a policy manual because the manual, which was not the product of notice-and-comment rulemaking, did not qualify for *Chevron* deference. The *Albert* court concluded that

> [In *Estate of Landers*], the Second Circuit concluded that the Policy Manual, while not entitled to deference under *Chevron*, is nonetheless entitled to deference under *Skidmore*. This case is admittedly somewhat different from *Estate of Landers,* since the Council is here interpreting the Policy Manual, and thus, in effect, interpreting an interpretation. However, given the Council's institutional expertise in interpreting the Part B statute and regulations, the reasoning of *Estate of Landers* is just as applicable in this case. Accordingly, the Court concludes that the Council's interpretation of the Chiropractic LCD should be accorded *Skidmore* deference.

Id. at 512–13.

By contrast, the Ninth Circuit recently held in a case factually similar to the instant case that *Chevron* deference applies. In that case, the appellants received dental services that were medically necessary to prevent potentially fatal heart infections. While their medical conditions that caused the underlying problems were complex, the required dental work was not. As a result, the appellants received dental services from a dentist, rather than from the doctor who treated them for the underlying conditions, and received those services on a different occasion. They sought but were denied coverage under Part B. The Ninth Circuit affirmed denial of coverage, holding that the interpretation at issue was the same-physician rule's broad policy determination that incident-and-integral services would only be covered in narrow circumstances and that, while the statute was ambiguous, the agency's consistent application of its interpretation, given the force of law through thousands of ALJ determinations every year, deserves *Chevron* deference. *Fournier v. Sebelius*, 718 F.3d 1110, 1117 (9th Cir. 2013).[9]

VII. Discussion

Defendant moves for summary judgment, urging the Court to accord *Chevron* deference to the MAC's interpretation of the statute and regulations and to affirm the Secretary's determination as based on substantial evidence. Plaintiff cross-moves for summary judgment, asserting that the MAC misapplied the unambiguous statutory directive or, alternatively, that the amendment of regulations striking the word "routine" violated the APA and that this violation

[9] Two factors lead this Court to question the reasoning in *Fournier*. First, the *Fournier* court appears to have misread the statutory exception for hospital services introduced by amendment in 1972 and mistakenly concluded that that exception permits Medicare to cover dental services, as opposed to only covering inpatient hospital services. Second, although the *Fournier* court appears to have concluded that the incident-and-integral exception did not factor into its decision because the services at issue fell into a third category of non-covered services, it had to tacitly rely on the validity of the narrow incident-and-integral categorization of services to reach that conclusion.

vitiates the MAC's decision. Beyond the minor factual challenges lodged in Defendant's 56a(2) statement, the parties do not dispute the material facts of the case.

A. *Chevron* Deference is Inappropriate

Before addressing the substantive question of whether *Chevron* deference is appropriate, it is important to isolate the appropriate recipient of any such deference. The parties diverge over whether the MAC's decision or the agency manuals should be the recipient of deference. Defendant contends that the Court should defer to the decision of the MAC as the Secretary's final interpretation of the statute, the regulations and her own policy manuals, while Plaintiff urges that deference is due "not to the decision below, but to the agency's interpretation of the statute," which is set forth in the MBPM. Pl.'s Mem. Opp'n. Summ. J. [Doc. # 42] at 7. Plaintiff argues that the only "interpretation" of the statute is the "same physician rule," which is included in the MBPM. Pl.'s Mem. Opp'n. at 6-7. Defendant argues, by contrast, that the MAC's decision gives the force of law to the regulations and the MBPM, and is the appropriate recipient of any such deference. The Secretary further argues that the two levels of deference tend to converge when it is a question of a "highly expert agency administer[ing] a large and complex regulatory scheme." *Cmty. Health Ctr. v. Wilson-Coker*, 311 F.3d 132, 138 (2d Cir. 2002).

A review of the MAC's decision reveals that it does not provide any interpretation of ambiguous statutory language. The MAC does not take up the ambiguity of the phrase "in connection with" in either the statute or the regulations; rather, it simply applies the general dental services exclusion and the agency-devised incident-and-integral exception to the facts of Mr. Lodge's case. Rather, the Secretary's interpretations appear in her manuals: in her definition of "physician" she interprets the phrase "in connection with" to mean "for the primary purpose of" and in the MBPM's discussion of the incident-and-integral exception, she interprets, and

ultimately synthesizes, the statutory definition of medical and other services, the statutory entitlement to payment for services "incident to" medical and other services, and the statute's general dental exclusion.

Unlike the kinds of legislative rules that are promulgated through notice-and-comment rulemaking or that arise through adjudications that bind third-parties through a system of precedent, the MAC's decisions have no precedential power. As the Secretary acknowledges and the Plaintiff emphasizes, "it is neither feasible, nor appropriate at this time to confer binding, precedential authority upon decisions of the MAC." 74 F.R. 65296, 65327 (Dec. 9, 2009); *see also* Pl.'s Mem. Opp'n. at 8. Since the MAC's decisions do not have the kind of binding power associated with rules issuing from an agency adjudicatory process and since the MAC does not interpret, but merely applies interpretations that are found in the Secretary's manuals, the Court concludes that the appropriate locus of investigation for purposes of *Chevron* analysis is the agency manuals.

The substantive *Chevron* analysis proceeds by first asking whether Congress has directly spoken to the precise issue, in which case the inquiry is over, or whether the statute is ambiguous. As noted above, the dental services exclusion in the Act is ambiguous because it is possible to read the phrase "in connection with" as meaning either "for the purpose of" or merely "as incident to." Such reasoning led the Ninth Circuit to observe that

> Section 1395y(a)(12) prohibits Medicare coverage of expenses for services "in connection" with the care of the teeth. It is arguable, however, that the Secretary could interpret Appellants' services to have been provided not "in connection with" the care and treatment of teeth, but rather "in connection with" a medical need to prevent life-threatening heart infections. Viewed in this light, the services provided here could plausibly be viewed as either in connection with the care of teeth or with alleviating a symptom caused by a serious prior disease . . . .

Fournier v. Sebelius, 718 F.3d 1110, 1119 (9th Cir. 2013).[10]

The Secretary, however, has not alleviated this ambiguity in her regulations. Instead, she simply repeats the same ambiguous phrase in her regulations and postpones any interpretation to the manuals she issues. But "interpretations contained in . . . agency manuals . . . lack the force of law [and] do not warrant *Chevron*-style deference." *Christensen*, 529 U.S. at 587. For this reason, *Chevron* deference is inappropriate in this case.[11]

B. Agency Manuals Do Not Receive Dispositive *Skidmore* Weight

While the Court does not ascribe *Chevron* deference to the Secretary's manual provisions, it does find that they deserve some weight as interpretations of the statute because they are a plausible synthesis of several disparate parts of the Act and because the Agency, which has long

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[10] Interestingly, the Secretary appears to interpret "in connection with" to mean "for the purpose of," as made apparent in the excerpt from the Medicare General Information, Eligibility and Entitlement Manual cited above:

> Because the general exclusion of payment for dental services has not been withdrawn, payment for the services of dentists is also limited to those procedures *which are not primarily provided for* the care, treatment, removal or replacement of teeth or structures directly supporting the teeth.

Medicare General Information, Eligibility and Entitlement Manual, Pub. 100-01, Ch. 5, § 70.2. (emphasis added).

[11] In *Fournier*, the Ninth Circuit concluded that *Chevron* deference was appropriately ascribed to the Secretary's manuals under the *Mead* test, which requires a showing that (i) Congress has delegated to the agency the authority to make rules carrying the force of law, and (ii) that the agency interpretation claiming deference was promulgated in the exercise of that authority. *Fournier*, 718 F.3d at 1119-20. The Ninth Circuit reasoned that the Secretary's manuals satisfied the second prong because the agency's interpretation is interstitial, filling in gaps where "the dental exclusion is clear, with clear exceptions." *Id.* at 1121. The problem with this line of reasoning is that, as the Ninth Circuit admits, the dental exclusion as expressed in the Act is not clear, but ambiguous. The Agency's manuals are clear, with clear exceptions, but they are not merely interstitial gap-fillers.

been tasked with administering the Act, has developed some expertise in so doing. As noted above, § 1395y(a)(12) sets out a general ban on services "in connection with" the care, treatment, filling, removal, or replacement of teeth. This general ban, which is ambiguous in its use of the phrase "in connection with," must also be read in conjunction with (i) the definition of "physician," which Congress has expanded from a dentist performing complex surgeries to a dentist acting within the scope of his license, and (ii) the definition of "medical and other health services," which provides for payment of services "furnished as an incident to a physician's professional service, of kinds which are commonly furnished in physicians' offices and are commonly rendered without charge or included in the physicians' bills . . . ." 42 U.S.C. § 1395x(s)(2)(A).

In her "General Information, Eligibility and Entitlement Manual," the Secretary appears to interpret "in connection with" as meaning "for the primary purpose of," as is evident in her gloss on the definition of 'physician.' In that definition, she explains that payment may only be made for dental services whose primary purpose is not the care, treatment, removal or extraction of teeth. This appears to permit payment for services rendered as part of a broader course of treatment.

By contrast, the Secretary articulates a much narrower exception to the general ban in the MBPM that attempts to synthesize the Act's general exclusion, its definition of "dentist," and its allowance for payment of services or things usually rendered as incident to a physician's services. The so-called incident-and-integral exception requires that "if an otherwise noncovered procedure or service is performed by a dentist as incident to and as an integral part of a covered procedure or service performed by the dentist, the total service performed by the dentist on such an occasion would be covered." MBPM, Ch. 15, § 150 at 134-35 and Ch. 16, § 140 at 32. While preserving the general dental services exclusion, this rule carves out room for any service performed by a

physician so long as it is part of a broader, covered procedure and so long as the non-covered services are rendered *by the same person* and *on the same occasion* as the covered services.

Under *Skidmore*, an agency's interpretation "is still entitled to respect according to its persuasiveness, as evidenced by the thoroughness evident in the agency's consideration, the validity of its reasoning, its consistency with earlier and later pronouncements, and all those factors which give it power to persuade." *Estate of Landers*, 545 F.3d at 107. While the Court finds the incident-and-integral exception to be a plausible interpretive synthesis of the disparate parts of the Act, it does not deserve dispositive weight because its strict requirements stand in tension with the description of the dental services exclusion in the Secretary's definition of "physician," which would permit payment for dental services whose primary purpose is not merely the care or treatment of teeth. The strict requirements of the incident-and-integral exception are not compelled by the ambiguous language of the statute and, while they may ease administration of the Act, they do not enhance achievement of its remedial ends.

C. The Dental Services Exclusion Does Not Distinguish Between Routine and Non-Routine Dental Services

Plaintiff's first argument for summary judgment is based on his interpretation that "the dental coverage exclusion . . . is reserved for 'routine' dental services and was never intended to apply to non-routine, medically-essential physician services like those that Mr. Lodge required." Pl.'s. Mem. Supp. at 12.

On its face, Plaintiff's argument is undercut by the reality that the language of the Act simply does not distinguish between routine and non-routine services. Rather, it provides that no payment will be made "for services in connection with the care, treatment, filling, removal or replacement of teeth or structures directly supporting teeth . . . ." 42 U.S.C. § 1395y(a)(12).

The legislative history that Plaintiff cites likewise does not support the distinction between routine and non-routine services that Plaintiff urges, but rather one between routine services and "complex surgical procedures." This latter distinction is further supported by the Act's original definition of physician, which covered services performed by dentists "only with respect to (A) surgery related to the jaw or any structure contiguous to the jaw, or (B) the reduction of any fracture of the jaw or facial bone." Pub. L. No. 89-97, § 1861(r)(2), 79 Stat. 286, 321 (1965).

Further, the structure of the Act, which places the dental services exclusion next to an exclusion for "routine physical checkups" (42 U.S.C. § 1395y(a)(7)) or "routine foot care" (42 U.S.C. § 1395y(a)(13)(C), does not necessarily support the claim that Congress intended to exclude only routine dental services. Instead, the fact that Congress used the word "routine" in those adjacent sections suggests that it deliberately omitted the term from the dental services exclusion.

Contrary to Plaintiff's argument, the language of the dental services exclusion does not apply only to "routine" dental services. Rather, this language is part of a comprehensive statutory scheme that generally excludes payment for routine and non-routine dental services alike, but permits payment for complex surgeries.

D. The Incident-and-Integral Exception Does Not Apply to the Services Mr. Lodge Received

Plaintiff's alternative argument for summary judgment asserts that even if the dental services Mr. Lodge received fall within the dental services exclusion, those services should still be covered because the incident-and-integral exception, as articulated in the MBPM, covers these services as an integral part of Mr. Lodge's treatment for cancer and its sequelae. In doing so, Plaintiff argues that the Court should disregard the incident-and-integral exception's further requirement that the services be performed on the same occasion and by the same physician.

However, on the facts of this case, the MAC properly applied the Act to determine that the services Mr. Lodge received were appropriately excluded from coverage. Plaintiff argues that the services he received were "provided in connection with and as a continuation of his covered treatment for oral cancer," (Pl.'s Mem. Supp. at 20) and therefore covered as demonstrated by the opinion of his oncologist, Dr. Jeffrey Spiro:

> It is my opinion that all the dental care rendered in recent years for Mr. Lodge has been incident to, and an integral part of, care for his head and neck cancer and the after effects of the treatment he received for his head and neck cancer. This treatment is not routine and is specialized because issues related to dental sequelae of head and neck cancer treatment are not frequently seen by dentists in community practice and are therefore best managed in a University dental setting. Treatment such as dental extractions, hyperbaric oxygen therapy, and dental implants are medically necessary to help manage the after effects of his patient's cancer treatment. In particular, such efforts to help improve his nutritional intake and avoid serious bone infections of the upper and lower jaw are clearly medically necessary and are related to his previous cancer treatment.

Letter from Dr. Jeffrey Spiro, AR 123.

Despite Plaintiff's gloss of Dr. Spiro's letter, it does not clearly state that the services Mr. Lodge received were an integral part of his cancer treatment. The letter makes clear that Mr. Lodge's dental problems resulted from his cancer treatment, but the letter does not distinguish between the treatment itself and treatment of the "after effects" of radiation therapy.

By contrast, the record is clear the services were not part of Mr. Lodge's actual cancer treatment. Mr. Lodge's cancer treatment occurred in 1996, but his teeth were removed in 2012. Prior to the dental services, Mr. Lodge was tested for a return of his cancer, but no signs were found. AR 96. Dr. Hegde stated this clearly when he wrote that Mr. Lodge "had surgery followed by radiation therapy and subsequently has had no recurrence of the disease." AR 415. Against this background, the MAC properly concluded that the primary purpose of the dental services Plaintiff

received was the removal and replacement of teeth, and not treatment for cancer or some other covered procedure. As such, the services Mr. Lodge received fall within the statutory exclusion even if the ambiguous "in connection with" is given a broad reading to permit payment for dental services rendered as part of a broader covered course of treatment.

Plaintiff likens his case to that of the plaintiff in *Maggio v. Shalala*, 40 F. Supp. 2d 137 (W.D.N.Y. 1999), but that case is readily distinguishable. In *Maggio*, the plaintiff appealed from the MAC's denial of coverage for dental services and the district court sustained Plaintiff's appeal, finding that the dental services were incident to and an integral part of Plaintiff's treatment for cancer. However, unlike the instant case, the recital of facts in *Maggio* make it clear that the dental services were performed as part of the on-going cancer treatment. *See id.* at 140 ("ALJ Zahm determined that the dental services provided to plaintiff, as reflected in the medical records . . . was done to address plaintiff's nutritional difficulties, which were adversely affecting his treatment for leukemia and thrombocytopenia.") Mr. Lodge's treatment for cancer, by contrast, came to an end long before he received dental services.

Because the services Mr. Lodge received cannot plausibly be interpreted as in connection with his ongoing treatment for cancer, they must be understood as services rendered in connection with the care, treatment, removal and replacement of teeth. Indeed, the services Mr. Lodge received—removal and replacement of teeth—are singled out by the act's language as excluded.

While Mr. Lodge's services were not performed for any purpose beyond the removal and replacement of teeth, a too-literal application of the incident-and-integral exception of the Act requiring services to be performed by the same doctor and on the same occasion to qualify for coverage is not compelled by the language of the Act and could under certain circumstances lead to results at odds with the purpose of the Act, e.g. excluding coverage for dental services performed

a day after a covered procedure, even if the waiting time were medically necessary, or precluding coverage when one specialist performed a non-covered procedure at the direction of a different specialist performing a covered procedure.

For the foregoing reasons, the Court concludes that the MAC reached the correct decision on the particular facts of this case. Defendant's request for summary judgment is accordingly GRANTED with respect to Plaintiff's first cause of action. Plaintiff's request for summary judgment is DENIED with respect to Plaintiff's first cause of action.

E. Amendment of Regulations Did Not Violate the APA

In his second cause of action, Plaintiff asserts that the 1973 Amendment to 20 C.F.R. § 405.310(i) violated the notice and comment rule-making requirements of the Administrative Procedure Act ("APA"), 5 U.S.C. § 553(b) and (c), because the Secretary did not provide interested parties with notice of or opportunity to comment on the deletion of the word "routine" from the regulation. Defendant maintains that interested parties were on notice that the Secretary intended to introduce changes to the regulations to conform them to the Congressional amendments.

Both parties agree that the APA requires a period of notice and comment when the Secretary advances amendments to regulations. The parties further agree that final regulations must be a "logical outgrowth" of the proposed rule. *Long Island Care at Home, Ltd. v. Coke*, 551 U.S. 158, 174 (2007). The test for logical outgrowth is whether the proposed amendments provide fair notice to interested persons. *Nat'l Black Media Coal. v. F.C.C.*, 791 F.2d 1016, 1022 (2d Cir. 1986)(interior citations omitted). The Second Circuit requires that agencies describe "with reasonable specificity" any proposed changes to a regulation because a general notice "that a new standard will be adopted," violates the notice-and-comment requirements of the APA. *Time Warner Cable Inc. v. F.C.C.*, 729 F.3d 137, 170 (2d Cir. 2013).

It is true that the Secretary did not announce her intention to delete the word "routine" from the proposed regulation, only that the purpose of the amendments "is to reflect the changes made by . . . the Social Security Amendments of 1972 . . . ." 38 F.R. 17246 (June 29, 1973) at 17246, Ex J to Pl.'s Mot. Summ. J. [Doc. # 39-11]. The proposed regulation that was printed at the commencement of the notice-and-comment period thus retained the word routine and added only the exception for payment of hospitalization costs in connection with certain inpatient dental procedures.

However, Plaintiff's contention that deletion of the word routine "greatly broaden[ed] the coverage exclusion" (*id.* at 15) is less plausible because it relies on the assumption the "routine dental services" excluded by the 1966 regulations were limited in scope. Other passages in the Act suggest this was not the case. For example, the Act's original definition of "physician," to include "a doctor of dentistry or of dental or oral surgery," but "only with respect to (A) surgery related to the jaw or any structure contiguous to the jaw, or (B) the reduction of any fracture of the jaw or facial bone" (Pub. L. No. 89-97, § 1861(r)(2), 79 Stat. 286, 321 (1965)) highlights that coverage under Part B for physician's services could only extend to jaw surgery or the reduction jaw or facial bone fractures, and not to other services performed by dentists. When taken out of context, deletion of the word 'routine' appears to effect a significant change in the standard, as Plaintiff suggests, but when placed back in context, it is apparent that Congress enacted a general exclusion that did not distinguish between 'routine' and 'non-routine' procedures, but only between 'routine' procedures and 'complex surgical procedure.'

The Secretary did not simply give general notice that a new standard will be adopted, but rather announced that the regulations would be amended to reflect changes to the Act, including the dental services exclusion. While this does not specifically address the use or deletion of the

word routine, and so was not an ideal form of notice, it did put interested persons on notice that the regulations would be amended to conform to the statute. Since deletion of the word "routine" brought the regulation into conformity with the statute, and as a result it did not materially modify the scope of the dental services exclusion, the final regulation can be seen as a logical outgrowth of the proposed regulation.

For the foregoing reasons, Plaintiff's motion for summary judgment with respect to Count Two is DENIED. Defendant's motion for summary judgment with respect to Count Two is GRANTED.

VIII. Conclusion

For the foregoing reasons, Defendant's Motion for Summary Judgment is GRANTED and Plaintiff's Motion for Summary Judgment is DENIED. The Clerk is requested to close the case.

IT IS SO ORDERED.

/s/
Janet Bond Arterton, U.S.D.J.

Dated at New Haven, Connecticut this 30th day of December 2016.