

No. _____

**In The
Supreme Court of the United States**

DELORES BERG and THOMAS DICECCO, JR., on
behalf of themselves and all others similarly situated,

Petitioners,

v.

KATHLEEN SEBELIUS, Secretary of the
Department of Health and Human Services,

Respondent.

**On Petition For A Writ Of Certiorari
To The United States Court Of Appeals
For The Ninth Circuit**

PETITION FOR A WRIT OF CERTIORARI

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January 2014

QUESTION PRESENTED

The Secretary of Health and Human Services uses Medicare manual provisions to interpret a statutory provision that excludes routine dental care from coverage. The manual interpretation, however, excludes far more than routine care, as it denies coverage for extraordinary surgical work related to a covered medical condition, simply because the work is performed in the mouth. Relying on the fact that the manual provisions are applied by the Medicare Appeals Council, which is the final stage of review in the Medicare administrative appeals system, the Ninth Circuit accorded *Chevron* deference to the Secretary's interpretation and found it reasonable. The question presented is:

Whether a court should accord *Chevron* deference to Medicare Appeals Council decisions, which lack the force of law, when the Medicare Appeals Council applies Medicare manual provisions, which also lack the force of law.

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OPINIONS BELOW

The opinion of the Ninth Circuit is reported at 718 F.3d 1110 and reproduced in the Appendix (“App.”) at App. 1. The opinion of the District Court for the District of Arizona is reported at 839 F. Supp. 2d 1077 and reproduced at App. 31. The Ninth Circuit’s unreported Order denying the petition for rehearing or rehearing en banc is reproduced at App. 47.



JURISDICTION

The judgment of the Ninth Circuit was entered on May 31, 2013. App. 1. On July 12, 2013, the petitioners filed a petition for rehearing or rehearing en banc, which was denied on October 22, 2013. App. 47. The jurisdiction of this Court is invoked under 28 U.S.C. § 1254(1).



PROVISIONS INVOLVED

42 U.S.C. § 1395y(a) Items or services specifically excluded

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, except that payment may be made under part A of this subchapter in the case of inpatient hospital services in connection with the provision of such dental services if the individual, because of his underlying medical condition and clinical status or because of the severity of the dental procedure, requires hospitalization in connection with the provision of such services. . . .

42 C.F.R. § 411.15 Particular services excluded from coverage.

The following services are excluded from coverage:

* * *

(i) *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.
[Footnote omitted.]



STATEMENT OF THE CASE

A. Medicare Coverage of Dental Services

The underlying issue of this case is the respondent Secretary's exclusion from Medicare coverage of virtually all medical work performed in a patient's mouth, regardless of its complexity, its necessity to treat a larger illness or injury, and its connection to a covered medical condition. The district court's jurisdiction was predicated on 42 U.S.C. § 405(g) (as incorporated by 42 U.S.C. §§ 1395w-22(g)(5) and 1395ff(b)(1)).

The issue before this Court is whether the lower court properly accorded *Chevron* deference to Medicare Appeals Council (MAC) decisions, which lack the force of law.¹ That decision conflicts not only with *Christensen v. Harris County*, 529 U.S. 576, 587 (2000) and *United States v. Mead Corp.*, 533 U.S. 218, 234 (2001), but with the opinions of six appellate courts that have rejected *Chevron* deference in the identical context of non-precedential decisions by the Board of Immigration Appeals. See *infra* at 10.

When Congress created Medicare in 1965, it carved out several routine services for which Medicare coverage would not be available, including eye and hearing examinations, physical checkups, and regular dental care. 42 U.S.C. § 1395y(a)(7)-(12); see

¹ See *Chevron, U.S.A., Inc. v. Natural Res. Def. Council, Inc.*, 467 U.S. 837, 843 (1984).

also 42 C.F.R. § 411.15. Through the dental exclusion, Congress did not intend to deprive beneficiaries of coverage for extraordinary surgical work performed in the mouth, but for routine dental care, as the legislative history underscored:

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. Thus, . . . a routine annual or semi-annual checkup would not be covered. . . . Similarly, too, routine dental treatment – filling, removal, or replacement of teeth or treatment of structures directly supporting the teeth, would not be covered.

S. Rep. No. 89-104 (1965), reprinted in 1965 U.S.C.C.A.N. 1943, 1989-1990. Accordingly, the original implementing regulation limited the exclusion to “[r]outine dental services.” 20 C.F.R. § 405.310(i) (published at 31 F.R. 13534, 13535 (Oct. 20, 1966)).

Despite this straightforward legislative demarcation between the routine and the complex, the Secretary’s manual provisions have constructed an elaborate and enigmatic patchwork of coverage rules, exceptions, and exceptions to the exceptions. Thus, for instance, “[w]hen an excluded service is the primary procedure involved, it is not covered regardless of its complexity or difficulty.” Medicare Benefit Policy Manual, CMS Pub. 100-02, Ch. 15, § 150; Ch.

16, § 140.² As a consequence of the manual's restrictive gloss, most non-routine medical procedures performed in the mouth, such as those required to treat an underlying disease or condition, are not covered.

B. Proceedings Below

1. The petitioners, Delores Berg and Thomas DiCecco, suffer from autoimmune diseases that have destroyed their salivary glands and, in turn, their teeth and gums. Untreated, their dental problems exacerbated their medical conditions, causing life-threatening infections and other systemic complications, as the court below recognized. App. 4-6.

After exhausting administrative remedies via MAC decisions affirming their coverage denials, Ms. Berg and Mr. DiCecco joined an ongoing lawsuit. Amending the complaint to request certification of a nationwide class of Medicare beneficiaries, the petitioners contended that the Secretary's manual provisions had misinterpreted the routine dental exclusion provision.

The district court accorded *Chevron* deference to the Secretary's interpretation and rejected the petitioners' claims. *Id.* at 40-41.

² The manuals are available online at <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Internet-Only-Manuals-IOMs.html>.

2. On appeal, the Ninth Circuit panel observed that the statute was ambiguous and thus turned to *Chevron's* step two. *Id.* at 18. Stating that the Secretary's interpretation was not the product of notice-and-comment rulemaking or formal adjudication, the court then considered the appropriate level of deference. *Id.* at 19. Although agreeing with the Secretary's acknowledgment that Medicare manual provisions do not carry the force of law (*id.*), the panel, citing *Barnhart v. Walton*, 535 U.S. 212 (2002), held that the manual provisions "gain[ed] the force of law through the process of adjudication," that is, through the decisions on individual cases by the MAC. App. 24. That determination led to the penultimate conclusion that *Chevron* deference should be accorded, and then, pursuant to that deferential review, that the Secretary's interpretation was reasonable. *Id.* at 25-28.

Thus, while recognizing the established principle that manual provisions are not entitled to *Chevron* deference, the Ninth Circuit panel treated MAC decisions as possessing an alchemic quality. The panel thereby accorded MAC decisions a degree of significance that belies their reality, as the court ignored that those decisions, which are not binding on third parties and do not establish precedent, lack the force of law. The effect of the Ninth Circuit's analysis is to elevate MAC decisions to a status equivalent to formal adjudication, thus putting the court's decision

in conflict with numerous appellate decisions rejecting an authoritative role for such low-level adjudication.



REASONS FOR GRANTING THE PETITION

The Panel’s Decision Conflicts with this Court’s and Other Appellate Courts’ Rulings that Preclude *Chevron* Deference for Agency Actions that Lack the Force of Law.

A. It is impossible to reconcile the conflict created by the Ninth Circuit’s holding on the proper level of deference accorded adjudications that do not have the force of law.

“[I]nterpretations contained in policy statements, agency manuals, and enforcement guidelines, all of which lack the force of law – do not warrant *Chevron*-style deference.” *Christensen*, 529 U.S. at 587. Thus, agency manuals “are beyond the *Chevron* pale.” *Mead*, 533 U.S. at 234. Just this past Term, this Court reiterated that “[i]nterpretations contained in . . . agency manuals . . . lack the force of law [and] do not warrant *Chevron*-style deference.” *Wos v. E.M.A.*, 133 S.Ct. 1391, 1402 (2013) (quoting *Christensen*, 529 U.S. at 587). No one disputes this point: “The Secretary agrees that her interpretation in the CMS Manual does not by itself carry the force of law.” App. 19.

The panel, however, theorized that Medicare manual provisions “gain the force of law through the process of adjudication of a ‘vast number of claims’

under [42 U.S.C.] § 405(b).” App. 24. That is, MAC decisions possess an unknown ingredient that infuses them with the de facto status of formal adjudications, thus trumping the manual provisions’ lack of authority.

In taking this approach, however, the panel ignored the fact that MAC decisions are as lacking in authority as manual provisions. They are binding only on the parties to the adjudication. 42 C.F.R. § 405.1130. As the Secretary has explicitly acknowledged, they have no precedential or binding effect on third parties: “After thorough consideration, [the Department of Health and Human Services] determined that 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).

The Secretary recently confirmed this position, stating that she would not “afford precedential weight to . . . Medicare Appeals Council decisions.” 78 F.R. 50496, 50929 (Aug. 19, 2013). She explained that MAC decisions primarily involve individual fact situations that do not translate well into precedential authority:

[C]overage and liability determinations on Medicare claims are largely unique to the specific set of facts in a given case, and requiring precedential authority or deference to certain decisions would prove extremely difficult. . . . For these reasons, we continue to believe it would be inappropriate to afford

precedential weight or require deference to appeals decisions on inpatient admissions even in situations where the admissions involve a similar set of facts or issues.

Id.

Thus, the purpose of MAC decisions is not to set policy, but to provide a final level of review for individual cases. As a consequence, different MAC decisions, which are usually decided by a single adjudicator, interpret the coverage rules differently. MAC decisions are made without public scrutiny or input and thus do not “foster the fairness and deliberation that should underlie a pronouncement” of a rule with the force of law. *Mead*, 533 U.S. at 230. Like the tariff classification rulings in *Mead* that also have no binding effect on third parties and were issued at a rate of 10,000 per year, the sheer volume of MAC decisions – 2,515 appeals decided involving more than 26,000 individual claims in fiscal year 2012³ – precludes any suggestion that they are intended to have the force of law. See *id.* at 233.

One other appellate court has held that a MAC decision is entitled to *Chevron* deference. *Gentiva Healthcare Corp. v. Sebelius*, 723 F.3d 292, 295 (D.C. Cir. 2013). Like the panel in this case, the D.C. Circuit failed to recognize that MAC decisions are

³ Thomas E. Herrman, *The Medicare Appeals Process – Is It Working In 2013?* at 7 (Mar. 2013), available at <http://www.compliance.com/the-medicare-appeals-process-is-it-working-in-2013>.

neither binding on third parties nor precedential, and therefore lack the force of law. The court seems to have assumed, without analysis, that a MAC decision represents a type of formal adjudication.

The Ninth and D.C. Circuits' decisions stand in sharp contrast to the decisions of six appellate courts that have expressly rejected *Chevron* deference for the identical type of decision made by the Board of Immigration Appeals (BIA), which is the highest level of administrative review for interpreting the immigration laws. *Dhuka v. Holder*, 716 F.3d 149, 154-156 (5th Cir. 2013); *Arobelidze v. Holder*, 653 F.3d 513, 519-520 (7th Cir. 2011); *Carpio v. Holder*, 592 F.3d 1092, 1097-1098 (10th Cir. 2010); *Quinchia v. U.S. Attorney General*, 552 F.3d 1255, 1258 (11th Cir. 2008); *Rotimi v. Gonzales*, 473 F.3d 55, 57-58 (2d Cir. 2007); *Garcia-Quintero v. Gonzales*, 455 F.3d 1006, 1011-1014 (9th Cir. 2006); see also *De Leon-Ochoa v. Attorney General of United States*, 622 F.3d 341, 350 (3d Cir. 2010) (agreeing that BIA decisions do not carry the force of law but not deciding the deference issue). The conflict could not be more direct, and reconciliation with the decisions according *Chevron* deference to the MAC decisions is not possible.

In the decisions about the BIA, the courts considered the appropriate level of deference accorded to statutory interpretations by the BIA, which, unless specifically so designated, are not precedential or binding on third parties and thus lack the force of law. As the Fifth Circuit, the most recent court to rule in this area, concluded:

We view the key here as being whether the BIA decision made law that binds third parties. . . . We conclude that a non-precedential opinion of the BIA does not, due to the terms of the regulation itself, bind third parties and is not entitled to *Chevron* deference.

Dhuka, 716 F.3d at 156 (citation omitted); see also, e.g., *Arobelidze*, 653 F.3d at 520 (emphasizing this point in overruling prior Seventh Circuit law to conform with other circuits).

The two administrative review schemes are identical in all relevant respects. Decisions by the MAC are not binding on third parties or precedential. Most decisions by the BIA, and all of those at issue in the cited decisions, are not binding on third parties or precedential.⁴ Both entities churn out thousands of decisions per year. See Department of Justice, “Fact Sheet,” at 2 (Aug. 23, 2002), available at <http://www.justice.gov/eoir/press/02/BIARulefactsheet.pdf>. Consequently, neither MAC decisions nor the relevant BIA decisions have the force of law. Nevertheless, Medicare beneficiaries (and, by extension, other Social Security Act beneficiaries) will be at a significant disadvantage when challenging interpretations of the

⁴ The exceptions are three-member decisions specifically designated as precedential or decisions that rely on precedential decisions. See, e.g., *Dhuka*, 716 F.3d at 156; *Arobelidze*, 653 F.3d at 519-520; *Carpio*, 592 F.3d at 1097; see also *de Osorio v. Mayorkas*, 695 F.3d 1003, 1011 (9th Cir. 2012) (en banc), *cert. granted*, 133 S.Ct. 2853 (2013).

Medicare statute as compared to their counterparts challenging interpretations of immigration law. This distinction is illogical, and it also runs directly contrary to the definitive prohibition in *Mead* against according *Chevron* deference to manual provisions.

At the very least, the contrast between the appellate courts' view of deference for the review systems of two important federal agencies reflects confusion. The Ninth Circuit's and the D.C. Circuit's failure to recognize the non-authoritative nature of MAC decisions represents a refusal to follow *Mead*'s directive "that the *sine qua non* of *Chevron* deference is an agency statement carrying the force of law." *Arobelidze*, 653 F.3d at 520 (citing *Mead*, 533 U.S. at 226-227); see also, e.g., *Dhuka*, 716 F.3d at 155; *De Leon-Ochoa*, 622 F.3d at 350; *Rotimi*, 473 F.3d at 58. MAC decisions do not carry that imprimatur.

The ultimate illogic of the Ninth Circuit's decision is that according deference to a MAC decision gives that decision more authority in the court system than it enjoys in the administrative process. Noting this irony, the Tenth Circuit agreed with a law review article that "it would be extremely odd to give . . . decisions [by administrative law judges] greater legal force in court than they have within the agency itself." *Carpio*, 592 F.3d at 1097 (internal quotation marks and citation omitted; brackets in opinion).

The appellate courts' inconsistent application of *Mead*'s force-of-law directive requires this Court's intervention.

B. In addition to the conflict that it creates, the Ninth Circuit's decision establishes an irrational policy and misconstrues *Barnhart*.

The panel's approach also reflects misunderstandings of the decision's ramifications and of the *Barnhart* decision. First, the effect of the decision is to require courts to accord *Chevron* deference for the peculiar reason that beneficiaries must exhaust administrative remedies. See, e.g., *Mathews v. Eldridge*, 424 U.S. 319, 328 (1976). Although there are valid reasons for the exhaustion obligation, that requirement, which leads to MAC decisions, was not intended to impose *Chevron* deference in the ensuing litigation. In effect, a beneficiary's ability to challenge a statutory interpretation is circumscribed by the obligation to obtain complete administrative review.

Second, the panel's theory has expansive ramifications. Any Medicare manual provision would be entitled to *Chevron* deference by simply passing through the lens of administrative adjudication that results in MAC decisions. In fact, the analysis applies to all combinations of a Social Security Act manual provision and the required administrative review under 42 U.S.C. § 405(g), thus implicating the Social Security old age and disability programs and the Supplemental Security Income program, Titles II and XVI of the Social Security Act. Indeed, the Ninth Circuit's approach would be applicable to every federal program that relies on both manual-type guidance and administrative review.

The panel cited no specific authority for its analysis, but purported to derive support from *Barnhart*, 535 U.S. at 221-222. The Ninth Circuit found significant that, in dicta, this Court accorded deference to a Social Security Ruling. App. 23-24. It equated that Ruling with a Medicare manual provision, but they are qualitatively different.

The Social Security program's guidance that is comparable to Medicare manual provisions is the Program Operations Manual System (POMS). Like Medicare manuals, the POMS is merely "the publicly available operating instructions for processing Social Security claims," and, accordingly, is not accorded *Chevron* deference but is assessed under *Skidmore v. Swift & Co.*, 323 U.S. 134, 140 (1944). *Washington State Dept. of Soc. & Health Servs. v. Guardianship Estate of Keffeler*, 537 U.S. 371, 385-386 (2003).

In contrast to the POMS and Medicare manuals, Social Security Rulings "are binding on all components of the Social Security Administration. These rulings represent precedent final opinions and statements of policy and interpretations that we have adopted." 20 C.F.R. § 402.35(b)(1). The panel thus erred in equating those Rulings with manual provisions. *Barnhart's* according of *Chevron* deference to a Social Security Ruling cannot carry over to Medicare manual provisions.⁵

⁵ Medicare (or Centers for Medicare and Medicaid Services (CMS)) Rulings *are* the equivalent of Social Security Rulings, as
(Continued on following page)

Furthermore, nothing in *Barnhart* alludes to or suggests that a “process of adjudication” supports *Chevron* deference to an administrative review system’s decisions that lack the force of law.

◆

CONCLUSION

For the foregoing reasons, the petition for a writ of certiorari should be granted.

Respectfully submitted,
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they are binding on all CMS components, on the Department of Health and Human Services components that adjudicate CMS matters, and on some components of the Social Security Administration. 42 C.F.R. §§ 401.108(c), 405.1063(b). The policy at issue, however, is not the product of a Medicare Ruling, but of manual provisions.

FOR PUBLICATION
UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

RONALD FOURNIER,

Plaintiff,

and

DELORES BERG;
THOMAS DiCECCO, JR.,

Plaintiffs-Appellants,

v.

KATHLEEN SEBELIUS, Secretary
of the Department of Health
and Human Services,

Defendant-Appellee.

No. 12-15478

D.C. No.
2:08-cv-02309-ROS

OPINION

Appeal from the United States District Court
for the District of Arizona,
Roslyn O. Silver, Chief District Judge, Presiding

Argued and Submitted
March 5, 2013 – Pasadena, California

Filed May 31, 2013

Before: Alfred T. Goodwin, Kim McLane Wardlaw,
and Ronald M. Gould, Circuit Judges.

Opinion by Judge Gould

SUMMARY*

Medicare

The panel affirmed the district court's judgment affirming the Secretary of Health and Human Services' decisions denying plaintiffs' claims for Medicare coverage for dental services.

Plaintiffs are Medicare beneficiaries who suffer from medical conditions that caused significant dental problems, and they received dental services to correct those problems. The panel held that the Medicare Act under which the Secretary denied coverage was ambiguous on the question plaintiffs raised. The panel further held that *Chevron* deference applied, and the Secretary's interpretation of the statute was reasonable. Finally, the panel held that the Secretary's denial of coverage did not violate plaintiffs' equal protection rights under the Fifth Amendment.

COUNSEL

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* This summary constitutes no part of the opinion of the court. It has been prepared by court staff for the convenience of the reader.

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OPINION

GOULD, Circuit Judge:

Appellants Delores Berg and Thomas DiCecco are Medicare beneficiaries who suffer from medical conditions that caused significant dental problems, and they received dental services to correct those problems. But the Secretary of the Department of Health and Human Services (HHS) denied coverage for those services. Appellants contend that this denial was premised on the Secretary's unreasonable interpretation of the Medicare Act, which contravenes the intent of Congress and violates Appellants' right to equal protection under the Fifth Amendment. We affirm the district court, holding (1) that the statute under which the Secretary denied coverage is ambiguous on the question Appellants raise; (2) that *Chevron* deference applies; (3) that the Secretary's interpretation of the statute is reasonable; and (4)

that the denial does not violate Appellants' Fifth Amendment rights.¹

I

Berg is a Medicare Advantage beneficiary. She suffers from Sjogren's Syndrome, which has left her unable to produce saliva. As a result, she lost teeth, her gums deteriorated, and her bite collapsed. Berg's lack of saliva made her prone to gum infections, which put her at risk of a life-threatening heart infection. In response to the grave conditions and risks caused by Sjogren's syndrome, Berg's dentist recommended a treatment plan that would "develop and reconstruct a leveled bite," with procedures including a partial denture, several crowns, and bridgework. Berg underwent the recommended procedures on February 27, 2008, at a total cost of \$28,750.00.

Berg submitted a claim for these services to her Medicare Advantage provider. Her provider denied the claim because Berg was enrolled in a plan that did not cover "[r]outine dental care (such as cleanings,

¹ Appellants do not directly challenge the Secretary's final decision on their individual claims for benefits but instead challenge the policy leading to those unfavorable rulings. Because we affirm the district court on both of Appellants' substantive claims, we need not and do not reach their claim that the district court erred in concluding that putative class members did not qualify for waiver of exhaustion of administrative remedies.

fillings, or dentures) or other dental services.” Berg’s provider sent her appeal to an independent outside review entity, which told Berg that the dental services related to Sjogren’s syndrome do not fall within the limited dental coverage of her Medicare Advantage plan and denied her appeal. Berg then appealed to an Administrative Law Judge (“ALJ”), who ruled that the services Berg received were excluded by Medicare’s dental-services exclusion. Although the plan representatives and the ALJ acknowledged that Berg’s dental problems stemmed from her Sjogren’s syndrome, the ALJ concluded that the services at issue did not fall under any exception to the dental exclusion because Berg’s “dental work was the primary procedure, rather than necessary to or incident to any Medicare covered procedure.” The Medicare Appeals Council (“MAC”) adopted the ALJ’s decision and denied Berg’s appeal, explaining, “Services performed in connection with the care, treatment, filling, removal, or replacement of teeth or structures directly supporting teeth are not covered and, to the extent coverage is provided, it is only under limited circumstances not applicable to this case.”

Thomas DiCecco, Jr., is a Medicare beneficiary under Parts A and B. In 1996, several years before becoming eligible for Medicare, DiCecco received an allogeneic bone-marrow transplant to treat chronic myelogenous leukemia. He received a donor lymphocyte infusion in June 1999. As a result of these treatments, DiCecco developed graft-versus-host disease,

with a resulting loss of salivary function. As it did with Berg, DiCecco's lack of saliva led to tooth loss. DiCecco's tooth decay was so severe that it caused "certain teeth to just crack off," and forced him to use a feeding tube for nearly a year. More than a decade after DiCecco's bone-marrow transplant, his dentist prescribed a course of treatment, responding to the graft-versus-host disease with frequent examinations and restorative dental work such as fillings and crowns. DiCecco had this treatment from April to July 2008. DiCecco then submitted a claim for reimbursement for resin, crown, and fluoride treatments to his Medicare Part B contractor. His contractor denied the claim in full, and an independent contractor upheld the denial. DiCecco appealed to an ALJ, who recognized that DiCecco needed the dental care because of his graft-versus-host disease but upheld the denial because "dental services are excluded from Medicare coverage regardless of the medical need for those services." The MAC adopted the ALJ's decision and acknowledged that DiCecco's need for dental services was provoked by a medical condition. But the MAC explained that the relationship between DiCecco's graft-versus-host disease and his dental services does not, by itself, qualify the dental services for Medicare coverage. DiCecco's treatments would be covered only if they were furnished along with a covered procedure that was performed by the dentist on the same occasion.

Berg and DiCecco joined a lawsuit filed by Ronald Fournier, who raised similar claims to those

of Berg and of DiCecco.² The plaintiffs challenged the MAC decisions, which were the Secretary's final decisions in their cases, and sought declaratory and injunctive relief advocating the views that the Secretary's decision to deny coverage for their extraordinary, medically related dental services violated HHS policy, the Medicare Act, and their right to equal protection. The district court held (1) that substantial evidence supported the Secretary's decisions denying coverage to Berg and DiCecco, (2) that the Secretary's statutory interpretation excluding coverage was reasonable, and (3) that the Secretary's policy does not violate the equal protection guarantee in the Fifth Amendment's due process clause. This appeal followed.

II

This appeal centers on the broad exclusion of dental services from Medicare coverage, so we discuss the development of that exclusion. Congress established Medicare in 1965 as Title XVIII of the Social Security Act ("Medicare Act"). Pub. L. No. 89-97, 79 Stat. 286 (1965). Medicare provides medical services to (1) the aged, (2) the disabled, and (3) those who have end-stage renal (kidney) disease. 42 U.S.C. § 1395c. The Secretary of Health and Human Services

² Fournier received a favorable ruling from an ALJ before the district court issued its order, so Fournier's claims were dismissed as moot. *Fournier v. Sebelius*, 839 F. Supp. 2d 1077, 1081 (D. Ariz. 2012).

administers the program, and she has authority to prescribe necessary regulations, § 1395hh(a)(1), and determine which claims will be covered, § 1395ff(a). The Secretary may issue National Coverage Determinations to define what services are considered reasonable and necessary. § 1395ff(f)(1)(B).

Medicare provides institutional care, including inpatient hospital services, through Part A, § 1395d(a), and authorizes payment for supplemental and outpatient services in Part B, § 1395k. Part C, known as Medicare Advantage, allows beneficiaries to receive services authorized under Parts A and B through managed-care or fee-for-service plans. § 1395w-22(a)(1)(A), (a)(1)(B)(i).

Medicare coverage is broadly limited to services that are medically “reasonable and necessary.” *See* § 1395y(a)(1)(A)-(C). Medicare coverage is also subject to specific restrictions, one of which, prominent here, excludes most dental services from reimbursement. That exclusion denies payment for any expenses incurred:

for services in connection with the care, treatment, filling, removal, or replacement of teeth or structures directly supporting teeth, except that payment may be made under part A of this subchapter in the case of inpatient hospital services in connection with the provision of such dental services if the individual, because of his underlying medical condition and clinical status or because of the severity of the dental procedure, requires

hospitalization in connection with the provision of such services;

§ 1395y(a)(12). The exclusion, without the exception for inpatient services under Part A, was included in the initial form of the Medicare Act. *See* Pub. L. No. 89-97, § 1862(a)(12), 79 Stat. 286, 325 (1965). The Senate Report accompanying the Medicare Act said that this exclusion was intended “to make clear that the services of dental surgeons covered under the bill are restricted to complex surgical procedures” and that “routine dental treatment – filling, removal, or replacement of teeth or treatment of structures directly supporting the teeth – would not be covered.” S. Rep. No. 89-404, at 49 (1965), *reprinted in* 1965 U.S.C.C.A.N. 1943, 1989-90. This explanation moves us towards the core of the problem presented on this appeal. When the Secretary first promulgated regulations under the dental exclusion in § 1395y(a)(12), she added the word “routine” to the statutory exclusion, excluding coverage for “[r]outine dental services in connection with the care, treatment, filling, removal, or replacement of teeth, or structures directly supporting the teeth.” 31 Fed. Reg. 13534, 13535 (Oct. 20, 1966).

Congress also limited coverage for dental services in a second way: by restricting the definition of “physician.” The Medicare Act distinguished between complex, covered dental procedures and common, excluded procedures by defining “physician” to include dentists and oral surgeons only when they performed “(A) surgery related to the jaw or any

structure contiguous to the jaw or (B) the reduction of any fracture of the jaw or any facial bone.” Pub. L. No. 89-97, § 1861(r)(2), 79 Stat. 286, 321 (1965).

Covered services, such as surgery related to the jaw, often require individual procedures, such as tooth removal, that standing alone would not be covered as primary procedures. As a result, the Secretary needed to determine when a dental service was provided “in connection with” a covered primary procedure such that the dental service would be covered. Shortly after passage of the Medicare Act, the Director of the Bureau of Health Insurance answered this question in policy guidance to clarify the coverage of secondary dental services in his Intermediary Letter No. 193 of January 30, 1967.

The Director reasoned that because a dentist was defined as a “physician” only when performing surgery “related to the jaw or structures contiguous to the jaw (including the reduction of any fracture of the jaw or any facial bone), all such surgical procedures performed by a dentist” would be covered unless specifically excluded. By contrast, any services rendered in connection with the examination, care, treatment, filling, removal, or replacement of teeth and any services rendered in connection with the examination, care, or treatment of structures directly supporting the teeth were excluded.³ The Director

³ According to the Secretary, “[s]tructures directly supporting the teeth’ means the periodontium, which includes the gingivae,
(Continued on following page)

explained that Medicare would cover these procedures when performed on the same occasion by a dentist “as an incident to and as an integral part of a covered procedure or service *performed by him*.” If an excluded service were the primary procedure, however, that procedure and any adjuncts “would not be covered regardless of the complexity or difficulty of the procedure.” This is known as the “same physician rule.”⁴ See *Wood v. Thompson*, 246 F.3d 1026, 1030 (7th Cir. 2001).

Congress revisited the exclusion of primary dental services in 1972, when it amended § 1395y(a)(12) to give coverage for dental services “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

dentogingival junction, periodontal membrane, cementum of the teeth, and alveolar process.” Centers for Medicare & Medicaid Servs., Publ’n No. 100-02, *Medicare Benefit Policy Manual*, ch. 15, § 150, at 134.

⁴ The same-physician rule is often described as an exception to the exclusion of coverage for dental procedures as primary services under 42 U.S.C. § 1395y(a)(12). See *Fournier v. Sebelius*, 839 F. Supp. 2d 1077, 1081 (D. Ariz. 2012) (“[T]o be covered by [the] exception, the dental services would have to be furnished along with another covered procedure *performed by the dentist on the same occasion*.”) (quoting the MAC). Section 1395y(a)(12), however, excludes coverage for services “in connection” with dental services. It does not provide, limit, or consider dental services that are provided “in connection” with services “furnished as an incident to a physician’s professional service” as defined in 42 U.S.C. § 1395x(s)(2)(A).

hospitalization.” Pub. L. No. 92-603, § 256(c), 86 Stat. 1329, 1447 (1972). The next year, Congress again amended this subsection to clarify the coverage of inpatient dental services, allowing coverage only if the patient’s “underlying medical condition and clinical status require[d] hospitalization in connection with the provision of such services.” Pub. L. No. 93-233, § 18(k)(3), 87 Stat. 947, 970 (1973). In response to these amendments, the Secretary issued a new regulation “[t]o conform the regulatory language regarding hospital admissions for excluded dental services with the statutory language.” 39 Fed. Reg. 28622, 28623 (Aug. 9, 1974). This 1974 revision removed the word “routine” from the coverage exclusion and noted that the 1973 statutory amendment, Pub. L. 93-233, § 18(k), “confirmed the substantive position taken in the proposed regulations.” *Id.*; *see also* 42 C.F.R. § 411.15(i).

In 1980, Congress amended the Medicare Act to expand the role of dentists in two ways. First, the definition of “physician” was amended 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.” Pub. L. No. 96-499, § 936(a), 94 Stat. 2599 (1980); *see also* 42 U.S.C. § 1395x(r). The accompanying House Report stated that “there are some services which are covered under Medicare only if performed by a physician . . . but are not covered when furnished by a dentist.” H.R. Rep. No. 96-1167 at 372 (1980),

reprinted at 1980 U.S.C.C.A.N. 5526, 5735. The amended language “provide[d] the same coverage for services performed by a dentist . . . that is provided for services performed by physicians.” *Id.*

Second, Congress granted admitting privileges to dentists and expanded coverage of inpatient dental services. Before the 1980 amendment, inpatient dental services were covered only when a patient was hospitalized for an underlying, nondental condition. *See id.* Coverage was “precluded where, in the judgment of the patient’s dentist, the severity of the dental procedure alone require[d] hospitalization.” *Id.* Congress amended the section to cover “hospital stays based on a dentist’s (or physician’s) certification that hospital inpatient services are necessary for the performance of noncovered dental procedures either because of the severity of the dental procedure or the patient’s underlying condition warrants such hospitalization.” *Id.* at 5735-36. These changes were meant to bring parity to the role of dentists and provide for greater inpatient dental coverage under Part A, not expand the provision of outpatient dental services under Part B, so the “exclusion of routine dental services . . . remain[ed] in effect.” *Id.* at 5735.

These changes to the role of dentists did not change the scope of coverage of dental services on an outpatient basis, and the text of the dental exclusion has not changed since passage, apart from the allowance for inpatient coverage under Part A. *Compare* Pub. L. No. 89-97, § 1862(a)(12), 79 Stat. 286, 325, *with* 42 U.S.C. § 1395y(a)(12). Medicare contractors

must still determine whether dental services are provided “in connection” with a covered, primary service. As a result, the same-physician rule remains in effect. The Centers for Medicare and Medicaid Services (CMS) *Medicare Benefit Policy Manual* (CMS Manual) describes the rule in language similar to that found in the 1967 Intermediary Letter No. 193, explaining:

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 is covered.

Centers for Medicare & Medicaid Servs., Publ’n No. 100-02, *Medicare Benefit Policy Manual*, ch. 15, § 150, at 134.; *see also id.* ch. 16 § 140.

An exception to the same-physician rule allows for reimbursement of dental services provided in preparation for a covered procedure performed by a different physician: the extraction of teeth to prepare a patient’s jaw for radiation treatment of neoplastic disease. *Id.* at ch. 15, § 150. Most often, a dentist will extract the patient’s teeth and a radiologist will administer the radiation treatments. *Id.* In a similar situation, Medicare covers dental examinations on an inpatient basis as part of a work-up before kidney transplant surgery. Centers for Medicare & Medicaid Servs., Publ’n No. 100-03, *Medicare National Coverage Determinations Manual*, § 260.6. This examination is only provided on an inpatient basis, so it now likely falls under the general allowance for inpatient

services under Part A.⁵ In both situations, however, the purpose of the dental procedure is not the care of teeth or structures supporting teeth but the preparation for a subsequent, covered procedure.

III

We have jurisdiction under 42 U.S.C. §§ 405(g), 1395w-22(g)(5), and 1395ff(b)(1)(A) and 28 U.S.C. § 1291. We review a district court's decision upholding the MAC's decisions de novo. *Conahan v. Sebelius*, 659 F.3d 1246, 1249 (9th Cir. 2011). We review de novo a district court's constitutional rulings, *Wright v. Incline Vill. Gen. Improvement Dist.*, 665 F.3d 1128, 1133 (9th Cir. 2011), as well as its decisions on questions of statutory interpretation, *Portland Adventist Med. Ctr. v. Thompson*, 399 F.3d 1091, 1095 (9th Cir. 2005).

IV

Appellants contest the MAC's rulings denying coverage for their dental services by challenging the Secretary's underlying policy decision to exclude

⁵ This second situation is nevertheless described as an exception or corollary to the same-physician rule. *See Wood*, 246 F.3d at 1030. In addition to the potential provision of this service under Part A, Kidney-transplant surgery is in a unique category under Medicare because end-stage renal disease is the only condition that guarantees Medicare eligibility. *See* 42 U.S.C. § 1395rr.

dental procedures that are not performed at the same time and by the same dentist as a covered procedure. Appellants contend (1) that the Secretary has not carried out Congress's intent to cover complex surgical procedures and (2) that the Secretary's coverage policy is irrational and thus violates the equal protection component of the Due Process Clause of the Fifth Amendment. We consider first statutory interpretation, and then the constitutional challenge.

A

When we review an agency's interpretation of a statute that it is charged with administering, "[f]irst, always, is the question whether Congress has directly spoken to the precise question at issue." *Chevron, U.S.A., Inc. v. Natural Res. Def. Council, Inc.*, 467 U.S. 837, 842 (1984). "If the intent of Congress 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." *Id.* at 842-43. But if "the statute is silent or ambiguous with respect to the specific issue," we will not "impose [our] own construction on the statute." *Id.* at 843. Instead, we ask "whether the agency's answer is based on a permissible construction of the statute." *Id.* If the agency's construction is permissible, we defer to it. See *Palomar Med. Ctr. v. Sebelius*, 693 F.3d 1151, 1164 (9th Cir. 2012).

Before we address whether in the statute Congress has spoken clearly, we must identify the precise

question at issue. Appellants do not allege that they received dental services in connection with a covered procedure. Because they do not, the same-physician rule does not come into play, and any ambiguity in the Secretary's implementation of that rule is not relevant here.⁶

Appellants also do not allege that they received dental care on an inpatient basis, and they do not seek reimbursement under Part A. As a result, they do not qualify for § 1395y(a)(12)'s inpatient exception. Appellants received outpatient services and sought reimbursement under Part B, so they cannot benefit from the coverage rules provided for inpatient care under Part A. *Accord Chipman v. Shalala*, 90 F.3d 421, 422-23 (10th Cir. 1996). Any ambiguity in the inpatient-coverage provision does not reach Appellants.

Appellants are in a third category. They received primary dental services on an outpatient basis and sought coverage under Part B. Appellants contend that those services should be covered because they were "medically necessary" to prevent potentially fatal heart infections. The Secretary disagrees, arguing that § 1395y(a)(12) unambiguously rejects Appellants' claims: Services "in connection with the care,

⁶ One of our sister circuits held § 1395y(a)(12) to be ambiguous in that context, *see Wood*, 246 F.3d at 1031-32. After examining the rule, the Seventh Circuit applied *Chevron* deference and concluded that the Secretary's interpretation of the same-physician rule was reasonable. *Id.* at 1035.

treatment, filling, removal, or replacement of teeth or structures directly supporting teeth” are excluded from coverage, so primary dental services that are not provided on an inpatient basis are excluded by the statute. According to the Secretary, the relationship between Appellants’ services and their risk of infection is irrelevant.

Having distinguished Appellants’ situation from related questions about dental coverage under Medicare, we do not think that “Congress has directly spoken to the precise question at issue.” *Chevron*, 467 U.S. at 842. 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, namely Sjogren’s Syndrome or graft-versus-host disease. We can see that there are fair arguments on both sides of the issue and conclude that the statute is ambiguous. Accordingly, we turn to the second step of *Chevron*. *See* 476 U.S. at 843.

B

Having concluded that § 1395y(a)(12) is ambiguous as to the extent of the dental-services exclusion, we now address whether the Secretary's construction of that exclusion is reasonable. *See id.* The Secretary did not issue her interpretation through notice-and-comment rulemaking or formal adjudication, so we must first determine what level of deference we should give to her interpretation. *See United States v. Mead Corp.*, 533 U.S. 218, 229 (2001). Appellants contend that the Secretary's interpretation of § 1395y(a)(12) does not merit *Chevron* deference because the interpretation, as published in the CMS Manual, does not carry the force of law. Instead, Appellants suggest that the Secretary's interpretation is entitled to respect only to the extent that it has the "power to persuade" under *Skidmore v. Swift & Co.*, 323 U.S. 134, 140 (1944). *See Christensen v. Harris County*, 529 U.S. 576, 587 (2000) ("Interpretations 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."). Under that standard, Appellants believe, the Secretary's interpretation is unpersuasive.

The Secretary agrees that her interpretation in the CMS Manual does not by itself carry the force of law. *See* 42 C.F.R. § 405.1062(a) ("ALJs and the MAC are not bound by . . . manual instructions."). Instead, the Secretary explains that her interpretation deserves *Chevron* deference because the process

of adjudication leading to the MAC's decisions was "provided for by Congress" and the Secretary's interpretation was given effect through this "relatively formal administrative procedure." *Mead*, 533 U.S. at 230.

Under *Mead*, we will give *Chevron* deference to an agency's interpretation of a statute "only when: (1) 'it appears that Congress delegated authority to the agency generally to make rules carrying the force of law,' and (2) 'the agency interpretation claiming deference was promulgated in the exercise of that authority.'" *Price v. Stevedoring Servs. of Am., Inc.*, 697 F.3d 820, 833 (9th Cir. 2012) (en banc) (quoting *Mead*, 533 U.S. at 226-27).

The Secretary's interpretation meets the first prong of the *Mead* test. The Secretary has general rulemaking authority under § 1395hh(a)(1). Congress decided that Medicare should pay for reasonable and necessary medical expenses, but it also restricted coverage of outpatient dental care. Congress delegated to the Secretary the authority to "promulgate regulations and make initial determinations with respect to benefits" within the bounds of these provisions. 42 U.S.C. § 1395ff(a). The authority to promulgate regulations indicates that Congress delegated to the Secretary to make rules carrying the force of law. *See Mead*, 533 U.S. at 229 (citing *EEOC v. Arabian Am. Oil Co.*, 499 U.S. 244, 257 (1991) (explaining that we give no *Chevron* deference to agency guideline where congressional delegation did not include the power to "promulgate rules or regulations"))).

Addressing the second prong of *Mead*, we ask whether the Secretary’s interpretation of the dental exclusion “was promulgated in the exercise of that authority [to make rules carrying the force of law].” *Id.* at 227. The answer “depends on the form and context of that interpretation.” *Price*, 697 F.3d at 826. That the Secretary reached her interpretation “through means less formal than ‘notice and comment’ rulemaking does not automatically deprive that interpretation of the judicial deference otherwise its due.” *Barnhart v. Walton*, 535 U.S. 212, 221 (2002). The Secretary’s interpretation of the dental exclusion is similar in both form and context to the interpretation given *Chevron* deference in *Barnhart*, *id.* at 225, and we follow *Barnhart* to conclude the Secretary’s interpretation meets the second prong of the *Mead* test.

In *Barnhart*, the Supreme Court reversed a Fourth Circuit decision holding that a section of the Social Security Act forbade the Secretary’s interpretation of the meaning of the word “inability” in the definition of “disability.” *Id.* at 214. The statute defined “disability” as an “inability to engage in any substantial gainful activity . . . which has lasted or can be expected to last for a continuous period of not less than 12 months.” *Id.* (emphasis omitted) (quoting 42 U.S.C. § 423(d)(1)(A)). Under the Secretary’s interpretation, this duration requirement was prospective if the inability was ongoing at the time of adjudication. But if an applicant’s inability resolved itself in less than 12 months, the applicant would not

be found disabled and would receive no benefits, even if the inability were one that initially might have been expected to last that long. *Id.* The Supreme Court first examined and upheld this definition as the agency’s interpretation of its own regulation. *Id.* at 217 (citing *Auer v. Robbins*, 519 U.S. 452, 461 (1997)).

The petitioner in *Barnhart* objected to the Court’s application of *Auer*, however, because the regulation in question came into effect long after the agency denied his claim for benefits, possibly in response to the litigation. *Id.* at 221; see *Walton v. Apfel*, 235 F.3d 184, 188 n.6 (4th Cir. 2000), *rev’d sub nom. Barnhart*, 535 U.S. at 221 (the proposed regulation did not apply retroactively). But the Court explained that the agency’s long-held interpretation would warrant *Chevron* deference even if it had not been bolstered by the rulemaking. *Id.*⁷ The Court reasoned that “the interstitial nature of the legal question, the related expertise of the Agency, the importance of the question to administration of the statute, the complexity of that administration, and the careful consideration

⁷ Appellants contend that this section of *Barnhart* was dicta because the Court decided the outcome under *Auer*. Even if this were true, we afford “considered dicta from the Supreme Court . . . a weight that is greater than ordinary judicial dicta as prophecy of what that Court might hold.” *United States v. Montero-Camargo*, 208 F.3d 1122, 1132 n.17 (9th Cir. 2000) (en banc). Given the similarities between Appellants’ situation and *Barnhart*, we choose not to ignore the Supreme Court’s reasoned guidance in that case.

the Agency has given the question over a long period of time all indicate that *Chevron* provides the appropriate legal lens through which to view the legality of the Agency interpretation here at issue.” *Barnhart*, 535 U.S. at 222 (citing *Mead*).

The Secretary’s interpretation here exhibits those factors. The legal question is interstitial: the dental exclusion “is clear, with clear exceptions,” *Wood*, 246 F.3d at 1035, and the Secretary’s interpretation fills the interstices dividing the exceptions from the exclusion. The rule limiting coverage is important to the Secretary’s administration of Medicare given the scarce resources available and the “vast number of claims that [Medicare] engenders.” *Barnhart*, 535 U.S. at 225. That vast number of claims, each of which involves distinct medical facts, speaks also to the complexity of administering Medicare “and the consequent need for agency expertise and administrative experience.” *Id.*

The origins and legal contexts of the two interpretations are also similar. The interpretation in *Barnhart* originated in a disability-insurance letter, was later published in a state disability-insurance manual, and was included in Social Security Ruling 86-52 before being issued as a regulation following notice-and-comment rulemaking. *Id.* at 219-20. Here, the Secretary first issued her interpretation in an intermediary letter and later published it in a manual. Social Security rulings, like interpretations in the CMS Manuals, do not have the force of law; both are interpretative rules constituting the agencies’

interpretations of the statutes they administer. Compare *Chavez v. Dep't of Health & Human Servs.*, 103 F.3d 849, 851 (9th Cir. 1996) (Social Security rulings), with *Cnty. Hosp. of Monterey Peninsula v. Thompson*, 323 F.3d 782, 788 (9th Cir. 2003) (CMS Manual provisions). Both gain the force of law through the process of adjudication of a “vast number of claims” under § 405(b). See 42 U.S.C. § 1395w-22(g)(5) (incorporating administrative hearing and judicial review provisions of § 405(b) and (g) from Social Security into Medicare); 42 U.S.C. § 1395ff(b)(1)(A) (same).

In *Barnhart*, the Court gave particular weight to the long history and stability of the interpretation in question. The agency in *Barnhart* first adopted its interpretation of “inability” in 1957, and the Court noted that it “will normally accord particular deference to an agency interpretation of ‘longstanding’ duration.” 535 U.S. at 220 (citing *North Haven Bd. of Ed. v. Bell*, 456 U.S. 512, 522, n.12 (1982)). Here, the Secretary first adopted her interpretation of the exclusion of primary dental services in her 1967 Intermediary Letter No. 193. More than eleven years have now passed since the Supreme Court decided *Barnhart*, so the Secretary’s interpretation of the dental exclusion is even older than the agency’s interpretation of the word “inability” was when the Court decided *Barnhart*. In addition to the weight of years of consistent administrative interpretation, the Secretary’s interpretation of the dental exclusion was issued shortly after passage of the Medicare Act. See Health Insurance for the Aged Act, Pub. L. No. 89-97,

tit. I, 79 Stat. 290 (1965). Such a nearly contemporaneous construction is entitled to significant deference. See *Good Samaritan Hosp. v. Shalala*, 508 U.S. 402, 414 (1993).

As in *Barnhart*, the Secretary's interpretation of the dental exclusion is a half-century old interpretation given effect through a system of adjudication authorized under § 405(b). Moreover, the Secretary's interpretation shows the same factors deemed critical in *Barnhart*. These similarities "all indicate that *Chevron* provides the appropriate legal lens through which to view the legality of the [Secretary's] interpretation here at issue." *Barnhart*, 535 U.S. at 222.

Appellants contend that the Secretary's interpretation has been inconsistent and is "entitled to considerably less deference than a consistently held agency view." *I.N.S. v. Cardoza-Fonseca*, 480 U.S. 421, 446 n.30 (1987) (internal quotation and citation omitted). But when Appellants describe the Secretary's interpretation as inconsistent, they refer not to the challenged interpretation – the policy guidance on outpatient primary dental procedures – but to 42 C.F.R. § 411.15(i), the regulation that paraphrases the statutory dental exclusion in § 1395y(a)(12). In 1974, the Secretary removed the word "routine" from the description of dental services excluded from coverage. The Secretary made that change to accommodate the new exception for inpatient services under Part A. See 39 Fed. Reg. 28622, 28623 (Aug. 9, 1974). The policy guidance at issue here did not change; it has been consistent since 1967. As discussed in Section

IV(A) above, Appellants' claims do not implicate the same-physician rule or the inpatient exception. Changes to the Secretary's guidance on those questions do not undermine her interpretation here, and *Cardoza-Fonseca* does not reduce the deference we will give to this long-standing, "consistently held agency view." 480 U.S. at 446 n.30. Like the United States Court of Appeal [sic] for the Seventh Circuit in *Wood*, we conclude that the Secretary's interpretation of § 1395y(a)(12) warrants *Chevron* deference. See 246 F.3d at 1035.⁸

Having so concluded, and in light of our prior conclusion that the statute is ambiguous, we must decide whether the Secretary's interpretation is a reasonable one. Congress required the Secretary to deny payment for "services in connection with the care, treatment, filling, removal, or replacement of teeth or structures directly supporting teeth" that are not provided on an inpatient basis to hospitalized patients. 42 U.S.C. § 1395y(a)(12). She has done so since 1967 by reading "services in connection with" to

⁸ The Second Circuit considered a different interpretation in a CMS manual without reference to the factors enumerated in *Barnhart. Estate of Landers v. Leavitt*, 545 F.3d 98, 106 (2d Cir. 2008). The court there did not apply *Chevron*, but even without considering the *Barnhart* factors or any similarity to the context of the interpretation in *Barnhart*, it recognized that where "CMS, a highly expert agency, administers a large complex regulatory scheme in cooperation with many other institutional actors, the various possible standards for deference – namely, *Chevron* and *Skidmore* – begin to converge." *Id.* at 107 (quotation and alteration omitted).

refer to services related to dental procedures provided as primary services based on her reasonable definition of “structures directly supporting teeth.” In the decades since, “Congress has frequently amended or reenacted the relevant provisions” without altering this exclusion, “provid[ing] further evidence . . . that Congress intended the Agency’s interpretation, or at least understood the interpretation as statutorily permissible.” *Barnhart*, 535 U.S. at 220 (citing *Commodity Futures Trading Comm’n v. Schor*, 478 U.S. 833, 845-46 (1986)).

Appellants contend that the legislative history of § 1395y(a)(12) contradicts the dental exclusion’s plain language and makes the Secretary’s interpretation unreasonable. The Senate Report accompanying the Medicare Act expressed the desire to provide coverage for “complex surgical procedures.” *See* S. Rep. No. 89-404, at 49. House and Senate reports describe the excluded coverage as “routine” dental care, which Appellants believe does not include their “extensive, medically related procedures.” *See, e.g., id.* When a statute is plain on its face, “we ordinarily do not look to legislative history as a guide to its meaning.” *Tennessee Valley Auth. v. Hill*, 437 U.S. 153, 184 n.29 (1978). Because we have concluded that the statutory dental exclusion is ambiguous, legislative history permissibly may be considered. But we conclude that the legislative history more amply supports the agency’s argument than that of the Appellants. The second part of § 1395y(a)(12) gives coverage under Part A for inpatient dental services when a patient

requires hospitalization because of the severity of the required procedure. An exception for inpatient services is perhaps not the only way to provide for coverage for dental work that is part of a complex surgical procedure and non-routine care, but it is the one that Congress chose. The statute does not compel the Secretary to cover dental work that is related to complex procedures under Part B. The text of § 1395y(a)(12) does not indicate that there need be further exceptions beyond those for inpatient care and the same-physician rule. We conclude that the Secretary's interpretation is reasonable and therefore permissible.

V

Appellants contend that the Secretary's coverage rules for dental services create irrational classifications and violate their right to equal protection under the Fifth Amendment. The "promise that no person shall be denied the equal protection of the laws must coexist with the practical necessity that most legislation classifies for one purpose or another, with resulting disadvantage to various groups or persons." *Romer v. Evans*, 517 U.S. 620, 631 (1996). Equal protection "does not forbid classifications." *Nordlinger v. Hahn*, 505 U.S. 1, 10 (1992). "It simply keeps governmental decisionmakers from treating differently persons who are in all relevant respects alike." *Romer*, 517 U.S. at 631. Appellants concede that the classification they challenge is subject to the rational basis test, under which we will uphold a classificatory

scheme if it “bears a rational relation to some legitimate end.” *Id.* Under this standard, Appellants “have the burden to negat[e] every conceivable basis which might support it.” *Diaz v. Brewer*, 676 F.3d 823, 826 (9th Cir. 2012) (quoting *FCC v. Beach Commc’ns, Inc.*, 508 U.S. 307, 315 (1993)).

Appellants assert that the “favored classes” of (1) patients who receive their dental services on the same day and from the same physician who provided a covered service, (2) patients who need extractions of teeth to prepare the jaw for radiation treatment, and (3) patients who require a comprehensive dental workup before a kidney transplant do not collectively demonstrate any logical principle. But each of these “favored classes” describes patients with undoubtedly covered primary procedures who receive dental treatment in connection with those covered procedures. By contrast, Appellants’ primary procedures were noncovered dental treatments. Appellants concede that the goal of limiting coverage is a legitimate governmental objective, and the distinction here is rationally related to that goal. Moreover, because their dental treatments were not ancillary to a covered procedure, Appellants are not similarly situated to the “favored classes” they cite. “Evidence of different treatment of unlike groups does not support an equal protection claim,” *Wright*, 665 F.3d at 1140 (quoting *Thornton v. City of St. Helens*, 425 F.3d 1158, 1168 (9th Cir. 2005)). We conclude that there is no violation of the Constitution’s guarantee of equal protection.

VI

Appellants' illnesses, Sjogren's Syndrome and graft-versus-host disease, are serious, and the conditions that these diseases present strongly require dental treatment to maintain a patient's health against catastrophic health risks. The claims of Appellants are sympathetic, and their desire for coverage is understandable. But not all medically necessary services are covered by Medicare, and the Secretary has implemented a coverage framework consistent with the goals of Congress that there be broad denial of coverage for dental services. Although we have concluded that the statutory provision for exclusion of dental services is ambiguous in the sense that plausible divergent constructions can be urged, we also conclude that the Secretary's interpretation of the statute is reasonable. The underlying conditions of Sjogren's Syndrome and graft-versus-host disease are complex, but the consequent need is for dental services that are routine in the sense that they are not different from services commonly given others, that is, preparation and application of crowns, bridgework, and fillings. In light of this comprehensive and specific legislative command, which broadly excludes primary dental services from Medicare coverage, we have concluded both that the Secretary's statutory interpretation warrants *Chevron* deference, and that the Secretary's statutory interpretation is reasonable.

AFFIRMED.

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF ARIZONA

Ronald Fournier, et. al.,) No. CV 08-2309-PHX-ROS
 Plaintiffs,) **ORDER**
 vs.) (Filed Feb. 14, 2012)
Kathleen Sebelius,)
Secretary of the)
Department of Health)
and Human Services,)
 Defendant.)

Plaintiffs appeal the final decisions of the Secretary of Health and Human Services (“Defendant” or “Secretary”) denying Plaintiffs’ claims for Medicare coverage for dental services. For the reasons below, the Court affirms the Secretary’s decisions regarding Berg and DiCecco, and dismisses Fournier’s claim as moot.¹

BACKGROUND

Plaintiffs Ronald Fournier (“Fournier”), Delores Berg (“Berg”), and Thomas DiCecco (“DiCecco”) (“Plaintiffs”) lost salivary functioning due to medical conditions and treatment. The loss of salivary function

¹ The Court has reviewed the briefing and concluded it would not be aided by oral argument. The parties have had full opportunity to brief the issues.

damaged Plaintiffs' teeth. Plaintiffs sought Medicare coverage for dental services to repair or extract damaged teeth. Plaintiffs' respective claims for coverage were denied, and Plaintiffs sought administrative review. The denials were upheld, and Plaintiffs appealed the Secretary's decisions.

After this lawsuit was filed, on November 1, 2009, the ALJ issued a favorable decision in Fournier's claim, which became the final decision of the Secretary. (Doc. 77 at 2-3). The ALJ found Fournier's requested treatment was for a serious infection, and therefore covered because it was medically "reasonable and necessary for the . . . treatment of an illness or injury or to improve the functioning of a malformed body member" pursuant to 42 U.S.C. § 1395y(a)(1)(A). (Doc. 85, Ex. A at 10).² As discussed below, in light of the decision to approve coverage, Fournier's claim is moot.

Berg was diagnosed with Sjogren's syndrome in 2003 while she was enrolled in a Medicare Advantage ("MA") plan under Medicare Part C. Because of the syndrome, she lost saliva production and her teeth decayed and began to break off. (Doc. 54 at 7). Berg presented to Dr. Steven S. Swidler, D.D.S., who prepared a treatment plan that included partial dentures

² Plaintiffs filed their initial Complaint before the final, favorable ALJ decision. Only the second favorable decision is under review (*See* Doc. 28 at 3). Humana did not seek review by the Medical [sic] Appeals Council ("MAC"), making the ALJ decision the Secretary's final decision in the case.

and crowns. (Id.). Berg sought coverage for abutments and a partial denture and testified she needed bridges. (AR 458, 466, 784). On March 3, 2008, Plaintiff Berg's MA plan denied coverage and upheld its denial on review. (AR 471). On November 18, 2008, the ALJ denied her appeal, stating although Berg's dental problems were caused by her disease, the dental work was the primary procedure and did not fall under any exclusion. (AR 478). On March 27, 2009, the MAC denied Berg's appeal from the ALJ's decision. (Doc. 77 at 3, AR 437). The MAC cited the general exclusion of dental services under Medicare, and noted coverage is provided "only under limited circumstances not applicable to this case." (Id.) (citing Medicare Benefit Policy Manual ("MBPM") (CMS Pub. 100-2), Chap. 15, § 150 (dental services) and Chap. 16, § 140 (dental service exclusion)). "[I]n particular," the MAC noted, "when an excluded dental service is the primary procedure involved, coverage is excluded regardless of the complexity of the procedure." (Id.) (citing MBPM, Chap. 16, § 140).

DiCecco received an allogeneic bone marrow transplant and a donor lymphocyte infusion as part of his chronic myelogenous leukemia treatment in the 1990s. (Doc. 77 at 3-4; AR 858). As a result of the treatment, DiCecco developed chronic graft versus host disease ("GVHD"). The GVHD affected his saliva production and caused his teeth to decay and break off at the roots a decade later. DiCecco was denied coverage for the dental services his doctor prescribed. The MAC affirmed the denial of coverage. The MAC

acknowledged DiCecco's need for dental services that were caused by his medical condition, but stated:

Nonetheless, the fact that there was a relationship between a medical condition and the dental services does not, by itself, qualify the dental services for Medicare coverage. . . . In order to be covered by [the] exception, the dental services would have to be furnished along with another covered procedure *performed by the dentist on the same occasion* (AR at 795) (emphasis in original).

ANALYSIS

A. Standard of Review

Pursuant to 42 U.S.C. § 405(g) and 1395ff(b), the Court will uphold the findings of the Secretary if supported by substantial evidence. *Wood v. Thompson*, 246 F.3d 1026, 1029 (7th Cir. 2001). The Court may set aside the Secretary's denial of coverage if the denial was based on legal error. *Stevenson v. Chater*, 105 F.3d 1151, 1153 (7th Cir. 1997).

B. Fournier

Fournier's second appeal was favorable. He has obtained the coverage he sought to obtain in this appeal. Therefore, his claim for coverage is moot. *See Heckler v. Ringer*, 466 U.S. 602, 621-22 (1984) (holding the court cannot issue advisory opinions regarding future benefits under the Medicare Act).

C. Berg and DiCecco

The Medicare program, established under Title XVIII of the Social Security Act (“the Act”), 42 U.S.C. §§ 1395 to 1395iii, pays for covered medical care provided to eligible aged and disabled persons. Medicare has two main parts, Part A and Part B. Part A authorizes payment primarily for institutional care, including inpatient hospital care. 42 U.S.C. § 1395d(a). Part B is optional and authorizes payment for outpatient hospital care. 42 U.S.C. § 1395k. Under Medicare Part C, individuals qualified for Medicare enroll in a health plan (MA plan) with a private insurance company. 42 U.S.C. §§ 1395w-21 – 1395w-29. The MA Plan must enter into a contract with the Secretary of Health and Human Services, 42 U.S.C. § 1395w-27, and agree to provide the same benefits an individual is eligible to receive under Medicare, 42 U.S.C. § 1395w-22(a)(1)(A). Berg was enrolled in an MA plan, while DiCecco received services under Medicare Parts A and B. (Doc. 81 at 3).

To be “covered” under the Act, the medical care must be both “reasonable and necessary” for treatment of illness or injury or to improve the functioning of a malformed body member, and not excluded by any other provision of the Act. 42 U.S.C. § 1395y(a)(1)(A).

Medicare generally does not provide coverage for dental services. The statute at issue, 42 U.S.C. § 1395y(a)(12), excludes from coverage under Parts A and B:

such expenses . . . for services in connection with the care, treatment, filling, removal, or replacement of teeth or structures directly supporting teeth, except that payment may be made under part A . . . in the case of inpatient hospital services in connection with the provision of such dental services if the individual, because of his underlying medical condition and clinical status or because of the severity of the dental procedure, requires hospitalization in connection with the provision of such services.

The Secretary has taken the position,³ “when a patient is hospitalized in connection with the performance of noncovered dental procedures, but the hospitalization was required in order to assure proper medical management, control, or treatment of a non-dental impairment . . . the *inpatient hospital services would be covered* under the hospital insurance program even though the *dentist’s services are not covered.*” (Doc. 81-1, at 5, AR 2982) (emphasis added). But when a patient is hospitalized solely for a non-covered dental procedure, neither the dental services nor the inpatient hospital services are covered. (Doc. 81-1 at 4, AR 2981).

³ On January 30, 1967, the predecessor agency to the Department of Health and Human Services issued a letter regarding “Coverage of dentists’ services under medicare,” relevant portions of which were later manualized. (Doc. 81-1, AR 2979). The letter sets forth the Secretary’s interpretation of the broad dental exclusion under Medicare.

“[W]hen an excluded service is the primary procedure involved it would not be covered regardless of the complexity or difficulty of the procedure.” (Doc. 81-1, at 4, AR 2981). Thus, the complexity of a non-covered dental procedure does not convert it into a covered procedure. When a covered service is performed by a dentist, payment will be made regardless of whether it is inpatient or outpatient, and services and supplies incident to a covered dental service are covered. (Id.). Therefore, coverage of X-rays, anesthesia and other related procedures by the dentist and her staff depends on whether the underlying dental procedure is covered. (Id.).

The text of the statute excludes coverage for dental 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). Plaintiffs’ dental services fall under this exclusion. Unless they show an applicable exception to this exclusion, Plaintiffs’ claims are not covered. The Secretary properly denied Berg and DiCecco’s claims because each sought excluded dental treatment and failed to demonstrate an exception applied.

The MAC’s decision regarding Berg was free from legal error and supported by substantial evidence because Berg sought coverage for abutments and a bridge. (AR at 450, 472-74). This dental treatment was in connection with the care and replacement of teeth, treatment not covered by Medicare under 42 U.S.C. § 1395y(a)(12). The MAC properly held coverage was excluded, regardless of the complexity, because the

dental service was the primary procedure involved. Medicare “excludes from coverage specific services, including those related to dental care, regardless of whether those services are considered medically necessary.” *Chipman v. Shalala*, 894 F.Supp. 392, 398 (D. Kan. 1995) (coverage for crown implants denied); *Goodman v. Sullivan*, 891 F.2d 449, 450 (2d Cir. 1989) (“we find the Medicare statute does not require coverage for all medically necessary procedures”). Because Berg’s dental services fall under the exclusion “for services in connection with the care, treatment, filling, removal, or replacement of teeth or structures directly supporting teeth,” coverage was properly denied.

The MAC’s decision regarding DiCecco was free from legal error and supported by substantial evidence because DiCecco sought and received treatment of crowns and resins more than a decade after he received treatment for chronic myelogenous leukemia. (AR 800, 813, 857-58). As DiCecco sought treatment under Part B, the MAC correctly held a relationship between a medical condition and dental services does not, by itself, qualify the dental services for Medicare coverage. In order to be covered by the exception for services that are “incident to and integral part of” covered dental procedures, the dental services would have to be covered and performed by the dentist on the same occasion. (AR 796); (Doc. 81, Ex. 1 at 2); see *Bick v. Sec’y Health & Human Servs.*, No. CV 95-0313-ABC (RMC), 1996 WL 393656 at *3 (C.D. Cal. 1996) (“the ‘underlying medical condition’ exception is

applicable only to claims for inpatient services-not claims such as this one, brought under Part B for outpatient dental work”); *cf. Maggio v. Shalala*, 40 F.Supp.2d 137, 142 (W.D.N.Y. 1999) (holding dental work performed by cancer dental surgeon at the same time plaintiff received treatment for underlying leukemia covered under Part B). Here, the dental services were not covered, and were not performed by the dentist on the same occasion. Therefore, the MAC properly denied coverage.

Plaintiffs contend Congress’s intent was to exclude “routine” dental care, and Plaintiffs’ dental services were not routine and therefore covered. (Doc. 77 at 14-15). Defendant cites to the 1965 Senate Report that indicated this “specific exclusion” of “routine dental care” was “to make clear that the services of dental surgeons covered under the bill are restricted to complex surgical procedures.” (Doc. 81 at 3) (citing S. Rep. 89-404 at 49 (1965)). In 1966, the Secretary issued a final rule providing that no payment shall be made for “[r]outine dental services in connection with the care, treatment, filling, removal or replacement of teeth, or structures directly supporting the teeth.” (Doc. 81 at 4) (citing 31 Fed. Reg. 13534, 13535 (Oct. 20, 1966)).

The Secretary’s interpretation of these broad exclusions of dental services does not conflict with the statute or the statutory intent. As stated in *Wood*, “[l]ater in the report, the committee notes that ‘routine dental treatment – filling, removal or replacement of teeth or treatment of structures directly

supporting teeth – would not be covered.’ This evidence of congressional intent arguably supports the Secretary’s view, and certainly is not authority for us to fashion an additional exception out of thin air.” *Wood*, 246 F.3d at 1035 (citing S. Rep. 89-404).

When interpreting a statute, it must first be determined whether the intent of Congress is unambiguous. *Chevron, U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837, 842 (1984). If the meaning of the statute is clear, no deference is due to an agency’s interpretation. If the meaning of the statute is ambiguous, an agency’s interpretation will be afforded deference if it is reasonable. *Id.* at 844. If the agency’s interpretation conflicts with its prior interpretation, the current interpretation is “‘entitled to considerably less deference’ than a consistently held view.” *INS v. Cardoza-Fonseca*, 480 U.S. 421, 446 n.30 (1987) (quoting *Watt v. Alaska*, 451 U.S. 259, 273 (1981)).

Even if the statute is ambiguous, the Secretary’s regulations are reasonable as applied to deny Berg and DiCecco’s claims. Berg sought coverage for abutments and a partial denture and testified she needed bridges. (AR 458, 466, 784). DiCecco sought treatment for frequent exams, fillings, crowns and resins. (AR 800, 813, 857). These dental services fall under the general exclusion in 42 U.S.C. § 1395y(a)(12). The MAC’s decisions classifying Berg’s and DiCecco’s respective dental work as “care, treatment, filling, removal or replacement” of teeth was reasonable. (AR at 796). Medicare generally excludes dental procedures,

but “allow[s] for coverage of dental procedures in a few limited circumstances.” *Wood*, 246 F.3d at 1031. Berg and DiCecco do not point to a specific exception that would provide coverage. The Secretary’s interpretation for the statute is reasonable as applied to the facts for this case. *Chipman v. Shalala*, 894 F.Supp. at 396 (“In this case, the court finds that the Secretary’s interpretation of the dental exclusion, as embodied in [the Medicare Carrier’s Manual (“MCM”)] § 2136, is not unreasonable or inconsistent with the Medicare statute and regulations.”). Therefore, the Secretary’s decision will be affirmed.

D. Equal Protection

Plaintiffs argue the Secretary’s policy does not draw rational distinctions between covered and non-covered dental services, and thus violates the equal protection guarantee in the Fifth Amendment’s due process clause. (Doc. 77 at 15). Defendant argues it is Congress, not the Secretary, who decided to exclude dental services. 42 U.S.C. § 1395y(a)(12). “[O]ur review is deferential. Governmental decisions to spend money to improve the general public welfare in one way and not another are not confided to the courts. The discretion belongs to Congress unless the choice is clearly wrong, a display of arbitrary power, not an exercise of judgment.” *Bowen v. Gilliard*, 483 U.S. 587, 598 (1987) (quotation omitted). A statute or regulation will be struck down only if it “manifests a patently arbitrary classification, utterly lacking in rational justification.” *Weinberger v. Salfi*, 422 U.S.

749, 768 (1975) (citation omitted); *see also Clinton Memorial Hosp. v. Sullivan*, 783 F.Supp. 1429, 1440 (D.D.C. 1992), *aff'd* 10 F.3d 854, 860-61 (D.C. Cir. 1993) (applying rational basis standard to Medicare regulations). (Doc. 81 at 17-18).

Congress chose to exclude from coverage dental services pertaining to the care, treatment, filling, and removal of teeth. 42 U.S.C. § 1395y(a)(12). An exception was created under Part B: “if an otherwise noncovered service is performed by a dentist as an incident to and as an integral part of a *covered* procedure or service *performed by him*, the total service performed by the dentist on such [an] occasion would be covered.” (Doc. 81, Ex. 1 at 2) (emphasis added); MCM § 2136; MBPM Chap 15 § 150 at 132. Plaintiffs challenge this exception. The exception allows coverage for dental services provided by a dentist as part of the same procedure of a covered treatment. The Secretary’s interpretation is consistent with Congress’ intent to limit dental coverage under Medicare. Congress’ decision to provide for limited dental coverage is not patently arbitrary. Congress has provided other mechanisms to obtain dental coverage, such as optional Medicare insurance.

“In the area of economics and social welfare, a State does not violate the Equal Protection Clause [and correspondingly the Federal Government does not violate the equal protection component of the Fifth Amendment] merely because the classifications made by its laws are imperfect. If the classification has some ‘reasonable basis,’ it does not offend the

Constitution simply because the classification ‘is not made with mathematical nicety or because in practice it results in some inequity.’” *Schweiker v. Wilson*, 450 U.S. 221, 234 (1981) (quoting *Lindsley v. Natural Carbonic Gas Co.*, 220 U.S. 61, 78 (1911)). Although this rational basis standard is “not a toothless one,” it does not allow the courts to substitute their personal notions of good public policy for those of Congress. *Mathews v. Lucas*, 427 U.S. 495, 510 (1976). Here, Congress has created a classificatory scheme that rationally advances a reasonable and identifiable governmental objective. The Court will not substitute its own policy. *See Schweiker*, 450 U.S. at 234-35.

E. Class

Plaintiffs attempt to bring this suit on behalf of a nationwide class of persons “who are or will be entitled to Medicare benefits, but are denied Medicare coverage of extraordinary, medically related dental services.” (Doc. 56 at 3).⁴ Because the claims arise under Medicare, Plaintiffs must proceed under 42 U.S.C. § 405(g). That is, they must satisfy the presentment and exhaustion requirements under that subsection prior to seeking judicial relief. *See Heckler v. Ringer*, 466 U.S. 602, 605-06 (1984). Of these two requirements, the second is waivable but the first is not. *Kaiser v. Blue Cross of Cal.*, 347 F.3d 1107, 1115

⁴ Plaintiffs have not filed a motion to certify class.

(9th Cir. 2003) (citing *Mathews v. Eldridge*, 424 U.S. 319, 328 (1976)).

Setting aside the presentment question, it is apparent Plaintiffs do not meet the conditions for waiver of exhaustion. Exhaustion may be waived, but only upon satisfying a three-prong test requiring the Complaint be “(1) collateral to a substantive claim of entitlement (collaterality), (2) colorable in its showing that denial of relief will cause irreparable harm (irreparability), and (3) one whose resolution would not serve the purposes of exhaustion (futility).” *Kaiser*, 347 F.3d at 1115 (citing *Johnson v. Shalala*, 2 F.3d 918, 921 (9th Cir. 1993)). “Plaintiff must satisfy all three elements in order for waiver to attach.” *Davis v. Astrue*, 513 F. Supp. 2d 1137, 1145 (N.D. Cal. 2007); *see also Kaiser*, 347 F.3d at 1115-16 (denying waiver for failure to satisfy two of the three prongs).

Plaintiffs have not shown collaterality. On April 24, 2009, the Court issued an order finding Fournier failed to show collaterality. (Doc. 33 at 3-4). The Court stated, “Collaterality requires the prior Complaint be ‘wholly “collateral” to [any] claim for benefits under the Act.’” (Doc. 33 at 3) (citing *Heckler v. Ringer*, 466 U.S. 602, 618 (1984)); *see also Bass v. Soc. Sec. Admin.*, 872 F.2d 832, 833 (9th Cir. 1989) (per curiam). A complaint is “not collateral” if it “directly concerns [the] substantive claim” for benefits. *Bass*, 872 F.2d at 833; *see also Indep. Living Center of S. Cal., Inc. v. Leavitt*, No. 2:06-cv-0435-MCE-KJM, 2006 WL 4498214 at 5 (E.D. Cal. June 29, 2006) (a complaint is not “wholly collateral” if it is “inextricably intertwined

with claimed . . . benefits”). The Court also distinguished *Johnson v. Shalala*, on which Plaintiffs rely. Moreover, Plaintiffs do not have a substantive claim of entitlement. (*Id.*). The Court finds there is no collaterality.

In addition, Plaintiffs’ argument that there would be irreparable harm is speculative. Past injury does not meet the irreparability requirement and the class must show a denial of relief will cause a future harm. *Kaiser*, 347 F.3d at 1115. Even if Plaintiffs’ claims raised are broader than those suitable for resolution by the Secretary, deciding Plaintiffs’ claims would mean also passing judgment on questions which are appropriately first answered by the Secretary. These claims must first be raised in the administrative process which Congress has provided for the determination of claims for benefits. *Id.* at 1116; *see also Heckler*, 466 U.S. at 614. Future claimants could apply for dental coverage and they could receive favorable decisions if they meet the statute’s exclusion requirements. Based on these pleadings, Plaintiffs will not be permitted to bring this case on behalf of a nationwide class.

Accordingly,

IT IS ORDERED the Secretary’s decision regarding Berg and DiCecco is **AFFIRMED**.

IT IS ORDERED Fournier’s appeal of the Secretary’s decision is dismissed as moot.

IT IS ORDERED the **Clerk of the Court** shall enter judgment in favor of Defendant.

DATED this 14th day of February, 2012.

/s/ Roslyn O. Silver
Roslyn O. Silver
Chief United States
District Judge

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

RONALD FOURNIER, Plaintiff, And DELORES BERG; THOMAS DICECCO, Jr., Plaintiffs-Appellants, v. KATHLEEN SEBELIUS, Secretary of the Department of Health and Human Services, Defendant-Appellee.	No. 12-15478 D.C. No. 2:08-cv-02309-ROS District of Arizona, Phoenix ORDER (Filed Oct. 22, 2013)
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Before: GOODWIN, WARDLAW, and GOULD, Circuit Judges.

Plaintiffs-Appellants's [sic] Petition for Rehearing is DENIED.

The full court has been advised of the Petition for Rehearing En Banc and no judge of the court has requested a vote on the Petition for Rehearing En Banc. Fed. R. App. P. 35. Plaintiffs-Appellants's [sic] Petition for Rehearing En Banc is also DENIED.
