No. _____

In the
Supreme Court of the United States

VITREO RETINAL CONSULTANTS OF THE PALM BEACHES, P.A.,

Petitioner,

v.

U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES,

Respondent.

On Petition for Writ of Certiorari to the United States Court of Appeals for the Eleventh Circuit

PETITION FOR WRIT OF CERTIORARI

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December 21, 2016

QUESTION PRESENTED

Part B of the Medicare Act provides Medicare beneficiaries with insurance to pay for a variety of outpatient items and services. The Act empowers the Secretary of Health and Human Services to declare a given item or service "reasonable and necessary" to treat a Medicare beneficiary. If she does so, the item or service is covered by Medicare, and the Secretary becomes obligated to pay physicians who administer it to beneficiaries. For drugs covered under Part B, the Act requires the Secretary to pay physicians for each unit of drug they administer. The statute declares that payment must be based on the lower of (1) the amount the physician actually charged, or (2) an amount equal to 106% of the drug's "average sales price," which is determined by a formula Congress wrote directly into the statute. As the D.C. Circuit has held, these payment benchmarks are exclusive and mandatory, affording the Secretary no discretion to depart from them. Nevertheless, splitting with the D.C. Circuit, the Eleventh Circuit held below that the Secretary has discretion to make only partial payments for covered drugs whenever a physician's acquisition costs fall below the Act's statutory payment rate—even when doing so does not save Medicare any money, but instead just redistributes profits from physicians to drug manufacturers.

The question presented is:

Whether the Secretary may ignore the statutory payment rate for a drug covered under Part B and instead cap payments at a physician's costs to acquire that drug, either directly or under the guise of assessing "medical reasonableness."

PARTIES TO THE PROCEEDING

Petitioner, the plaintiff-appellant below, is Vitreo Retinal Consultants of the Palm Beaches, P.A. Respondent, the defendant-appellee below, is the U.S. Department of Health & Human Services.

CORPORATE DISCLOSURE STATEMENT

In accordance with United States Supreme Court Rule 29.6, petitioner discloses that it has no parent corporation and has no stock held by any publicly held company.

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PETITION FOR WRIT OF CERTIORARI

The Medicare Act is notoriously complex, but in one respect it is perfectly clear: When a physician administers a drug covered under Part B of the Act, the Secretary must pay the physician at the rate dictated by the framework and formulas Congress specified. The Act does not empower the Secretary to deviate from those statutory payment rates based on her own view of how much a physician should be paid under the particular circumstances of any given case. The D.C. Circuit recognized as much in its decision in *Hays v. Sebelius*, 589 F.3d 1279 (D.C. Cir. 2009), which held that the Act gives the Secretary only a "binary choice" to cover a drug at the statutory rate or not to cover it at all; it does not authorize her to cover a drug at a payment rate different from the one selected by Congress. Yet according to the decision below, the Secretary may do exactly that. In the Eleventh Circuit's view, the Secretary may opt to pay only what it cost the physician to *obtain* a drug, even if that cost is less than the payment rate Congress mandated.

That holding cannot be reconciled with *Hays* or the plain text of the statute. Indeed, it cannot even be reconciled with the Secretary's own views, as the Secretary has acknowledged repeatedly that payments under Part B of the Medicare Act do not vary based on a physician's acquisition costs. And this is a particularly odd case for the Secretary to reverse course, as her insistence that petitioner should be paid only for its costs in acquiring the drugs in question is *fiscally neutral to Medicare*.

The Secretary's complaint here is not that petitioner acquired drugs at an unusually low cost. It is that petitioner decided to disregard the drug manufacturer's peculiar instruction that physicians must purchase a brand-new 2.0-mg vial of its drug for every 0.5-mg dose they administer, and discard fully 75% of the contents of each vial. Like many a physician, petitioner instead opted to repackage each 2.0-mg vial into three 0.5-mg doses. Yet the Secretary refused to follow Congress' instruction to pay petitioner based on how much of the drug it *administered*, and instead insisted on reducing petitioner's payments to reflect how many 2.0-mg vials it *purchased*. That payment practice would not, however, actually require physicians to decrease the volume of their use of the drug or of their Medicare payment claims. It would just lead physicians to adhere to the manufacturer's inexplicable insistence that they purchase a new 2.0-mg vial for every 0.5-mg dose, so that they will receive full payment for each dose they administer. The Secretary's approach thus did not save her any money; it just effectively renegotiated prices and redistributed money from physicians to drug manufacturers—something Congress has never authorized her to do.

The Eleventh Circuit alternatively concluded that even if the Secretary cannot unilaterally slash statutory payment rates, she can achieve the same effect by simply declaring the practice that saved the physician money to be "medically unreasonable." But that conclusion is every bit as inconsistent with the D.C. Circuit's decision in *Hays*, which squarely rejected the notion that the Act's "reasonable and

necessary" inquiry looks beyond whether a drug is reasonable and necessary *to treat the patient's condition*. And a drug treatment certainly does not become any less *medically* necessary based on whether it was the first, second, or third 0.5-mg dose obtained from the same 2.0-mg vial. Indeed, the Secretary's own contractors initially conceded that they had no concerns about the *medical* reasonableness of the drug treatments in question; their only concern was with the "reasonableness" of petitioner's expenses in obtaining the drug. The Secretary changed course only after the D.C. Circuit issued its *Hays* decision, which rejected her attempt to alter payment rates based on the supposed unreasonableness of a drug's cost.

That about-face not only confirms the square conflict between the Eleventh Circuit's principal holding and *Hays*, but also underscores that the Eleventh Circuit's alternative holding has nothing to do with medical reasonableness in any ordinary sense. Indeed, the Secretary routinely covers "multi-dosing" and other "off-label" uses and practices in other contexts without ever questioning their medical reasonableness or necessity. The only difference here is that petitioner's multi-dosing *increased its profit margin*, which of course has nothing whatsoever to do with the *medical* propriety of the practice. The Eleventh Circuit's contrary conclusion is therefore just a thinly veiled effort to inject into the "reasonableness" analysis the same cost considerations that the D.C. Circuit rejected in *Hays*. Thus, both prongs of the Eleventh Circuit's decision effect a clean break with the D.C. Circuit, in favor of a rule that badly distorts Congress' statutory scheme,

places large sums of money in jeopardy, and threatens to destabilize a vital government program.

The decision here is important because it goes to the heart of Congress' regime for Medicare payment. The Secretary claims an authority to regulate both drug prices and medical practices that Congress simply did not provide. And given the importance of Medicare and the billions of dollars that flow through the program, a split between two circuits that handle not only a sizable volume of Medicare litigation, but also some of the most important questions underlying the program, is simply not tenable.

Finally, this case is related to the pending petition in *Menendez v. United States*, No. 16-755. That petition concerns the scope of the Speech or Debate Clause and, *inter alia*, whether U.S. Senator Robert Menendez's discussions with executive branch officials about the payment questions at issue here were protected legislative acts or mere constituent service. The reality that the circuits are split on this statutory payment issue underscores the seriousness of the legal and policy issues underlying the question presented here. This Court should grant certiorari.

OPINIONS BELOW

The Eleventh Circuit's opinion is reported at 649 F. App'x 684. App.1-26. The district court's minute orders granting summary judgment to the Secretary and denying summary judgment to Vitreo Retinal Consultants of the Palm Beaches, P.A. (VRC) are unreported. App.46-51. The district court's opinion denying reconsideration is reported at 2015 WL 1608458. App.31-45.

JURISDICTION

The Eleventh Circuit issued its opinion on April 29, 2016, and denied VRC's timely petition for rehearing on August 22, 2016. Justice Thomas extended the time to file a petition for certiorari to and including December 21, 2016. This Court has jurisdiction under 28 U.S.C. §1254(1).

CONSTITUTIONAL, STATUTORY, AND REGULATORY PROVISIONS INVOLVED

The relevant provisions of the Social Security Act, 42 U.S.C. §§1395*l*(a)(1), 1395w-3a, and 1395y(a), are reproduced at App.101-28. The relevant Medicare Program regulation, 42 C.F.R. §414.904, is reproduced at App.128-37.

STATEMENT OF THE CASE

A. Statutory And Regulatory Background

Medicare Part B details how the Secretary must pay for outpatient drugs. Congress authorized the Secretary and regional Medicare contractors to issue coverage determinations to define when items and services will be deemed "reasonable and necessary for the diagnosis or treatment of illness or injury" and thus payable by Medicare Part B. *See* 42 U.S.C. §1395y(a)(1)(A); *see id.* §1395ff(f)(2)(B). Once the Secretary finds that a drug is "reasonable and necessary for the diagnosis or treatment of illness or injury," the Act gives her no discretion to alter the predetermined payment rate. Rather, it dictates that "with respect to drugs and biologicals … not paid on a cost or prospective payment basis, the amounts paid *shall be* 80 percent of the lesser of the actual charge or the payment amount established" in one of several

sections, depending on the drug. *Id.* §1395*l*(a)(1)(S) (emphasis added); *see also id.* §1395u(o)(1)(C). Here, the relevant section is 42 U.S.C. §1395w-3a. The applicable Medicare regulations are equally cut and dry: "Payment for a drug furnished on or after January 1, 2005 is based on the lesser of—(1) The actual charge on the claim for program benefits; or (2) 106 percent of the average sales price." 42 C.F.R. §414.904(a).

In terms of the first payment benchmark—a physician's "actual charge"—the Secretary defines it to be "[t]he amount of money a doctor or supplier charges for a certain medical service or supply. This amount," the Secretary continues, "is often more than the amount Medicare approves." Centers for Medicare & Medicaid Services ("CMS"), Glossary, "Actual Charge," *available at* https://www.cms.gov/apps/glossary/search.asp?Term=actual+charge.

As for the second payment benchmark—a given drug's "payment amount"—42 U.S.C. §1395w-3a codifies what is known as the average sales price ("ASP") payment rule. The ASP rule defines the payment amount as "106 percent of the average sales price." *Id.* §1395w-3a. The statute goes on to specify precisely how the Secretary must calculate a drug's average sales price, namely, by dividing nationwide sales each quarter (with certain exceptions inapplicable here) by the total number of "units" of drug sold. *Id.* §1395w-3a(c)(1). The Secretary then pays physicians at the average sales price rate for each "dosage unit" administered. *Id.* §1395w-3a(b)(1); 42 C.F.R. §414.904(a).

The statutory and regulatory puzzle may have many pieces, but they fit together to make a clear picture: When a physician administers drugs that are covered under Part B, the Secretary must base her payments either on the amount that the physician actually charged Medicare, or on 106% of the drug's average sales price, whichever is lower. Whether a physician's acquisition costs come in above or below that amount is simply irrelevant.

B. Factual Background

This case involves a drug known as Lucentis. Lucentis is a drug covered under Medicare Part B when used to treat age-related macular degeneration (AMD) via injection into the eye. During the time period at issue here, Medicare instructed physicians administering Lucentis to bill for each 0.1-mg unit of the drug they inject, and during the same period, the Part B statutory formula dictated a payment rate of just over $400 per 0.1-mg unit.

Although a standard dose of Lucentis is 0.5 mg (*i.e.*, five units), the manufacturer of Lucentis sold the drug only in 2.0-mg vials (*i.e.*, 20 units). Yet according to the manufacturer's labeling instructions, each vial was to be used to administer only a single 0.5-mg dose. CA11 JA.169. In other words, according to the manufacturer, physicians must purchase 2.0 mg (20 units) of the drug for each 0.5 mg (5 units) that they administer, and then discard fully 75% of the contents of each vial that they purchase (15 units). The manufacturer's instructions did not so much as hint at a medical justification for this patently wasteful instruction. Unsurprisingly, physicians often were loath to waste perfectly good

medicine and so ignored it, and instead repackaged multiple 0.5-mg doses of the drug into separate syringes, each for one use only. This repackaging practice, which is not unique to Lucentis, is commonly known as "multi-dosing."

Because Medicare paid physicians $400 for each 0.1-mg unit of Lucentis that they *inject*, not for each unit of Lucentis that they *purchase*, multi-dosing makes no fiscal difference to Medicare. Whether a physician purchases three 2.0-mg vials and uses each for only a single 0.5-mg treatment, or purchases only one vial and uses its contents for three treatments, the cost to Medicare is the same: about $400 for each 0.1-mg unit of the drug that the physician actually administers (*i.e.*, about $2,000 for every 0.5-mg dose). Multi-dosing is of fiscal consequence to the *drug manufacturer*, however, as the practice allows physicians to avoid purchasing massive quantities of the drug only to waste the vast majority of the medicine.

C. Administrative Proceedings

1. VRC is a Florida ophthalmology practice. During the relevant time period, and like many such practices, VRC frequently administered Lucentis to its patients. Also like other such practices, VRC opted not to follow the drug manufacturer's wasteful instructions and thus repackaged each 2.0-mg vial of Lucentis into approximately three separate 0.5-mg doses. In accordance with the Secretary's instructions, and with Medicare's local instructions, *see* CA11 J.A.176, VRC then billed Medicare for each 0.1-mg unit it administered. For purposes of this case, it is undisputed that VRC administered

Lucentis only to patients who needed it, that VRC accurately billed Medicare for each 0.1-mg unit it administered, and that the statutory payment rate for each of those units was approximately $400. And consistent with Medicare Part B's payment provisions, the Secretary initially paid VRC $400 for each of unit of the drug that it administered, regardless of whether it came from a multi-dosed vial.

Before long, however, the Secretary began to take issue with VRC's practice. In November 2007, Medicare contractors began investigating VRC "to determine whether [its] invoices for Lucentis" reflected that VRC purchased "a sufficient supply of the drug to cover what was billed to Medicare." CA11 J.A.487. From the start, the contractors emphasized that they were driven purely by economic, not medical, concerns. "Medical records were not the source" of the investigation, they repeatedly stressed, and "were ultimately not needed for the overpayment calculation." *Id.* Rather, even though Medicare would pay the exact same amount whether petitioner multi-dosed or wasted medicine, their concern was that "if a single use vial is administered to multiple patients …, then providers could be reimbursed significantly higher than their actual acquisition costs for the drug." CA11 J.A.505. As they told VRC, in their view, the problem was that "you administered the single use vial of Lucentis™ to as many as three patients per vial," but "did not reduce your billed amount for each patient so that the amount allowed per patient would accurately reflect your cost or expense for obtaining each vial." CA11 J.A.499.

The investigation ultimately culminated in a determination that the Secretary had "overpaid" VRC by nearly $9 million in 2007 and 2008. *See* App.62-63. VRC timely pursued review and paid the Secretary the $9 million her agents claimed she was owed.

2. Throughout the administrative proceedings that followed, those acting on the Secretary's behalf consistently invoked an "overstated expense" rationale, *not* any concern about whether multi-dosing is medically "reasonable and necessary." Indeed, if multi-dosing rendered Lucentis no longer "reasonable and necessary for the diagnosis or treatment of illness or injury," 42 U.S.C. §1395y(a)(1)(A), then Medicare could not have paid physicians for *any* units administered from a 2.0-mg vial that had been repackaged into three separate 0.5-mg syringes. Yet Medicare contractors repeatedly took the position that physicians who multi-dose Lucentis should be paid for every milligram they administer; their position was just that the statutory payment rate mandated by Congress should be reduced to reflect the physician's actual cost to purchase each dose. CA11 J.A.504;499;182.

The Secretary began to shift gears, however, after the D.C. Circuit decided *Hays v. Sebelius*, 589 F.3d 1279 (2009), which explicitly rejected the argument that the Secretary has discretion to adjust the statutory payment rates that Congress has mandated. As *Hays* explained, "the statute unambiguously authorizes the Secretary to make only a binary choice: either an item or service is

reasonable and necessary, in which case it may be covered at the statutory rate, or it is unreasonable or unnecessary, in which case it may not be covered at all." *Id.* at 1283. Apparently recognizing that her "overstated expense" theory could not be reconciled with *Hays* (or, as *Hays* held, with the plain text of the statute), the Secretary began to argue instead that, contrary to her earlier view, multi-dosing Lucentis is not medically reasonable after all.

3. The ALJ accepted both the overstated expense theory and the medical reasonableness theory. CA11 J.A.375-76. As to the former, the ALJ candidly acknowledged that he "reduce[d] the average sales price of each dose to $679.65"—one-third the statutory rate—"to reflect [VRC's] actual billing practices" and to counteract VRC's having "benefitted financially by extracting more [than one] dose[] from a single vial of Lucentis." CA11 J.A.375&n.1. The Medicare Appeals Council affirmed, but shifted theories yet again. The Appeals Council came to rest on the idea that when a physician multi-doses Lucentis, the *first* dose is medically reasonable—and therefore eligible for payment at the full statutory rate—but any subsequent doses from the same vial are *not* medically reasonable, and thus not eligible for payment, period App.85-86;95. Having found that new theory sufficient to justify its result, the Appeals Council did not address the Secretary's "overstated expense" theory. App.95n.19.

D. Proceedings Below

VRC challenged the Secretary's final decision in court, and, by minute orders, the district court upheld the Secretary's overpayment determination.

App.46-51. Although the district court stated that a "complete, written order is forthcoming," App.48;50, no order explaining its rationale ever came forth. The district court then denied VRC's subsequent motion for reconsideration. App.31-45. The opinion denying reconsideration did not mention the overstated expense rationale, and confined its limited discussion to the Secretary's assertion that multi-dosing Lucentis is medically unreasonable.

VRC appealed, and the Eleventh Circuit affirmed in a *per curiam* opinion. App.1-26. Although the court acknowledged "the truth of VRC's position that the resolution of this case is fiscally neutral to Medicare," App.12n.5, it nonetheless concluded that the Secretary could deny VRC the full statutory payment rate for each dose of Lucentis that it administered.

The court began by reviving the Secretary's "overstated expense" theory. According to the Eleventh Circuit, because the Medicare Act entitled VRC to more payment per dose than it spent to acquire each dose, the Secretary was entitled to unilaterally adjust the statutory payment rate. Claiming that "[n]othing in the statute forbids the Secretary from relating Medicare reimbursement to the physician's expense," App.14, the court gave an unqualified endorsement to the Secretary's "policy that reimbursement to providers should reflect more-or-less actual expense to the physician," App.16-17. In the court's view, the Secretary is free to "demand[] … that VRC's bill to Medicare reflect the expense incurred by VRC in purchasing the drug." App.13; *see also* App.17 (ratifying "Medicare's

decision to reimburse VRC for only its actual expenditure on Lucentis").[1]

While the court made clear that the Secretary could reduce the statutory payment rate *even if* the treatments at issue were medically "reasonable and necessary," it also went on to rubberstamp the Secretary's alternative argument that multi-dosing makes the second and third doses extracted from a

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[1] The Eleventh Circuit also cited Medicare's policy that "the cost of the drug … must represent an expense to the physician" in order for the drug to be covered. App.9 (quoting Medicare Benefit Policy Manual, Pub. No. 100-02, Ch. 15, §50.3). The court apparently understood this policy to mean that VRC could not receive a payment for units of Lucentis beyond the first 0.5 mg in each vial.

That is simply untrue. The Medicare policy just cited is not implicated by the present dispute, because VRC *did* incur an expense for each and every dose of Lucentis it administered—and therefore, each and every dose it administered remained eligible for payment. Medicare's own explanation of its policy confirms as much. As Medicare later put it, "when a provider purchases a vial or container of product, *the provider is purchasing an amount of drug defined by the product packaging or label*." CMS, Medicare Program, Payment Policies under the Physician Fee Schedule and Other Revisions to Part B for CY 2011 ("2011 Medicare Part B Payment Policies"), 75 Fed. Reg. 73170, 73466 (Nov. 29, 2010) (emphasis added). And during the relevant period, the manufacturer's product packaging defined the amount of Lucentis in each vial as four doses (2.0 mg). CA11 J.A.172. ("Each LUCENTIS carton … contains a 0.2 mL fill of 10 mg/mL ranibizumab in a 2-cc glass vial"). Therefore, whenever VRC purchased a vial of Lucentis, it was buying all 2.0 mg of the drug for approximately $2,000, with each 0.5-mg dose costing approximately $500. Because the cost of each unit represented an expense to VRC, each unit remained eligible for payment.

single vial of Lucentis not medically "reasonable and necessary." App.17-23. Notably, the panel did not ask, and the Secretary did not explain, *why* the "first" dose from a given vial (to the extent anyone can even distinguish among the three doses) is medically reasonable while additional doses from the same vial are not. Instead, the panel simply accepted the proposition that multi-dosing must be unreasonable because it departs from the instructions on the drug manufacturer's FDA-approved label. App.17 ("Because administering more than one dose of Lucentis from one vial violated the drug's FDA-approved labeling, the Secretary reasonably could have concluded that multi-dosing was medically inappropriate.").

REASONS FOR GRANTING THE PETITION

While the Medicare Act may be complex in many respects, on one issue, it is crystal clear: Congress, not the Secretary, decides how to calculate the payment rate for a drug covered under Medicare Part B. Yet according to the decision below, the Secretary may unilaterally slash Congress' statutory payment rates, even when doing so will not save the Secretary a dime, whenever she deems that a physician's payments rates are too high vis-à-vis the physician's acquisition costs. That conclusion squarely conflicts with the D.C. Circuit's conclusion in *Hays* that the Medicare Act unambiguously authorizes the Secretary to make only a binary choice: either a drug is covered at the rate Congress mandated, or it is not covered at all.

The Eleventh Circuit's "alternative holding" is equally inconsistent with *Hays*. According to the

Eleventh Circuit, even if the Secretary cannot *directly* alter statutory payment rates whenever she thinks they leave physicians with too high of a profit margin, she can achieve the same result *indirectly* by simply declaring cost-saving practices like multi-dosing "medically unreasonable." But as the D.C. Circuit recognized in *Hays*, the only question under the Medicare Act's "reasonable and necessary" prong is whether a drug is reasonable and necessary *to treat the patient's condition*. Perhaps the Secretary could deem all repackaging impermissible, and deny all payment, but that is decidedly not what she did. And the Eleventh Circuit did not and could not explain how the medical reasonableness of a 0.5-mg dose of Lucentis could differ depending on which of three indistinguishably repackaged syringes it came from. That is because, as her contractors initially conceded, the Secretary's efforts to claw back payments to VRC have nothing to do with *medical* reasonableness, and instead have everything to do with the Secretary's view that VRC should not be paid at a rate that is higher than what it cost VRC to acquire the drug.

The Secretary is certainly entitled to her opinion on that, but her opinion is not shared by Congress. As the D.C. Circuit correctly recognized, the Medicare Act mandates a single payment rate for covered drugs; it does not empower the Secretary to alter that rate at her discretion. And it certainly does not empower her to alter that rate when doing so will not even save the Secretary any money. The Secretary's motives might at least be understandable—even if ultimately inconsistent with the statute—if her attempt to distort the Act could

save Medicare money or drive down drug prices. But all it did was to force physicians to waste medicine, with no benefit to the federal fisc. The only party that stood to benefit from the Secretary's *ultra vires* intervention was the drug manufacturer. And the ultimate result of the Secretary's assertion of a rate-revising power is massive uncertainty and disruption that will ripple through the Medicare landscape, threatening to destabilize established practices to no apparent medical gain. Accordingly, this Court should grant certiorari to resolve the circuit split that the decision below creates.

I. The Decision Below Squarely Conflicts With The D.C. Circuit's Holding That The Secretary Cannot Alter The Payment Rates That The Medicare Act Mandates.

The Eleventh Circuit's decision adopts a legal rule that is squarely contrary to the D.C. Circuit's holding in *Hays*. According to the Eleventh Circuit, the Secretary has the power to cap a physician's Medicare Part B drug payments at whatever amount the physician paid to acquire the drugs administered. The D.C. Circuit, by contrast, has rejected that reasoning—and rightly so, for it is foreclosed by the plain text of the statute.

The Medicare Act spells out in painstaking detail how the Secretary must pay for Part B drugs such as Lucentis: "[W]ith respect to drugs and biologicals … not paid on a cost or prospective payment basis …, the amounts paid *shall be* 80 percent of the lesser of the actual charge or the payment amount established … under section … 1395w-3a … of this title[.]" 42 U.S.C. §1395*l*(a)(1)(S) (emphases added). Section

§1395w-3a, in turn, explains that "the amount of payment … is … 106 percent of" the average sales price. *Id.* §1395w-3a. The statute then instructs the Secretary to make payments at the statutory rate unless the "items or services" for which payment are sought "are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.'" *Id.* §1395y(a)(1)(A). Interpreting those statutory provisions, the D.C. Circuit concluded that "the statute unambiguously authorizes the Secretary to make only a binary choice: either an item or service is reasonable and necessary, in which case it may be covered at the statutory rate, or it is unreasonable or unnecessary, in which case it may not be covered at all." *Hays*, 589 F.3d at 1283. The statute does not give the Secretary to discretion to pay something *less* than the statutory payment rate based on her views as to whether *the rate itself* is reasonable and necessary under the circumstances.

As the D.C. Circuit explained, the Act's drug payment "formulas" are "mandatory," and they decree that "'the amount of payment ... *is*' 106% of the average sales price, as determined under the statutory formula." *Id.* at 1282 (quoting 42 U.S.C. §1395w-3a(b)(1)). The court found it "quite unlikely" that "Congress, having minutely detailed the reimbursement rates for covered items and services, intended that the Secretary could ignore these formulas whenever she determined that the *expense* of an item or service was not reasonable or necessary." *Id.* at 1282 (quotation marks omitted). The court thus rejected the Secretary's claim that she could reduce the payment for a *medically* reasonable

drug treatment on the theory that "the *expense* of an item or service was not reasonable or necessary" because the physician could have used a "less costly alternative." *Id.* at 1282 (quotation marks omitted).

The decision below cannot be reconciled with the D.C. Circuit's decision in *Hays*. According to the Eleventh Circuit, "[n]othing in the statute forbids the Secretary from relating Medicare reimbursement to the physician's expense." App.14. Setting aside the dubious suggestion that the Secretary may do anything that the statute does not "forbid,"[2] that is *exactly* what *Hays* found the statute forbids the Secretary from doing: When Congress said that "'the amount of payment ... *is*' 106% of the average sales price, as determined under the statutory formula," it necessarily precluded the Secretary from making anything other than a "binary choice" whether to cover the drug at all. *Hays*, 589 F.3d at 1282-83. The Eleventh Circuit's conclusion that the Secretary may insist "that reimbursement to providers should reflect more-or-less actual expense to the physician" *even if* she concludes that the treatment was medically reasonably and necessary is therefore impossible to square with *Hays*. App.16-17.

The Eleventh Circuit attempted to distinguish *Hays* on the theory that the case concerned only

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[2] *But see Aid Ass'n for Lutherans v. U.S. Postal Serv.*, 321 F.3d 1166, 1174-75 (D.C. Cir. 2003) ("[T]he Postal Service's position seems to be that the disputed regulations are permissible because the statute does not expressly foreclose the construction advanced by the agency. We reject this position as entirely untenable under well-established case law.").

whether the Secretary must make payments "without regard to alternative methods that would save Medicare money." App.13. That reasoning does not withstand scrutiny. To be sure, the specific question in *Hays* was whether the Secretary may reduce the statutory payment rate for a drug when a less costly alternative was available. But the interpretation of the statute that the D.C. Circuit adopted was not confined to that specific question. What the court concluded is that "the statute unambiguously authorizes the Secretary to make only a binary choice: either an item or service is reasonable and necessary, in which case it may be covered at the statutory rate, or it is unreasonable or unnecessary, in which case it may not be covered at all." *Hays*, 589 F.3d at 1283. The Secretary's *reasons* for wanting to pay something less than the statutory rate are beside the point under *Hays*.

Indeed, it would be more than passing strange if the statute precluded the Secretary from altering the statutory payment rate in the *Hays* context but permitted her to do so here. After all, at least the Secretary's policy in *Hays* was designed to save the Secretary money, as it meant that she would not have to pay the full statutory rate for the drug that the physician *actually* used if a less costly alternative was available. Here, by contrast, the decision below conceded that the Secretary's policy is fiscally neutral to Medicare in the long run, as she would have paid exactly the same amount for three treatments of Lucentis whether the physician drew the three 0.5-mg doses from one 2.0-mg vial or from three. The only entity that stands to benefit from the Secretary's policy of paying physicians based on their acquisition

costs, rather than on how many units of the drug they administered, is the drug manufacturer. In the Lucentis example, the Secretary's position let the manufacturer force physicians to purchase 75% more Lucentis than they actually needed. It would be bizarre indeed if Congress denied the Secretary authority to reduce payment rates to save the agency money, but gave her authority to reduce payment rates to maximize drug manufacturers' profits.

Tellingly, the Eleventh Circuit identified nothing in the text of the payment statute that supports its claim that the Secretary may "demand[] … that VRC's bill to Medicare reflect the expense incurred by VRC in purchasing the drug." App.13. Instead, the court just pointed to this Court's statement in *Bowen v. Georgetown University Hospital*, 488 U.S. 204 (1988), that "health care providers are reimbursed by the Government *for expenses incurred* in providing medical services to Medicare beneficiaries." *Id.* at 205 (quoted at App.14). But *Bowen* analyzed an entirely distinct part of the Medicare Act that dealt with payment rates for *inpatient hospital services*, and which expressly accounts for cost considerations. *See id.* at 206 (discussing hospital services and analyzing 42 U.S.C. §1395x(v)(1)(A)). Medicare Part B's outpatient drug provisions are completely different from those, as physician expenses are simply not part of Part B's payment formula. *See* 42 U.S.C. §1395w-3a.

Indeed, the Secretary herself has recognized on numerous occasions that she has no power to depart from the statutory payment scheme for covered Part B drugs and services based on a physician's

acquisition costs. As she explained earlier this year, "Medicare pays for most drugs that are administered in a physician's office or the hospital outpatient department at [average sales price] + 6 percent as described in section 1847A of the Act [42 U.S.C. §1395w-3a].... *The ASP payment amount does not vary based on the price an individual provider or supplier pays to acquire the drug.*" Medicare Program; Part B Drug Payment Model, 81 Fed. Reg. 13230-01, 13231 (proposed March 11, 2016) (to be codified at 42 C.F.R. pt. 511) (emphasis added); *id.* at 13253 ("Medicare pays this price [ASP + 6 percent] regardless of the price a provider pays to acquire the drug.").

The Secretary also admitted as much in *Hays*, telling the D.C. Circuit that "Part B drugs … are [not] reimbursed on a 'reasonable cost' basis." Br. for Appellant at 25, *Hays v. Sebelius*, 589 F.3d 1279 (D.C. Cir. 2009) (No. 08-5508), 2009 WL 3126592. Rather, she explained that "[t]he Medicare Act provides a detailed methodology for calculating the appropriate reimbursement for covered Part B drugs," and that "these provisions indicate that the appropriate reimbursement amount is equal to 106 percent of the drug's average sales price." *Id.* at 21-22. Accordingly, by the Secretary's own telling, the statute entitled VRC to payment at the average sales price rate for each unit of Lucentis that it administered, regardless of how much it spent to acquire the drug. The Eleventh Circuit's contrary decision cannot be reconciled with the plain text of the statute or the D.C. Circuit's decision in *Hays*.

II. The Eleventh Circuit's Alternative Holding Is No More Compatible With *Hays* Than Its Principal Holding.

The Eleventh Circuit's "alternative basis for denying reimbursement"—namely, that "multiple doses of Lucentis from a single vial were medically unreasonable," App.17—is equally inconsistent with *Hays*. Indeed, that reasoning allows the exact same end-run around the statute that *Hays* rejected.

The basic issue in *Hays* was whether the Medicare Act allows the Secretary to consider whether the physician's *expenses* were "reasonable and necessary," or only whether the treatment was *medically* "reasonable and necessary." *Hays*, 589 F.3d at 1281. The D.C. Circuit concluded that the statute plainly confines the Secretary's inquiry to the latter, as the statute asks only whether the "item or service" is "'reasonable and necessary *for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member*.'" *Id.* at 1287 (quoting 42 U.S.C. §1395y(a)(1)(A)) (emphasis added). Accordingly, in making the "binary choice" whether to cover a drug, the only question is whether its administration was *medically* "reasonable and necessary."

The Eleventh Circuit purported to apply that rule here, concluding that "the Secretary reasonably could have concluded that multi-dosing was medically inappropriate." App.17. But the court did not and could not explain how the Secretary could deem the "first" 0.5-mg dose obtained from a vial of Lucentis to be medically reasonable and necessary, but reach a different conclusion as to the "second"

and "third" doses obtained from that same vial. Indeed, there is not even any way to distinguish among the three, as each came from the same source and was repackaged into an identical separate syringe. *See* CA11 J.A.504. The contents of each syringe were identical, moreover, with the exact same chemical and medicinal properties. Arbitrarily declaring only one of the three treatments medically reasonable is thus plainly just a thinly veiled way of smuggling back into the payment analysis the same "reasonable expense" considerations *Hays* rejected.

Perhaps the best evidence of that is the fact that the Secretary initially advanced the "unreasonable *expense*" theory in this case, but then repackaged her argument to focus on *medical* reasonableness only after *Hays* rejected her original position. It is hard to take seriously the Secretary's belated claim that she had *medical* concerns about multi-dosing of Lucentis when her own contractors stated repeatedly that physicians who choose to multi-dose should be paid for each and every unit of the drug they administered—just at a lower rate than Congress mandated. *E.g.*, CA11 J.A.504;182. The Secretary's about-face thus not only confirms the conflict between the Eleventh Circuit's principal holding and *Hays*, but also underscores that the court's alternative holding is just another variant of the same "end-run around the statute" that *Hays* rejected. *Hays*, 589 F.3d at 1282.

Indeed, if anything, the Eleventh Circuit's alternative holding is even more pernicious than its principal holding. While the latter may be irreconcilable with the plain text of the statute, at

least tying the payment rate for a drug to the physician's acquisition cost is something the Secretary arguably has the competence (if not the power) to do. By contrast, tying the payment rate to whether the Secretary believes the "drug was administered properly," App.17, comes perilously close to allowing her to regulate the practice of medicine—something she plainly has *neither* the competence *nor* the power to do. *See* 42 U.S.C. §1395.

Implicitly recognizing as much, the Eleventh Circuit tried to outsource that responsibility to yet another agency, deeming it enough that "administering more than one dose of Lucentis from one vial violated the drug's FDA-approved labeling." App.17. But the FDA's approval of a label does not turn its text into medical requirements, because the FDA has no more power than the Secretary to regulate the practice of medicine. *See Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 350-51 (2001) (noting that the Food Drug and Cosmetic Act "expressly disclaims any intent to directly regulate the practice of medicine" (citing 21 U.S.C. §396)). Consistent with that understanding, the FDA itself has explicitly recognized that, once it approves a drug for sale, a "physician may, as part of the practice of medicine, lawfully … vary the conditions of use from those approved in the package insert, without informing or obtaining the approval of the Food and Drug Administration." FDA, Legal Status of Approved Labeling for Prescription Drugs; Prescribing for Uses Unapproved by the Food and Drug Administration, 37 Fed. Reg. 16503-02, 16503 (proposed Aug. 15, 1972).

Indeed, the FDA has even recognized that the specific practice at issue here is a permissible one. The agency recently issued draft guidance clarifying that ophthalmic drugs "packaged in a single dose vial" may permissibly be "repackaged into multiple single dose syringes despite the fact that the label of the approved product states, 'Single-use vial … Discard unused portion.'" FDA, Draft Guidance, Mixing, Diluting, Or Repackaging Biological Products Outside The Scope Of An Approved Biologics License Application Guidance for Industry, 2015 WL 1735391, at *8 & n.15 (Feb. 1, 2015) (discussing Avastin, a drug almost identical to Lucentis and made by the same manufacturer). It is hardly reasonable for the Secretary to rely on the FDA's approval of a label as grounds for rejecting a practice that the FDA itself has deemed reasonable.

In the end, then, the Secretary's efforts to find some way to claw back VRC's Medicare payments without running afoul of *Hays* (not to mention the statute's plain text) succeed only in confirming that no such path exists. Whether framed as an "overstated expense" theory or a "medical unreasonableness" theory, the upshot of the Secretary's position remains the same: She does not believe that a physician should be able to receive Medicare payments at a rate higher than the cost that the physician paid to obtain the drugs—even if making payments at the statutorily prescribed rate would be fiscally neutral to the Medicare program. That may be a reasonable position as a policy matter, but it is not the position Congress wrote into the Medicare Act. By sanctioning the Secretary's efforts to import her own policy preferences into the statute,

the Eleventh Circuit has enabled the same "end-run around the statute" that the D.C. Circuit condemned. *Hays*, 589 F.3d at 1282.

III. The Decision Below Threatens To Destabilize The Administration Of The Medicare Program.

Whether the Secretary may ignore Congress' statutory payment rate for drugs covered under Medicare Part B is a critically important question to Medicare beneficiaries and physicians alike. Any divergence among the courts on how to answer that question thus creates a destabilizing situation for all parties involved—particularly when the two courts that have reached different answers are among the two most likely to review Medicare payment disputes. Moreover, the Secretary's position that she may unilaterally reduce the statutory payment rate for a drug will have consequences far beyond the program itself.

In effect, the Secretary is claiming the power to renegotiate drug prices and decide who, as between *physicians and drug manufacturers*, should reap any profits that Congress' statutory rate enables. That might be a useful power for the Secretary to possess, but it is certainly not a power that Congress has assigned to the Secretary. Moreover, to the extent the statute speaks to that question, its fixed payment rates suggest that the Congress intended the answer to be physicians, as part of the point of fixing uniform payment rates is to facilitate administrative efficiencies on the provider side of the equation. The decision below thus not only grants the Secretary a power she does not have, but also sanctions a result

that is difficult to square with the broader objectives of Congress' payment scheme.

The decision below is all the more troubling because it empowers the Secretary to withhold payment for a drug whenever the physician departs from the manufacturer's instructions, with no questions asked. That is a startling new power with tremendous practical implications. As this Court has recognized, "off-label use is generally accepted," "widespread in the medical community[,] and often … essential to giving patients optimal medical care." *Buckman*, 531 U.S. at 351 & n.5 (quotation marks omitted). For example, ophthalmologists nationwide use both Lucentis and its molecular cousin Avastin, both made by the same manufacturer, *see* CA11 J.A.249, to treat AMD. But only Lucentis is actually FDA-approved for that purpose. Avastin, by contrast, is FDA-approved only to treat cancer via intravenous infusion, and it is sold only in "single-use" vials that are far larger than the dose needed to treat AMD. CA11 J.A.186-87. To treat AMD, Avastin thus *must* be both multi-dosed and used "for some other purpose than that for which it has been approved by the FDA," *see Buckman*, 531 U.S. at 350—even though that violates the manufacturer's instructions in every conceivable way.[3] While the

[3] As the U.S. Department of Health and Human Services Office of Inspector General observed: "Because Avastin is packaged in 100- and 400-mg vials that exceed the 1.25-mg dose commonly used for treating wet AMD, physicians often use compounding pharmacies to repackage the drug into single-use syringes that contain the smaller dose" for eye injections. CA11 J.A.249n.11.

Secretary currently covers the off-label and multi-dosed use of Avastin to treat AMD (which raises the question why she insists on strict adherence to the label for Lucentis), according to the decision below, she is free to change that practice at any time.

Physicians are thus left at sea as to whether and under what circumstances they may exercise their medical judgment to deviate from a manufacturer's labeling instructions without jeopardizing their receipt (or retention) of Medicare payments. By giving the Secretary the option of treating a drug manufacturer's instructions as inviolate—without any requirement that she exercise this option consistently or pursuant to any established guidance—the Eleventh Circuit has effectively turned every label instruction into a tripwire that the Secretary may set off without any advance warning to doctors and patients. And drug manufacturers, in turn, are now free to write labeling instructions that ultimately encourage waste and ensure greater profits for themselves. That state of affairs is not remotely contemplated by the Medicare Act, and should not be allowed to persist.

Finally, this case has implications for another case on this Court's docket, as VRC's ophthalmologist, Dr. Salomon Melgen, is also the co-defendant of U.S. Senator Robert Menendez in the prosecution underlying the petition for certiorari filed last week in *Menendez v. United States*, No. 16-755. The question presented in *Menendez* concerns whether certain official actions by Senator Menendez, including meeting with executive branch officials to discuss the Secretary's policy with respect

to Lucentis, were legislative acts protected by the Speech or Debate Clause. In an effort to deprive Senator Menendez of his protections under the Speech or Debate Clause, the government has belittled the substantial legal and policy questions surrounding the Secretary's payment policy and dismissed Senator Menendez's interest in the issue as mere constituent service and special pleading for Dr. Melgen. As this petition confirms, the legal and policy concerns raised by the Secretary's policy are real. Indeed, an issue on which the circuits can split is certainly an issue on which a Senator can express legitimate policy objections that go well beyond mere constituent service. The Court's consideration of this petition may therefore inform its consideration of the *Menendez* petition, and vice versa.

CONCLUSION

For the foregoing reasons, this Court should grant the petition.

Respectfully submitted,

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December 21, 2016

APPENDIX

TABLE OF APPENDICES

Appendix A

UNITED STATES COURT OF APPEALS
FOR THE ELEVENTH CIRCUIT

Nos. 14-15342 & 15-12005

VITREO RETINAL CONSULTANTS OF THE PALM BEACHES, P.A., a Florida corporation,

Plaintiff-Appellant,

v.

U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES,

Defendant-Appellee.

Appeals from the United States District Court
for the Southern District of Florida,
No. 1:13-cv-22782-MGC

Filed: April 29, 2016

Before Hull, Marcus, and Rosenbaum,
Circuit Judges.

OPINION

Per Curiam:

Plaintiff-Appellant Vitreo Retinal Consultants of the Palm Beaches, P.A. ("VRC"), brought suit in the Southern District of Florida against the United States Department of Health and Human Services

("HHS") and the Secretary of HHS Sylvia Burwell ("Secretary") seeking the recoupment of payments VRC returned to Medicare after it was issued notice of an overpayment. Throughout the Medicare administrative review process, HHS upheld the ruling denying recoupment. The district court similarly affirmed HHS's decision. After careful review, we now affirm the ruling of the district court upholding the administrative decision.

I.

A. Administration of Lucentis

During the years 2007 and 2008, VRC served patients covered by Medicare Part B who suffered from age-related macular degeneration ("AMD") and other retinal diseases. Among other treatment methods for AMD, VRC administered the intravitreal injection of Lucentis. Lucentis is FDA approved for the treatment of AMD. It is manufactured and sold by Genentech, Inc., in 2.0-mg vials.

The FDA-approved labeling on the drug instructs that a single 0.5-mg dose of Lucentis be injected into the patient's eye once each month. The proper method for extracting the drug and administering the injection described on the label requires the healthcare professional to extract the *full contents* of the 2.0-mg vial into a syringe. The contents of the syringe are then to be expelled until the plunger tip is aligned with the line that marks 0.05 mL (0.5 mg). Then the dose is to be injected into the patient's eye. The label further instructs that "[e]ach vial should only be used for the treatment of a single eye."

First Coast Service Options, Inc., administers Medicare payment processing in Florida. SafeGuard

Services LLC audits Medicare claims. In February 2008, First Coast issued its first Local Coverage Determination for Lucentis, acknowledging that the drug was "medically reasonable and necessary" for the treatment of AMD. The Local Coverage Determination incorporated the label's instruction that "[e]ach vial should only be used for treatment of a single eye."

VRC did not follow the Lucentis label's instructions limiting dosage to one per vial. Instead, VRC treated up to three patients from a single vial. It did so by extracting up to three doses of 0.5 mg each from one vial into three separate syringes. This process is referred to by the parties as "multi-dosing." VRC billed Medicare for every 0.5-mg dose of Lucentis it administered.

The reimbursement rate for Medicare Part B drugs is capped at the lower of the physician's billed charge or 106% of the drug's average sales price. 42 U.S.C. § 1395w-3a. The drug's average sales price, in turn, is calculated quarterly based on nationwide sales, divided by the total number of units of drug sold. *Id.* (c)(1), (5)(B). Physicians receive reimbursement based on the number of dosage units used to treat a patient. *Id.* (b)(1). Where a drug's administration results in wasted contents, Medicare reimburses the physician for the waste if it was a necessary part of administration. Medicare Claims Processing Manual, Pub. No. 100-04, Ch. 17, § 40.

The calculated reimbursement rate of Lucentis during the period at issue was approximately $405 per 0.1 mg administered or $2,025 for a standard 0.5-

mg dose.[1] This price was reached by determining the cost of an entire single-use vial of Lucentis. The average sales price for a vial was $2,025. This price was then assigned as the cost of one dose of 0.5 mg. The 0.5-mg dose was then broken down into individual units of 0.1 mg, with a reimbursement rate of $405 ($2,025 ÷ 5). Hence, if administered according to the label, a provider would inject 0.5 mg into a patient's eye, dispose of 1.5 mg, and receive reimbursement in the amount of approximately $2,025 for the single vial—or the total average cost of the 20-mg vial. VRC billed Medicare at the allowed rate for every 0.5-mg dose it administered,[2] resulting in a bill for approximately $2,025 for every dose. Because VRC was extracting up to three doses from a single vial, it was "reimbursed" for approximately $6,075 per single Lucentis vial, three times the average cost of the vial and three times the amount it would have received had it administered the drug according to the label.

B. Administrative Proceedings

In June 2009, SafeGuard issued to VRC a preliminary overpayment determination of approximately $8.9 million, representing the amount charged for two-thirds of the doses administered by VRC against the label's instructions. In July of the

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[1] During 2007-2009 the average sales price of Lucentis fluctuated between approximately $405 and $407. The exact amount is immaterial for the purpose of this opinion.

[2] VRC's billed charge was higher than the 106% statutory rate, so the lower rate based on the average sales price was applied in accordance with the Medicare statute. 42 U.S.C. § 1395w-3a.

same year, First Coast published an updated Local Coverage Determination under the title "Article Clarification" specifically aimed at eliminating payment for multi-dosing from single-use Lucentis vials. This publication stated that "when a single use vial is used and billed for three patients at 0.5 mg per patient . . . [t]he physician is then overstating his/her expense." In addition, First Coast adopted SafeGuard's overpayment determination and concluded that VRC "should have known [it was] not entitled to" the overpayment and was therefore liable to repay to Medicare $8,982,706.98. VRC's request for reconsideration was denied and VRC complied with the repayment demand. VRC also pursued administrative review.

An administrative law judge ("ALJ") upheld the overpayment determination. The ALJ noted that VRC had not complied with the drug's label. As a result, the ALJ concluded, the injection of more than one dose from one vial of Lucentis was not "safe and effective" and was not covered by Medicare Part B. The Medicare Appeals Council subsequently affirmed the ALJ's decision.[3] The Appeals Council held that

[3] The Appeals Council's decision refined the ALJ's decision in one detail. The ALJ found that VRC's administration of Lucentis was not medically reasonable and necessary. On the other hand, the ALJ calculated the proper payment for all three doses of Lucentis, allowing VRC to charge for all three doses from a single vial, but at a reduced billing rate that reflected a two-thirds decrease in the allowed rate. The Appeals Council held that this was contradictory: If VRC's administration of Lucentis was not reasonable, it should not receive reimbursement for more than one dose per vial. The Appeals Council modified the decision accordingly and held that the administration of a single 0.5-mg dose of Lucentis from a single

Lucentis injections are "medically reasonable and necessary [only] to the extent the drug [is] administered consistent with its FDA-approved label." In addition, the Appeals Council held that VRC "knew, or could reasonably be expected to know, that the Lucentis injections . . . would not be covered by Medicare," so it was liable for the overpayment under 42 U.S.C. § 1395pp(a).

C. District Court Proceedings

VRC filed suit in the Southern District of Florida. The district court granted summary judgment for HHS. It gave deference to the agency's decision because "[p]laintiff has failed to demonstrate that the Secretary[']s decision was arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." VRC now appeals.

II.

We review *de novo* grants of summary judgment, and we the same legal standards that bound the district court. *Whatley v. CNA Ins. Cos.*, 189 F.3d 1310, 1313 (11th Cir. 1999). Summary judgment is appropriate when the record reflects show no genuine issue of material fact and demonstrates that the moving party is entitled to judgment as a matter of law. *Connelly v. Metro. Atlanta Rapid Transit Auth.*, 764 F.3d 1358, 1363 (11th Cir. 2014).

In a dispute related to Medicare reimbursement, "[t]he findings of the [Secretary] as to any fact, if

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vial was reasonable and should be reimbursed at the full rate of $2,025, while the administration of second and third doses from the same vial was not reasonable because it did not comply with the drug's label.

supported by substantial evidence, shall be conclusive." 42 U.S.C. §§ 405(g), 1395ff(b)(1)(A). We therefore limit our review to whether substantial evidence supports the Secretary's findings and whether the Secretary applied the correct legal standards. *Wilson v. Barnhart*, 284 F.3d 1219, 1221 (11th Cir.2002); *see* 42 U.S.C. § 1395ff(b)(1)(A) (incorporating into Medicare Act the standard of review set forth in 42 U.S.C. § 405(g)). *Gulfcoast Med. Supply, Inc. v. Sec'y, Dep't of Health & Human Servs.*, 468 F.3d 1347, 1350 n.3 (11th Cir. 2006). Substantial evidence "is 'such relevant evidence as a reasonable mind might accept as adequate to support a conclusion.'" *Barnes v. Sullivan*, 932 F.2d 1356, 1358 (11th Cir. 1991) (citations omitted). "We review de novo the district court's decision on whether substantial evidence supports the ALJ's decision." *Wilson*, 284 F.3d at 1221.

As for legal conclusions, the Administrative Procedure Act limits our review to determining whether the agency's actions were "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706. "[T]his standard is exceedingly deferential." *Fund for Animals, Inc. v. Rice*, 85 F.3d 535, 541 (11th Cir. 1996). As we have previously explained, "the arbitrary and capricious standard gives an appellate court the *least* latitude in finding grounds for reversal; '[a]dministrative decisions should be set aside in this context . . . only for substantial procedural or substantive reasons as mandated by statute, . . . not simply because the court is unhappy with the result reached.'" *Rice*, 85 F.3d at 541-42 (citations omitted). We are not permitted to

substitute our judgment for that of the agency "concerning the wisdom or prudence of the proposed action." *Id.* We have further recognized that our deference to the Secretary's judgment is especially warranted in the context of Medicare "[b]ecause Medicare is a 'complex and highly technical regulatory program.'" *Gulfcoast Med. Supply*, 468 F.3d at 1353 (citation omitted).

III.

"Title XVIII of the Social Security Act, 79 Stat. 291, as amended, 42 U.S.C. § 1395, *et seq*., commonly known as the Medicare Act, establishes a federally subsidized health insurance program to be administered by the Secretary." *Heckler v. Ringer*, 466 U.S. 602, 605, 104 S. Ct. 2013, 2016 (1984). Medicare Part B creates voluntary supplemental medical insurance covering, among other things, doctors' services and outpatient care. 42 U.S.C. § 1395k(a)(2). Under the program, Medicare beneficiaries receive medical treatment, and providers submit claims for government reimbursement. 42 U.S.C. § 1395n. To prevent abuse and to control costs, Congress has authorized Medicare reimbursement for "medical and other health services" if they are "reasonable and necessary" only. *See* 42 U.S.C. §§ 1395k(a)(1), 1395y(a)(1)(A). "Medical and other health services" include "services and supplies [] furnished as an incident to a physician's professional service." 42 U.S.C. § 1395x(s)(2)(A). Under the Medicare Act, the Secretary has the authority "to determine what claims are covered by the Act 'in accordance with the

regulations prescribed by him.'" *Ringer*, 466 U.S. at 605, 104 S. Ct. at 2016 (citing 42 U.S.C. § 1395ff(a)).

The Centers for Medicare and Medicaid Services ("CMS") within HHS are responsible for the administration of Medicare Part B, including the determination of coverage for physician-administered drugs. *HHS, CMS Reorganization Order*, 66 Fed. Reg. 35437 (July 5, 2001). CMS published the Medicare Benefit Policy Manual to provide guidance on Medicare Part B coverage. This manual instructs that "[i]n order to meet all the general requirements for coverage under the 'incident to' provision . . . the cost of the drug or biological must represent an expense to the physician." Pub. No. 100-02, Ch. 15, § 50.3. The Policy Manual further requires that drugs be "safe and effective." *Id.* § 50.4.1. Drugs are "safe and effective" when "used for the indications specified on the labeling." *Id.*

Regional Medicare contractors, in turn, are authorized to issue Local Coverage Determinations governing when items and services are "reasonable and necessary" and therefore payable by Medicare. 42 U.S.C. § 1395ff(f)(2)(B). CMS published the Medicare Program Integrity Manual to guide regional contractors in their local coverage determinations. Pub. No. 100-08, Ch. 13. This manual instructs that coverage determinations should be based on whether an item is "[a]ppropriate . . . in terms of whether it is [f]urnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition." *Id.* § 13.5.1.

In the instant case, First Coast, the regional Medicare contractor for Florida, issued a Local Coverage Determination, acknowledging Medicare coverage for Lucentis. As described above, the Local Coverage Determination incorporated the label's instruction: "Each vial should only be used for treatment of a single eye. If the contralateral eye requires treatment, a new vial should be used." Based on this instruction, the Secretary, through First Coast and SafeGuard, determined that Medicare would not reimburse for multiple doses of Lucentis administered from the same vial.

VRC argues that the Secretary's determination was unlawful. First, VRC asserts that the Secretary exceeded her authority in calculating the reimbursement allowance for Lucentis at anything less than full payment for every 0.5-mg dose, regardless of how many doses were administered per vial. Second, VRC contends that the Secretary's determination that administering more than one dose per vial was medically unreasonable and unnecessary was arbitrary and capricious and not supported by substantial evidence. Finally, VRC maintains that even if the Secretary's decision was proper, it should be applied prospectively only, and VRC should not be held liable to repay Medicare the overpayment amount of $8.9 million. We do not find merit in VRC's arguments.

A. VRC's Charge to Medicare did not Reflect its Expense and was Not Medically Reasonable.

The Secretary denied payment to VRC on two grounds. Initially, the Secretary denied payment because VRC "overstated [its] expense" by billing

Medicare for each 0.5-mg dose of Lucentis it administered, when it did not purchase and incur the expense of a full 2.0-mg vial for each dose. Later in the review process, the Secretary based her denial of payment on the finding that multiple doses were not medically reasonable and necessary.

Before addressing the merits, we consider a procedural argument urged by VRC. There is some indication that the two reasons offered by HHS were not offered contemporaneously. In the initial overpayment letter, HHS based its decision on "overstated expense."[4] Only later in the review process—on review before the Medicare Appeals Council—did HHS assert that multi-dosing was medically unreasonable. VRC insinuates that this history automatically indicates arbitrariness. We disagree.

First, it is not clear that HHS ever surrendered its first reason. In the district court, the Secretary expressly relied on the overstated-expense theory.

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[4] In the initial overpayment letter from First Coast, HHS stated that "medical necessity is not an issue in this case" and that the only issue was the overstated expense. VRC attempts to argue that this statement waived the Secretary's subsequent position that multi-dosing was medically unreasonable. We disagree. Even without considering whether the Secretary can permissibly change her reasoning justifying a particular application of a rule in a given case, all that can be surmised from this single line in the letter is that the overpayment determination was not based on concerns that VRC was administering drugs to patients who did not need them. In other words, HHS was conceding that Lucentis is medically reasonable for the treatment of AMD in general. There is nothing in the letter indicating that HHS was condoning the practice of multi-dosing from single vials of Lucentis.

And on appeal, in its brief, HHS contests VRC's assertion regarding the fiscal effects of the Secretary's position, an argument closely related to the overstated-expense theory.[5] But even if HHS had changed its reason for denying payment, that, in and of itself, would not necessarily make the Secretary's decision arbitrary.

The Supreme Court has repeatedly held that an agency can change its position on an issue, so long as it gives a proper reason for doing so. *See, e.g.*, *F.C.C. v. Fox Television Stations, Inc.*, 556 U.S. 502, 129 S. Ct. 1800 (2009) (holding agency need not provide a more substantial reason for a change in policy than the arbitrary standard); *Nat'l Cable & Telecommunications Ass'n v. Brand X Internet Servs.*, 545 U.S. 967, 981, 125 S. Ct. 2688, 2699 (2005) ("Agency inconsistency is not a basis for declining to analyze the agency's interpretation under the *Chevron* framework"); *see also Am. Petroleum Inst. v. E.P.A.*, 661 F.2d 340, 355 (5th Cir. 1981) ("Nothing in the Administrative Procedure Act prohibits an agency from changing its mind."). Because it is not clear that the Secretary intended to forgo her initial argument, we address both reasons that the Secretary proffers.

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[5] Below, we disagree with the Secretary's argument on this point and recognize the truth of VRC's position that the resolution of this case is fiscally neutral to Medicare. *See infra* Part I.A. However, the point here is that the Secretary did raise the overstated expense issue on appeal and it is appropriate for us to address in this opinion.

1. Overstated Expense

VRC argues that the Secretary's first rationale is flawed because Medicare reimbursement is not related to the physician's expense. For support, VRC cites *Hays v. Sebelius*, 589 F.3d 1279 (D.C. Cir. 2009). That case concerned whether the Secretary could deny payment for DuoNeb, a drug used to treat Chronic Obstructive Pulmonary Disease. *Id.* at 1280. DuoNeb provides a combination of two separate drugs in one dose and is more expensive than purchasing the component drugs separately. *Id.* The Secretary argued that Medicare's "least costly alternative policy" required that reimbursement be limited to the cost of the two separate drugs rather than the higher cost of DuoNeb. *Id.* The District of Columbia Circuit held that the statute is unambiguous in its instruction to the Secretary: "either an item or service is reasonable and necessary, in which case it may be covered at the statutory rate, or it is unreasonable or unnecessary, in which case it may not be covered at all." *Id.* at 1282. As the court explained, "Nothing in the statute authorizes the least costly alternative policy." *Id.* at 1283.

We think *Hays* inapposite. *Hays* construed the Medicare statute to require Medicare to pay for any drug it deems reasonable and necessary, without regard to alternative methods that would save Medicare money. Here, the Secretary did not demand that VRC administer a cheaper alternative than Lucentis. Instead, the Secretary demanded only that VRC's bill to Medicare reflect the expense incurred by VRC in purchasing the drug. Medicare's policy is

that "[t]he charge . . . for the drug or biological must be included in the physician's bill, and the cost of the drug or biological *must represent an expense to the physician*." Medicare Benefit Policy Manual, Pub. No. 100-02, Ch. 15, § 50.3 (emphasis added). Nothing in the statute forbids the Secretary from relating Medicare reimbursement to the physician's expense. On the contrary, the very concept of "reimbursement" contemplates payment for money that was actually spent. *See Reimbursement*, *The Am. Heritage Dictionary* (4th ed. 2000) ("1. To repay (money spent); refund. 2. To pay back or compensate (another party) for money spent or losses incurred . . . ."); *see also Bowen v. Georgetown Univ. Hosp.*, 488 U.S. 204, 205, 109 S. Ct. 468, 470 (1988) ("health care providers are *reimbursed* by the Government for *expenses incurred* in providing medical services to Medicare beneficiaries.") (emphasis added).

VRC also points to a recent CMS publication that describes Medicare's policy for reimbursing medical providers. 81 Fed. Reg. 13229 (March 11, 2016). This publication explains that "Medicare pays for most drugs . . . at ASP+ 6 [Average Sales Price + six percent]. . . . The ASP payment amount does not vary based on the price an individual provider or supplier pays to acquire the drug." *Id.* at 13231; *see also id.* at 13253 ("Medicare pays this price regardless of the price a provider pays to acquire the drug."). VRC argues that this publication contradicts the Secretary's position.

Again, we disagree. Under CMS's policy, once it has determined the Average Sales Price and calculated the 106% reimbursement rate for a given

drug, CMS does not inquire into individual medical providers' costs when calculating reimbursement. Instead, CMS reimburses at the 106% rate, regardless of the possibility that a given provider may have obtained the drug at a reduced rate. That is not what happened here. VRC's profits from treating AMD with Lucentis did not stem from the advantage of purchasing the drug at a reduced rate. VRC bought Lucentis at the market rate. Its extraordinary profits arose from using a single-dose-approved vial for three patients, in violation of the FDA-approved instructions.

VRC next suggests that Medicare's policy to pay for overfill runs counter to the position that HHS has taken with respect to VRC. Under the overfill policy, CMS "reimburse[s] suppliers for the total number of units administered . . . . CMS does not make any payment determinations based on the absence or presence of 'overfill' in a vial." "Overfill" is "[a]ny excess free product . . . provided without charge" when a physician purchases a vial of a drug, in excess of amounts "defined by the product packaging." 75 Fed. Reg. 73170, 73466 (Nov. 29, 2010). VRC argues that if Medicare reimburses for overfill, even though overfill is obtained without cost, certainly Medicare should reimburse for the full contents of a vial of Lucentis in order to reimburse the full expense to the provider in purchasing the vial.

We are not persuaded. Medicare's policy to reimburse for overfill means only that where a manufacturer does not charge for excess drug, Medicare will not recalculate its unit price for the

excess drug. But this policy is inapplicable in a situation where Medicare has calculated the unit price for a drug based on the presumption that some of a vial's content will necessarily not be used per the drug's instructions. In such a case, if a physician does not comply with the instructions and multi-doses, the presumption for the calculation is lost and a recalculation is in order.

Here, Medicare determined the unit price for Lucentis, taking into account the full contents of a Lucentis vial and the label instructions for administration. Because only 0.5 mg of a 2.0-mg vial should actually be administered under the FDA-approved labeling, the price of the full vial was assigned as the price of a single 0.5-mg dose. Therefore, every time a physician buys a single 2.0-mg vial and administers a single 0.5-mg dose from the vial (disposing of 1.5 mg of the drug), the physician is compensated for the full cost of purchasing the 2.0-mg vial, despite the fact that the doctor administers only 0.5 mg. Indeed, upon discovery of VRC's actions, First Coast issued an article clarification specifically recalculating the unit price of Lucentis if a physician used a single vial to administer more than one dose.

We also reject VRC's argument that the Secretary's decision was arbitrary because the total amount of reimbursement would not have changed whether Medicare reimbursed at the full amount of $2,025 for three doses of a single vial or required that every dose be administered from separate vials. This argument fails to account for Medicare's lawful policy that reimbursement to providers should reflect more-

or-less actual expense to the physician. *See Bowen*, 488 U.S. at 205, 109 S. Ct. at 470. And since that policy is not arbitrary or capricious, Medicare's decision to reimburse VRC for only its actual expenditure on Lucentis cannot be arbitrary or capricious, either.

2. Medical Reasonableness and Necessity

As an alternative basis for denying reimbursement, the Secretary reasoned that multiple doses of Lucentis from a single vial were medically unreasonable, based on the FDA-approved labeling instructions allowing for only a single dose from a single vial. VRC contends that this decision was arbitrary.

a. Medical Distinction between Doses

First, VRC argues that it is arbitrary for the Secretary to treat the first dose of Lucentis from a given vial as medically reasonable and the other two doses from the same vial as medically unreasonable. We disagree. The inquiry into whether a drug is medically reasonable and necessary in the Medicare reimbursement context is not limited to an assessment of whether the drug is suited to treat the disease or condition for which it was administered. The inquiry also accounts for whether a drug was administered properly. *See* Medicare Policy Integrity Manual, Pub. No. 100-08, Ch. 13, § 13.5.1. Because administering more than one dose of Lucentis from one vial violated the drug's FDA-approved labeling, the Secretary reasonably could have concluded that multi-dosing was medically inappropriate.

b. Local Coverage Determination

Next, VRC argues that its administration of multi-doses of Lucentis complied with the then-existing conditions for Medicare coverage. First Coast's 2008 Local Coverage Determination stated that "Medicare will consider [Lucentis] medically reasonable and necessary for patients" with AMD. VRC asserts that nothing in this initial Coverage Determination described the proper process for preparation of injections or prohibited multi-dosing. In support, VRC points to the fact that in 2009 First Coast published an "Article Clarification" specifically reducing payment for multi-dosing, the implication being that until then multi-dosing was acceptable and would be reimbursed at the full rate.

We disagree. The 2008 Coverage Determination expressly incorporated the drug's labeling: "Each vial should only be used for the treatment of a single eye. If the contralateral eye requires treatment, a new vial should be used." We cannot say that it was arbitrary or capricious for HHS to read this instruction as a prohibition against administering more than one dose from a single vial, regardless of whether VRC proposes another reasonable interpretation of the labeling. Nor does the Secretary's issuance of the 2009 "Article Clarification" undermine the reasonableness of her original interpretation of the labeling. Rather, the Article Clarification is entirely consistent with the Secretary's original interpretation. We review the Secretary's decision for arbitrariness, and reading the instruction as prohibiting multi-dosing is not arbitrary.

c. Practice of Multi-Dosing

VRC also contends that CMS encourages the practice of multi-dosing from single-use vials and that the practice is widely accepted in the medical community. In support of this position, VRC invokes the Medicare Claims Processing Manual, which states that "CMS encourages physicians, hospitals and other providers to schedule patients in such a way that they can use drugs or biologicals most efficiently, in a clinically appropriate manner." Pub. No. 100-04, Ch. 17, § 40 [A162.]. In addition, VRC relies on a response to a "Frequently Asked Question" ("FAQ") that CMS published on its website in March 2011. The question asked whether Medicare would provide coverage "for a drug from a single dose vial if it is administered to more than one beneficiary[.]" CMS responded that it "encourages physicians . . . to care for and administer to patients in such a way that they can use drugs or biologicals most efficiently, in a clinically appropriate manner. . . . [O]ur policies neither encourage or [sic] prohibit the administration of more than one dose from a single dose vial to one or more beneficiaries."[6] Finally, VRC points to the Secretary's policy to

[6] VRC also cites FDA publications permitting repackaging and multi-dosing from single-use vials, arguing that even if it was required to follow the drug's label's instructions, the FDA itself disregards them. The relevant publications address repackaging in specialized, licensed facilities with a high level of air quality to avoid contamination. *See Draft Guidance Mixing, Diluting, Or Repackaging Biological Products Outside The Scope Of An Approved Biologics License Application Guidance For Industry*, 2015 WL 1735391. They are inapplicable to VRC, which is not a licensed repackaging facility.

reimburse physicians for multiple doses from single vials of Botox and Avastin. VRC contends that both of these drugs come in "single-use" vials, yet Medicare reimburses for multiple doses.

These arguments lack merit. Both publications on which VRC relies include the important disclaimer that multiple doses are acceptable only if administered "in a clinically appropriate manner." And the CMS response to the FAQ explains that "clinically appropriate methods" are determined by "numerous factors, including but not limited to: approved labeling."

VRC's analogy to Botox and Avastin is misplaced as well. Botox is a vacuum-dried powder that is available in 100-unit vials only. Before administration, the physician must reconstitute all of the powder from the single vial with saline solution. Once reconstituted, the drug must be stored in a refrigerator and used within 24 hours. To prevent physicians from saving the drug for use beyond 24 hours, Botox is labeled "Single Patient Use." But the Botox packaging insert instructs, "A new, sterile, needle and syringe should be used to enter the vial on each occasion for removal of Botox." So the drug's instructions expressly contemplate multiple doses from a single vial. That, of course, is not the case with Lucentis.

As for Avastin, it is sold in 100- or 400-mg vials, must be diluted before administration, and should be stored for no more than eight hours. Avastin is FDA-approved only for the treatment of certain forms of cancer; treatment of AMD is an off-label use. Therefore, although the Avastin instructions state

that the physician should "[w]ithdraw [the] necessary amount . . . [and] [d]iscard any unused portion," these instructions apply only where the drug is used for the treatment of cancer, in which case a single dose varies between 100 mg and 400 mg. But Medicare has a separate procedure for determining coverage for off-label use, taking into account accepted standards of medical practice for that drug's off-label use, which often vary from accepted standards for on-label use. *See* Medicare Benefit Policy Manual, Pub. No. 100-02, Ch. 15, § 50.2. When Avastin is used for the treatment of AMD, a single dose is as small as 1.25 mg. The accepted medical practice is to use multiple doses from a single vial of Avastin when it is being used to treat AMD. In this context, as with Botox, Avastin's admonition of "single use" is intended to prevent physicians from using product that has been stored past the acceptable eight-hour timeframe.

Unlike Avastin, Lucentis's on-label, FDA-approved use is for treating AMD. Its label expressly states that each vial should be used for only the treatment of a single eye and the excess drug should be drawn into the syringe and expelled. VRC administered Lucentis for its on-label use and failed to follow the instructions regarding that use, without any support from an established medical practice that differs from the label's instructions.[7]

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[7] VRC attempts to analogize Lucentis to Kenalog as well. This analogy also fails because, unlike Lucentis, Kenalog does not include an instruction to withdraw the entire contents and expel the excess.

In light of these distinctions between Lucentis and the other drugs VRC identifies, we cannot conclude that the Secretary's policy to treat Lucentis differently is arbitrary or capricious.

B. The Secretary's Decision was Supported by Substantial Evidence.

VRC argues that the Secretary's decision violated the Administrative Procedure Act because it was not based on substantial evidence. Above we have already discussed much of the basis for VRC's argument. In addition, VRC raises some additional points.

First, VRC argues that the Secretary placed undue reliance on Lucentis's labeling because the Local Coverage Determination is the definitive determination by a Medicare contractor "respecting whether or not a particular item or service is covered." 42 U.S.C. § 1395ff(f)(2)(B). Since First Coast's initial Local Coverage Determination did not incorporate the instruction to discard unused Lucentis as a condition for payment, VRC contends it was not bound to follow the FDA-approved instructions to receive reimbursement.

But even assuming that the Local Coverage Determination is the definitive one, the Local Coverage Determination at issue included the instruction that each vial be used for a single eye only. This instruction necessarily implies that excess drug above the 0.5-mg dose should be discarded. In addition, the Local Coverage Determination need not include all instructions regarding the administration of the drug. The purpose of the Local Coverage Determination is to instruct physicians under what

terms they will receive reimbursement. To that end, First Coast described the basic method of administering the drug, describing the amount of a single dose and requiring a new vial for each eye. The additional instructions on the label were not necessary for the description of the terms for reimbursement and do not absolve VRC of its disregard of the instruction to discard remaining amounts.

In addition to Lucentis's label, the *Physician's Desk Reference* includes the instruction to discard unused product. Courts have recognized the *Physician's Desk Reference* as evidence of the medical standard for a given drug. *See Haught v. Maceluch*, 681 F.2d 291, 303 (5th Cir. 1982) (relying on *Physician's Desk Reference* to establish standard of care in a medical malpractice suit). While the *Physician's Desk Reference* is not conclusive evidence of the standard or accepted practice, the drug's label instructed that the excess drug should be discarded, the *Physician's Desk Reference* repeated the instruction, and VRC presented no evidence of a contrary accepted medical practice.[8]

C. VRC is Liable for the Overpayment.

Having determined that the Secretary's legal interpretation withstands judicial scrutiny and was

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[8] VRC raises additional points regarding a letter sent from Lucentis's manufacturer and the Centers for Disease Control and Prevention standards for repackaging that were relied on by the district court as a basis for affirming the Secretary's decision. We need not reach these points because sufficient grounds exist to affirm the Secretary's decision based on the drug's label and the *Physician's Desk Reference*.

supported by substantial evidence, we next consider VRC's argument that it is not liable for the overpayment because it acted in good faith when it accepted the payment. In support, VRC cites two sections of the Medicare Act: 42 U.S.C. § 1395pp and 1395gg. Neither of these sections relieves VRC of liability.

a. 42 U.S.C. § 1395pp

Under 42 U.S.C. § 1395pp(a), Medicare must reimburse a provider if the provider "did not know, and could not reasonably have been expected to know, that payment would not be made for such items or services." VRC argues that it could not have reasonably been expected to know at the time that it administered the doses that the Secretary would not reimburse multi-doses of Lucentis.

In support of its argument, VRC once again relies on CMS's policy to encourage multi-dosing. But CMS does not maintain a general policy to encourage physicians to contravene FDA-approved instructions without evidence to support such a practice. And for the reasons we have previously discussed, VRC could have and should have reasonably known when it administered the doses that it would not be "reimbursed" three times for a single vial.

For the same reasons, we reject VRC's argument that the Secretary retroactively created policy through the HHS Medicare Appeals Council. Through the initial 2008 Local Coverage Determination issued by First Coast, Medical providers received sufficient notice that multi-dosing would not be covered at the rate of $405 per unit. In short, on this record, VRC could and should have

reasonably known when it administered the multiple doses that it would be reimbursed for only the number of vials it actually paid for.

b. 42 U.S.C. § 1395gg

Section 1395gg of the Medicare Act provides that the Secretary may waive recoupment where the provider was "without fault" when it received overpayment. 42 U.S.C. § 1395gg. The CMS Financial Management Manual instructs that a party is "without fault" when it "exercised reasonable care in billing for, and accepting the payment." Pub. No. 100-06, Ch. 3, § 90. "Reasonable care," in turn, requires that the provider "made full disclosure of all material facts" and that, "[o]n the basis of information available to it, . . . [the provider] had reasonable basis for assuming that the payment was correct, or, if it had reason to question payment; it promptly brought the question to [Medicare's] attention." *Id.* VRC argues that HHS should waive its right to recoupment because VRC was without fault when it accepted the payment, and it dealt transparently with Medicare during the audit and review process.

We do not agree. VRC did not have a reasonable basis for assuming the payment was correct because its practice of multi-dosing was contrary to the drug's instructions and was not based on established medical practice. At best, VRC "had reason to question payment," in which case it should have brought the question to the attention of First Coast to resolve the issue. VRC dealt transparently with First Coast and SafeGuard *after* receiving notice of overpayment. Transparency at this stage did not

meet the standard of airing the question to the proper authorities before burdening them with an extensive review of VRC's records. We therefore agree with the Medicare Appeals Council that VRC was not "without fault" when it accepted the overpayment, and the Secretary was under no obligation to waive the right to recoupment.

IV.

For the foregoing reasons, we affirm the judgment of the District Court.

AFFIRMED.

Appendix B

UNITED STATES COURT OF APPEALS
FOR THE ELEVENTH CIRCUIT

Nos. 14-15342 & 15-12005

VITREO RETINAL CONSULTANTS OF THE PALM BEACHES, P.A., a Florida corporation,

Plaintiff-Appellant,

v.

U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES,

Defendant-Appellee.

Appeals from the United States District Court
for the Southern District of Florida,
No. 1:13-cv-22782-MGC

Filed: August 22, 2016

ORDER

Before Hull, Marcus, and Rosenbaum,
Circuit Judges.

Per Curiam:

The petition(s) for panel rehearing filed by the Appellant is DENIED.

ENTERED FOR THE COURT:

[handwritten: signature]
UNITED STATES CIRCUIT JUDGE

ORD-41

Appendix C

UNITED STATES COURT OF APPEALS
FOR THE ELEVENTH CIRCUIT

Nos. 14-15342 & 15-12005

VITREO RETINAL CONSULTANTS OF THE PALM BEACHES, P.A., a Florida corporation,

Plaintiff-Appellant,

v.

U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES,

Defendant-Appellee.

Appeals from the United States District Court
for the Southern District of Florida,
No. 1:13-cv-22782-MGC

Filed: August 22, 2016

ORDER

Before Hull, Marcus, and Rosenbaum,
Circuit Judges.

On Petition(s) for Rehearing and Petition(s) for Rehearing En Banc

Per Curiam:

The Petition(s) for Rehearing are DENIED and no Judge in regular active service on the Court having requested that the Court be polled on rehearing en banc (Rule 35, Federal Rules of Appellate Procedure), the Petition(s) for Rehearing En Banc are DENIED.

ENTERED FOR THE COURT:

[handwritten: signature]
UNITED STATES CIRCUIT JUDGE

ORD-42

Appendix D

UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF FLORIDA

No. 1:13-cv-22782-MGC

VITREO RETINAL CONSULTANTS OF THE PALM BEACHES, P.A., a Florida corporation,

Plaintiff,

v.

KATHLEEN SEBELIUS[1], in her official Capacity as Secretary of the U.S. Department of Health and Human Services,

Defendant.

Filed: April 23, 2015

ORDER DENYING PLAINTIFF'S MOTION FOR RECONSIDERATION

Plaintiff Vitreo Retinal Consultants of the Palm Beaches, P.A., a single-physician ophthalmology practice that serves Medicare beneficiaries in West Palm Beach, Florida, appealed the Secretary of Health and Human Services' determination that it improperly billed Medicare for its treatment of

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[1] On June 9, 2014, Sylvia Matthews Burwell replaced Kathleen Sebelius as Secretary of the U.S. Department of Health & Human Services.

multiple patients using a single vial of Lucentis—a drug that treats neovascular age-related macular degeneration. (*See* ECF No. 1.) In its Motion for Summary Judgment, Plaintiff argued that the Secretary's decision was arbitrary and capricious, and not based on substantial evidence, because she mischaracterized the record evidence in order to create a new legal standard that was inconsistent with the law, agency guidance, and agency practice. Pl.'s Mot. Summ. J. at 1. Defendant filed its own Motion for Summary Judgment (ECF No. 35) in response, arguing that the Secretary's decision must be upheld as it was based on substantial evidence.

On September 30, 2014, I entered an endorsed order denying Plaintiff's Motion for Summary Judgment (ECF No. 43) and a separate endorsed order granting Defendant's Motion for Summary Judgment (ECF No. 44). Plaintiff now files this Urgent Motion for Reconsideration of Summary Judgment and Renewed Request for Oral Argument (ECF No. 45) requesting that I reconsider my grant of summary judgment to the Defendant. Defendant filed its Opposition to Plaintiff's Motion to Reconsider on October 20, 2014 (ECF No. 46), to which Plaintiff filed its Reply to Secretary Burwell's Response to Motion for Reconsideration of Summary Judgment and Renewed Request for Oral Argument on October 28, 2014 (ECF No. 47). Therefore, Plaintiff's Motion for Reconsideration is ripe for adjudication.

After considering Plaintiff's Motion for Reconsideration, the Response and Reply thereto, relevant legal authorities, and the record, Plaintiff's Urgent Motion for Reconsideration of Summary

Judgment and Renewed Request for Oral Argument (ECF No. 45) is denied.

I. Background

In 2008, the Zone Program Integrity Contractor for the state of Florida, SafeGuard Services LLC, audited Plaintiff Vitreo Retinal Consultants of the Palm Beaches, P.A.'s ("Vitreo") Medicare billing records to determine if Vitreo multi-dosed single use vials of the drug Lucentis. Vitreo's sole physician, Dr. Salomon Melgen, "billed significantly higher for [Lucentis] in comparison to his peer group," raising "suspic[ion] that each vial of the drug [was being] administered to more than one patient." An investigation, that included interviews of Dr. Melgen and his staff, revealed that each vial of Lucentis was, indeed, administered to up to three patients.

In June 2009, SafeGuard determined that Vitreo overbilled Medicare for Lucentis by nearly $9 million in 2007 and 2008. SafeGuard concluded that multi-dosing Lucentis, contrary to the FDA-approved package insert instructions and the governing coverage determination, overstated Plaintiff's actual costs of the drug. In August 2009, SafeGuard forwarded its findings to the Medicare Administrative Contractor, First Coast Service Options, Inc. ("FSCO")[2], which sought to recoup the overpayments from Vitreo because Vitreo was not "without fault" in billing for multi-dosed vials of

[2] First Coast Service Options, Inc. is the Center for Medicare and Medicaid Services contractor tasked with administering Medicare payment processing and auditing functions in the Vitreo's geographic region.

Lucentis. On October 13, 2009, FSCO denied Vitreo's petition for a redetermination of the initial decision.

Thereafter, Vitreo exhausted all available administrative remedies. On June 13, 2011, an Administrative Law Judge ("ALJ") upheld FSCO's determination that Vitreo multi-dosed, and overbilled for, Lucentis. Vitreo then appealed the ALJ's decision to the Medicare Appeals Council ("MAC") of the Health and Human Services Departmental Appeals Board. On June 28, 2013, the Medicare Appeals Council concluded that Lucentis injections are only "medically reasonable and necessary to the extent the drug [is] administrated consistent with its FDA-approved label," multi-dosing was "not appropriate because it departs from accepted standards of practice," and it affirmed "that [Vitreo] was overpaid for the injections at issue." Vitreo timely moved for review by this Court.

II. Legal Standard

"A motion for reconsideration must demonstrate why the court should reconsider its prior decision and set forth facts or law of a strongly convincing nature to induce the court to reverse its prior decision." *Fla. Coll. of Osteopathic Med., Inc. v. Dean Witter Reynolds, Inc.*, 12 F. Supp. 2d 1306, 1308 (M.D. Fla. 1998) (internal quotation and citation omitted)). Courts generally grant motions for reconsideration when there is "(1) an intervening change in controlling law, (2) the availability of new evidence, and (3) the need to correct clear error or manifest injustice." *Id.* A motion for reconsideration "should raise new issues, not merely readdress issues previously litigated." *Id.* "[R]econsideration of a

previous order is an extraordinary remedy to be employed sparingly." *Bautista v. Cruise Ships Catering & Serv. Int'l, N.V.*, 350 F. Supp. 2d 987, 992 (S.D. Fla. 2004) (internal quotation and citation omitted).

III. Discussion

In its Motion to Reconsider, Plaintiff argues that my endorsed orders "evidence clear error" as I failed to "apply the correct legal standard and fail[ed] to address the constitutional and other fundamental deficiencies of the Secretary's underlying findings." Pl.'s Mot. Reconsider 1. Plaintiff then reargues issues already argued in its Motion for Summary Judgment. Ultimately, Plaintiff fails to meet its burden on a motion for reconsideration because the Secretary's decision was supported by substantial evidence and it did not violate Plaintiff's due process rights.

The Secretary of Health and Human Services' ("Secretary") findings "as to any fact, if supported by substantial evidence, shall be conclusive." 42 U.S.C. §§ 405(g), 1395ff(b)(1)(A). Therefore, "judicial review of the Secretary's decision regarding a claim for Medicare benefits is limited to 'whether there is substantial evidence to support the findings of the…[Secretary], and whether the correct legal standards were applied." *Gulfcoast Med. Supply v. Sec'y, Dep't Health & Human Services*, 468 F.3d 1347, 1350 n. 3 (11th Cir. 2006) (quoting *Wilson v. Barnhart*, 284 F.3d 1219, 1221 (11th Cir. 2002)). Substantial evidence is "such relevant evidence as a reasonable mind might accept as adequate to support a conclusion," even if the Court "would have reached a different result based upon the record." *Barnes v.*

Sullivan, 932 F.2d 1356, 1358 (11th Cir. 1991). It is "more than a scintilla, but less than a preponderance." *Bloodsworth v. Heckler*, 703 F.2d 1233, 1239 (11th Cir. 1983).

The Administrative Procedure Act ("APA") requires that the Secretary's decision must be upheld unless it is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2). The Eleventh Circuit has explained that this standard of review is "exceedingly deferential." *Fund for Animals v. Rice*, 85 F.3d 535, 541 (11th Cir. 1996). Thus, the reviewing Court considers only whether it "was based on a consideration of the relevant factors and whether there has been a clear error of judgment." *Citizens to Preserve Overton Park v. Volpe*, 401 U.S. 402, 416 (1971). "Along the standard of review continuum, the arbitrary and capricious standard gives an appellate court the *least* latitude in finding grounds for reversal." *Fund for Animals*, 85 F.3d at 541-42. An agency decision "should be set aside in this context . . . only for substantial procedural or substantive reasons as mandated by statute . . . not simply because the court is unhappy with the result reached." *Id.*

The Secretary's interpretation of what is "reasonable and necessary" under the Medicare statute is entitled to administrative deference. *Gulfcoast Med. Supply*, 468 F.3d at 1351; *see also Chevron USA, Inc. v. Natural Res. Def. Council, Inc.*, 467 U.S. 837, 844 (1984) ("considerable weight should be accorded to an executive department's construction of a statutory scheme it is entrusted to

administer."). The reviewing court must give "considerable weight" to the Secretary's interpretation of any ambiguous language so long as it is "based on a permissible construction of the statute" because the Secretary is charged with administering the Medicare statute. *Id.*; *see also Almy*, 679 F.3d at 302. The Secretary is entitled to "substantial deference" for her interpretation of the regulations that implement the Medicare Act's "reasonable and necessary" standard. *Thomas Jefferson Univ. v. Shalala*, 512 U.S. 504, 512 (1994). Thus, "the agency's interpretation must be given 'controlling weight unless it is plainly erroneous or inconsistent with the regulation.'" *Id.* (citation omitted). "The Supreme Court has emphasized the importance of careful adherence to this standard in the Medicare context, which deals with 'a complex and highly technical regulatory program, in which the identification and classification of relevant criteria necessarily require significant expertise and entail the exercise of judgment grounded in policy concerns.'" *Almy*, 679 F.3d at 302 (quoting *Thomas Jefferson Univ.*, 512 U.S. at 512). Finally, "[b]ecause the determination of what is 'reasonable and necessary' also requires a significant degree of medical judgment, [the Court] must be mindful that '[w]hen examining this kind of scientific determination, as opposed to simple findings of fact, a reviewing court must generally be at its most deferential.'" *Id.* (quoting *Baltimore Gas & Elec. Co. v. Natural Res. Def. Council*, 462 U.S. 87, 103 (1983)).

Therefore, in order to prevail at the summary judgment stage, Defendant Kathleen Sebelius needed only to show that the Department of Health and

Human Services' (the "Agency" or "Department") decision was based on substantial evidence. This highly deferential standard recognizes a district court's limited expertise in matters that fall within the Agency's purview, thus, precluding district courts from second-guessing Agency decisions.

A. The Department of Health and Human Services' Overpayment Determination is Supported by Substantial Evidence.

It is undisputed that the Department of Health and Human Services, through its various levels of review, relied principally on four pieces of evidence in reaching its overpayment determination: (1) the Food and Drug Administration approved package insert; (2) the Lucentis local coverage determination issued by First Coast Service Options ("FCSO") that reflects the majority view of local health care providers; (3) Genentech, Inc.'s, Lucentis' drug manufacturer, letter to FCSO explaining the proper dosing and administration of Lucentis; and (4) Centers for Disease Control and Prevention's 2007 injection safety guidelines. I shall address each in turn.

1. The Food and Drug Administration Approved Packet Insert

In 2006, the FDA approved Lucentis to treat neovascular age-related macular degeneration. Admin. R. at 258. Lucentis is packaged in single-use, single-dose vials that contain 2.0 mg of the drug. Admin. R. at 236. According to the "Dosage and Administration" section of the FDA-approved package insert, the entire contents of the vial (in other words, all 2.0 mg of the drug) should be drawn into the syringe, and then the excess drug product

should be expelled until the recommended dose of 0.5 mg is obtained. *Id.* at 233. The insert goes on to explain, "Each vial should only be used for the treatment of a single eye. If a contralateral eye requires treatment, a new vial should be used and the sterile field, syringe, gloves, drapes, eyelid speculum, filter, and injection needles should be changed before Lucentis is administered to the other eye." *Id.* at 236. Thus, when properly administered, each vial of Lucentis treats a single eye on a single patient.

Despite Plaintiff's protests to the contrary, the FDA-approved labeling should be considered evidence of accepted standards of medical practice. While the Eleventh Circuit has not squarely addressed the issue of whether FDA-approved labeling establishes the standard of care for the administration of a drug, it has noted that the Physician's Desk Reference, which contains FDA-approved labeling information for all FDA-approved drugs, is a "standard medical reference." *Newmann v. United States*, 938 F.2d 1258, 1260 (11th Cir. 1991). The Physician's Desk Reference is widely used throughout the medical community when prescribing various medications. Even the Fifth Circuit, just after its split, concluded, "the Physician's Desk Reference *adequately establishes* . . . the standard of care for the administration of [a drug]." *Haught v. Maceluch*, 681 F.2d 291, 303 n.12 (5th Cir. 1982) (emphasis added). Thus, it is quite natural that the Department of Health and Human Services would rely on, and refer to, the same FDA-approved labeling information contained within the Physician's

Desk Reference when determining the acceptable standard of care for administration of Lucentis.

2. The Lucentis Local Coverage Determination[3]

In 2008, First Coast Service Options published the first Lucentis local coverage determination ("LCD") that "was developed in cooperation with advisory groups . . . includ[ing] representatives from the Connecticut Society of Eye Physicians and the Florida Society of Ophthalmology." Admin. R. at 124. It stated, "Each vial should only be used for treatment of a single eye. If the contralateral eye requires treatment, a new vial should be used." *Id.* at 121. Thus, the LCD in effect during the relevant period *explicitly* limited coverage of "each vial" to the treatment of a "single eye." *Id.* Plaintiff's arguments otherwise are illogical. By not explicitly incorporating all of the FDA labeling requirements, the LCD cannot have intended for a single vial of Lucentis to be approved for use among multiple patients but prohibited for use on both eyes of the same patient. Such a result would be nonsensical.

In addition, that same LCD expressly noted that treatment must "be performed as indicated by current medical literature and/or standards of practice." *Id.* at 123. It stands to reason that current medical literature incorporates the FDA-approved packet insert. Any attempt by Plaintiff to raise

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[3] Local coverage determinations reflect the majority view of local health providers and are published after a public comment, consultation with experts in the field, and an advisory meeting. *See* Medicare Program Integrity Manuel, Ch. 13.

arguments to the contrary is simply unfounded and unsupported by the record.

3. Genentech, Inc.'s Explanation of Lucentis Dosing

It is well settled that "a drug manufacturer is . . . presumed to possess an expert's knowledge of the . . . administration of pharmaceutical products." *Reyes v. Wyeth Labs*, 498 F.2d 1264 (5th Cir. 1974).[4] Not only does a drug require intensive research before it is brought to market, a drug manufacturer faces substantial liability for failure to warn of potential risks. So it is incumbent upon a pharmaceutical company to have a heightened knowledge of any product that it manufactures. As the old adage holds, "no one can know you better than you know yourself." There is no question Lucentis' manufacturer Genentech, Inc. is the most authoritative source of information on Lucentis.

Genentech, Inc. explained, "the FDA-approved prescribing information does not . . . support the practice of administering the contents of one vial of Lucentis to more than one eye or to more than one patient." Admin. R. at 238. As stated in the prescribing information, each vial of Lucentis should only be used for the treatment of a single eye. *Id.* In fact, physicians are instructed to discard the excess drug product so that only enough drug product for one dose remains in the vial. According to Genentech, Inc., "[each] vial contains overfill . . . to account for

[4] The Eleventh Circuit adopted all decisions of the former Fifth Circuit handed down prior to the close of business on September 30, 1981 as binding precedent. *Bonner v. City of Prichard*, 661 F.2d 1206, 1209 (11th Cir. 1981) (en banc).

loss [drug] product when the dose is being prepared and administered appropriately and according to the FDA-approved labeling. The vial is designed to contain enough liquid so that a single 0.5 mg (0.05 mL) dose can be administered." *Id.* The Department rightfully gave considerable authoritative weight to Genentech, Inc.'s instruction regarding the administration of Lucentis.

4. The Centers for Disease Control and Prevention's 2007 Injection Safety Guidelines.

In 2007, the Centers for Disease Control and Prevention ("CDC") enunciated guidelines that cautioned against administering medications from single-dose vials to multiple patients. Centers for Disease Control and Prevention, 2007 Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings. It read, in relevant part, "Do not administer medications from single-dose vials or ampules to multiple patients or combine leftover contents for later use." *Id.* at 83. Plaintiff even relied on a CDC publication titled "Injection Safety FAQs for Providers" in its May 2011 supplemental memorandum to the Administrative Law Judge. That publication directly answered the question, "Is it acceptable to use single-use medication vials or pre-filled syringes for more than one patient?" The CDC answered, "NO. Medication vials that are labeled for single-use and pre-filled medication syringes *should never be used* for more than one patient." (emphasis added). So Plaintiff knew or should have known of the prevailing standard of care regarding the administration of single-use vial drugs, such as Lucentis.

Each piece of evidence mentioned above was relevant to the Agency's determination regarding the proper administration of Lucentis. And the totality of the evidence would persuade a reasonable mind to clearly see that it supports the Department's determination that the Plaintiff, contrary to prevailing standards of acceptable medical care, improperly administered multiple doses of Lucentis from a single-use vial. Thus, the Department's determination is well supported by substantial evidence in the record.

B. The Department of Health and Human Services Did Not Exceed its Authority Under the Medicare Act.

Plaintiff's argument that the MAC exceeded its authority under the Medicare Act by promulgating a new Medicare reimbursement policy for Lucentis and then retroactively applying said policy to Plaintiff is unpersuasive. *See* Pl.'s Mot. Summ. J. at 35. First, Plaintiff concedes that the MAC rendered its determination after an adjudicatory process, as opposed to a rulemaking process. *Id.* at 14-20. Second, a MAC decision "applies only to the specific claim being considered and does not have precedential effect." 42 C.F.R. § 405.1062. The MAC's decision is only binding on the parties to the instant action and not on future providers. Thus, it is not a new policy. Lastly, Plaintiff's argument against retroactivity smacks in the face of well-settled administrative law. Adjudications are inherently retroactive because they deal with what the law was at the time the aggrieved conduct occurred, and they implicitly seek to correct past behavior. Adjudications

merely apply existing policy to a particular set of circumstances. They do not make what was then perfectly legal conduct illegal by virtue of a change in policy. Plaintiff's mischaracterization of the Agency's adjudicatory process is unavailing.

IV. Conclusion

The law is clear regarding the standard for granting a Motion for Reconsideration under Federal Rule of Civil Procedure 59(e). Plaintiff presents no intervening change in controlling law, no new evidence, and no clear error or manifest injustice that needs to be corrected. Plaintiff has failed to demonstrate that the Secretary's decision was "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2). It is not this Court's job to question the weight and credibility of the evidence so long as there are no clear errors of judgment. *Citizens to Preserve Overton Park v. Volpe*, 401 U.S. 402, 416 (1971). A thorough review of the Agency's decision demonstrates that it is supported by substantial evidence. As the Eleventh Circuit noted, substantial evidence is "such relevant evidence as a reasonable mind might accept as adequate to support a conclusion," even if the Court "would have reached a different result based upon the record." Clearly, that standard is met here, and the Agency's decision is deserving of deference.

Accordingly, it is ORDERED and ADJUDGED that Defendant's Urgent Motion for Reconsideration of Summary Judgment and Renewed Request for Oral Argument (ECF No. 45) is DENIED.

DONE and ORDERED in Chambers, in Miami, Florida, this 10th day of April 2015.

[handwritten: signature]
MARCIA G. COOKE
United States District Judge

Appendix E

UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF FLORIDA

No. 1:13-cv-22782-MGC

VITREO RETINAL CONSULTANTS OF THE PALM BEACHES, P.A., a Florida corporation,

Plaintiff,

v.

KATHLEEN SEBELIUS, in her official Capacity as Secretary of the U.S. Department of Health and Human Services,

Defendant.

RELEVANT DOCKET ENTRIES

Date Filed	#	Docket Text
		* * *
9/30/14	43	ENDORSED ORDER denying 27 Motion for Summary Judgment. The Secretary of Health and Human Services (Secretary) findings as to any fact, if supported by substantial evidence, shall be conclusive. 42 U.S.C. §§ 405(g), 1395ff(b)(1)(A). Therefore, judicial review of the Secretarys decision regarding a claim for Medicare benefits is limited to whether there is substantial evidence

Date Filed	#	Docket Text
		to support the [Agencys], and whether the correct legal standards were applied. Gulfcoast Med. Supply v. Secy, Dept Health & Human Services, 468 F.3d 1347, 1350 n. 3 (11th Cir. 2006)(quoting Wilson v. Barnhart, 284 F.3d 1219, 1221 (11th Cir. 2002)). Substantial evidence is such relevant evidence as a reasonable mind might accept as adequate to support a conclusion, even if the Court would have reached a different result based upon the record." Barnes v. Sullivan, 932 F.2d 1356, 1358 (11th Cir. 1991). It is more than a scintilla, but less than a preponderance. Bloodsworth v. Heckler, 703 F.2d 1233, 1239 (11th Cir. 1983). "Even if [I] find that the evidence preponderates against the Secretary's decision, [I] must affirm if the decision is supported by substantial evidence." Id. The Administrative Procedure Act (APA) requires that the Secretarys decision must be upheld unless arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law. 5 U.S.C. § 706(2). The Eleventh Circuit has explained that this standard of review is exceedingly deferential. Fund for Animals v. Rice, 85 F.3d 535, 541 (11th Cir. 1996).

Date Filed	#	Docket Text
		Thus, the reviewing Court considers only whether it was based on a consideration of the relevant factors and whether there has been a clear error of judgment. Citizens to Preserve Overton Park v. Volpe, 401 U.S. 402, 416 (1971). Along the standard of review continuum, the arbitrary and capricious standard gives an appellate court the least latitude in finding grounds for reversal. Fund for Animals, 85 F.3d at 541-42. An agency decision should be set aside in this context . . . only for substantial procedural or substantive reasons as mandated by statute, . . . not simply because the court is unhappy with the result reached. Id. Plaintiff has failed to demonstrate that the the Secretarys decision was "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." Therefore, Defendant's Motion for Summary Judgment is granted. A complete, written order is forthcoming. Signed by Judge Marcia G. Cooke on 9/30/2014. (bgd) (Entered: 09/30/2014)
9/30/14	44	ORDER granting 35 Motion for Summary Judgment. Closing Case. The Secretary of Health and Human Services (Secretary) findings as to any

Date Filed	#	Docket Text
		fact, if supported by substantial evidence, shall be conclusive. 42 U.S.C. §§ 405(g), 1395ff(b)(1)(A). Therefore, judicial review of the Secretarys decision regarding a claim for Medicare benefits is limited to whether there is substantial evidence to support the [Agencys], and whether the correct legal standards were applied. Gulfcoast Med. Supply v. Secy, Dept Health & Human Services, 468 F.3d 1347, 1350 n. 3 (11th Cir. 2006)(quoting Wilson v. Barnhart, 284 F.3d 1219, 1221 (11th Cir. 2002)). Substantial evidence is such relevant evidence as a reasonable mind might accept as adequate to support a conclusion, even if the Court would have reached a different result based upon the record." Barnes v. Sullivan, 932 F.2d 1356, 1358 (11th Cir. 1991). It is more than a scintilla, but less than a preponderance. Bloodsworth v. Heckler, 703 F.2d 1233, 1239 (11th Cir. 1983). "Even if [I] find that the evidence preponderates against the Secretary's decision, [I] must affirm if the decision is supported by substantial evidence." Id. The Administrative Procedure Act (APA) requires that the Secretarys decision must be upheld unless arbitrary,

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		capricious, an abuse of discretion, or otherwise not in accordance with law. 5 U.S.C. § 706(2). The Eleventh Circuit has explained that this standard of review is exceedingly deferential. Fund for Animals v. Rice, 85 F.3d 535, 541 (11th Cir. 1996). Thus, the reviewing Court considers only whether it was based on a consideration of the relevant factors and whether there has been a clear error of judgment. Citizens to Preserve Overton Park v. Volpe, 401 U.S. 402, 416 (1971). Along the standard of review continuum, the arbitrary and capricious standard gives an appellate court the least latitude in finding grounds for reversal. Fund for Animals, 85 F.3d at 541-42. An agency decision should be set aside in this context . . . only for substantial procedural or substantive reasons as mandated by statute, . . . not simply because the court is unhappy with the result reached. Id. Plaintiff has failed to demonstrate that the the Secretarys decision was "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." Therefore, Defendant's Motion for Summary Judgment is granted. A complete, written order is forthcoming. Signed

Date Filed	#	Docket Text
		by Judge Marcia G. Cooke on 9/30/2014. (bgd) (Entered: 09/30/2014)
		* * *

Appendix F

DEPARTMENT OF HEALTH AND HUMAN SERVICES DEPARTMENTAL APPEALS BOARD

No. M-11-2393

IN RE VITREO RETINAL CONSULTANTS OF THE PALM BEACHES, P.A., a Florida corporation,

Appellant.

Appeal from the Administrative Law Judge,
No. 1-644039851

Claim for Supplementary Medical Insurance Benefits
(Part B)

Dated: June 28, 2013

DECISION OF MEDICARE APPEALS COUNCIL

The Administrative Law Judge (ALJ) issued an unfavorable decision, dated June 13, 2011, which concerned Medicare overpayments for injections of the drug Lucentis (ranibizumab) (HCPCS code J2788)[1] and related services provided to the

[1] The Centers for Medicare & Medicaid Services (CMS) has developed the Healthcare Common Procedure Coding System (HCPCS) to establish "uniform national definitions of services,

beneficiaries from February 1, 2007, through December 1, 2007, and from January 2, 2008, through December 23, 2008. Dec. at 1. The ALJ first concluded that the injections were not reasonable and necessary under section 1862(a) (1) of the Social Security Act (Act), they were therefore not covered by Medicare, and the appellant was liable for non-covered charges under section 1879 of the Act.[2] Dec. at 34-35. In the alternative, the ALJ reduced the drug's average sales price (ASP) to reflect the appellant's practice of obtaining three doses of Lucentis from one vial, and held that each "per 0.1 mg" dose would be reimbursed at $679.65 per dose billed (or approximately one-third of the national average sales price established by Medicare for a single Lucentis vial). *Id.*

The appellant asked the Medicare Appeals Council (Council) to review this action. The Council reviews the ALJ's decision *de novo.* 42 C.F.R. § 405.1108(a). The Council will limit its review of the ALJ's action to the exceptions raised by the party in the request for review, unless the appellant is an unrepresented beneficiary. 42 C.F.R. § 405.1112(c). As set forth below, the Council agrees with the ALJ's ultimate conclusion that the appellant was overpaid for the injections at issue. We modify the ALJ's

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codes to represent services, and payment modifiers to the codes." 42 C.F.R. § 414.40(a). Current Procedural Terminology (CPT) codes are a subset of the alphanumeric HCPCS code system that consist of 5 numbers and primarily reflect physician services.

[2] References to the appellant include physician practitioner Dr. S.M.

decision to clarify the rationale for reaching this conclusion. We find that the appellant has not shown that it was medically reasonable and necessary to extract and administer more than a single dose of Lucentis from a single use vial.

PRELIMINARY PROCEDURAL ISSUES

On August 16, 2011, the appellant filed its request for review (22 pages). On October 17, 2012, the Council denied the appellant's request for hearing and granted 30 days for the submission of additional written argument. On November 15, 2012, the appellant submitted a "supplemental submission" (22 pages, Exhibits A-J). On February 20, 2013, the Council issued its "Order to Develop the Record" (Order), requesting further submissions by the appellant and by CMS and/or its contractors in response to nine questions. In the Order, the Council also directed that "CMS and the appellant shall provide each other with a copy of any filing with the Council." *Id.* at 2.

On March 22, 2013, the Council received a facsimile from Zone Program Integrity Contractor (ZPIC) SafeGuard Services, LLC (9 pages) that did not address the nine questions in the Order and was not copied to the parties and other CMS representatives.[3] On March 27, 2013, the Medicare Administrative Contractor (MAC) First Coast Service Options (FCSO) submitted its response to the Order (9 pages, Exhibits A-N). On April 12, 2013, the appellant, through counsel, submitted its response

[3] The ZPIC is also referred to as the Program Safeguard Contractor (PSC).

(25 pages, Exhibits A-P). On April 24, 2013, the Council responded to the CMS and appellant submissions and stated that the case record was closed.

The Council admits the request for review, correspondence, Order, and responses into the record as Exhibits (Exhs.) MAC-1 through MAC-10. However, the ZPIC's submission did not respond to the Order questions and was not served on the appellant and other entities. The Council therefore strikes the ZPIC submission from the record, marks it for identification as Exh. MAC-7 (Excluded), and does not consider it in this decision.

BACKGROUND

Prior Reviews

On March 2, 2005, the FCSO Program Safeguards Division issued the results of a probe review for services billed under CPT codes 92226 (ophthalmoscopy, extended, with retinal drawing), 99235 (fluorescein angiography), and 99240 (indocyanine-green angiography). Exh. 1, at 175-81. The review consisted of four samples totaling 38 claims over a period of six months, for 71 services provided to 30 beneficiaries. *Id.* at 175. The contractor found that "documentation submitted met the medical necessity guidelines and the coverage criteria" for each of the 71 services billed. *Id.* at 179. On March 21, 2005, the contractor wrote that the probe review was completed and, "[biased on the results of this medical review, no additional review activity is indicated at this time." *Id.* at 165.

On July 3, 2007, FCSO requested medical records for a probe review of Medicare claims for CPT

code 76510 (ophthalmic ultrasound, diagnostic), based on a comparison of the appellant's billings to other providers. Exh. 1, at 142-51.[4] On August 22, 2007, the contractor issued results, finding that "[a]ll services were allowed as billed because the submitted documentation met the LCD [Local Coverage Determination] indications for coverage." *Id.* at 139.[5] On September 10, 2007, the contractor wrote that the probe review was completed and that the appellant's "medical record documentation meets the Medicare documentation guidelines for these services, and therefore, no additional review activity is indicated at this time." *Id.* at 136.

On July 2, 2008, the ZPIC (PSC) advised the appellant that, on July 15, 2008, four representatives would conduct an on-site inspection and retrieval of records. Exh. MAC-9, at G1. The ZPIC also stated that "[a]t that time, you will be asked to produce approximately 10 patients' records and other related business records as necessary." *Id.*[6]

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[4] An attachment to the notice of probe review is captioned "Medicare Part B Performing Provider Comparative Billing Report," dated June 28, 2007, and covers dates of service October 1, 2006, through March 31, 2007. Exh. 1, at 148. This document includes a comparison of the appellant's billings for Lucentis (HCPCS J3490) with peers, with "percent services" 1.34% for peers and 0.67% for the appellant, "allowed dollars" $104,059.00, and "percent allowed" 16.1% for peers and 2.65% for the appellant.

[5] Contractor LCDs can be found in the Medicare Coverage Database at http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx.

[6] The Council received the case record with 15 individual claims files for services in 2004-2006. One claims file contains

ZPIC Review

On March 10, 2009, the ZPIC prepared an unsigned memorandum regarding "Inappropriate Billing of Ranibizumab (Lucentis)," addressed to R.S., a CMS "Government Task Leader" in Baltimore, Maryland. Exh. 1, at 125-131. The contractor stated that it submitted "this Program Vulnerability Report" due to "proactive analysis" conducted after a "previous Program Vulnerability Report submitted by the New England Benefit Integrity Support Center (NE BISC) on July 24, 2008." *Id.* at 125. The memorandum involved billings for HCPCS codes J2778 (injection, Ranibizumab, 0.1 mg) and J3490 (unclassified drugs) and states that injections of Lucentis (Ranibizumab) were submitted under HCPCS codes J3490 before January 2008 and HCPCS code J2778 thereafter. *Id.* at 125.

The memorandum states that Lucentis "is supplied as a preservative-free, sterile solution in a single-dose vial and is used to treat patients with senile macular degeneration." Exh. 1, at 126. Lucentis received Food and Drug Administration (FDA) approval in 2006 and showed a substantial increase in use subsequent to approval, which the memorandum states "may be valid as it may be the most effective FDA-approved drug used in the treatment of senile macular degeneration." *Id.* The memorandum then states that data analysis identified "a South Florida physician who appears to be billing inappropriately for HCPCS code J2778 and

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documentation of a service billed under HCPCS code J3490. Box 2 of 3, Claims File for Beneficiary M.B.

J3490 for Lucentis. The data revealed that the physician billed significantly higher for these codes in comparison to his peer group. The suspected activity involves inappropriate billing and administration of the drug. *Specifically, it was suspected that each vial of the drug is administered to more than one patient." Id.* (emphasis supplied).

The memorandum discusses information on the Lucentis drug manufacturer label and states as follows:

> According to the drug manufacturer labeling specifications, "Each vial should only be used for the treatment of a single eye. If the contralateral eye requires treatment, a new vial should be used . . ." The labeling further states, "Single-use glass vial designed to provide 0.05 mL of 10 mg/mL solution for intravitreal injection." The preparation for administration instructions indicate that the entire contents of the vial (.2 ml) are to be withdrawn into a syringe and then the contents are to be expelled until the plunger tip is aligned with the 0.05 mL mark on the syringe. The recommended dosage for each eye is 0.5mg or 0.05 mL; thus the quantity billed on the claim should be "5" if the drug is administered according to the recommended dosage.

Id. (emphasis in original). FCSO also had issued an LCD "for HCPCS code J2778 which reiterates the dosing and administration instructions outlined in the drug manufacturer labeling." *Id.* The ZPIC concluded that "lilt is clear, based on the drug

manufacturer labeling and the MAC's Local Coverage Determination, that a single dose vial of Lucentis should be administered to treat a single eye for one patient." *Id.* The ZPIC further concluded that "billing of HCPCS code J2778 should represent the use of a single vial to treat one eye for one patient." *Id.*

The ZPIC next reviewed the Medicare allowance for a Lucentis injection, stating that "[t]he Medicare allowance for the drug is based on the Average Sales Price (ASP) . . . . The allowance for the drug is approximately $2030 when billed at 0.5 mg." Exh. MAC-1, at 126. The ZPIC declared that "[t]his amount represents payment for the entire single dose vial of Lucentis," which had an approximate invoice price of $1950. *Id.* The ZPIC noted Medicare authority which states: *"The charge, if any, for the drug or biological must be included in the physician's bill, and the cost of the drug or biological must represent an expense to the physician." Id.* at 126-27, *quoting* Medicare Benefit Policy Manual (MBPM) (Pub. 100-02) Ch. 15, § 50.3 (emphasis in original).[7] The ZPIC reasoned that, "[i]f a vial is used and billed for 3 patients at 0.5 mg per patient, then the provider would be receiving approximately $6180 in reimbursement per vial." *Id.* at 127. The ZPIC concluded that the provider "would be overstating his expenses for the drug when billing in this manner and, therefore, would be overpaid." *Id.*

The ZPIC acknowledged that Medicare cannot tell a physician how to practice medicine or how to

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[7] CMS manuals can be found at http://www.cms.hhe.gov/manuals.

provide services to the physician's patients. Exh. 1, at 127. The memorandum states, however, that Medicare "can impose coverage and billing Requirements" and continues as follows:

> To bill appropriately for the administration of Lucentis as described previously, the provider should:
>
> • Administer the drug according to the manufacturer specifications. That is, use one vial for one patient only for one eye.
>
> OR
>
> • IF the vial is used for multiple patients (e.g., 3 patients per vial), then the provider should reduce the billed amount of the drug for each of the patients so that the combined allowed amount for all patients does not exceed the cost associated with a single use vial. For example, if a vial is used to treat 3 patients, then the billed amount for each patient should be approximately $676.66.

The memorandum discusses the investigations and concludes that the appellant submitted more claims for Lucentis injections than supported by invoices provided. The memorandum states that the appellant's staff "explained how each vial is administered for up to 3 patients." The injection practice method included dividing vial contents "among 3 separate syringes for 3 different patients [and each] syringe contained 0.5 mg of the drug." Each syringe was also labeled with the vial invoice number. The appellant billed Medicare for Lucentis for "each of the patients" at amounts equal or slightly greater than the Medicare allowance. The ZPIC

concluded, "Because each vial was used to treat at least three patients and because the billed amount was equal to or greater than the allowance for the drug at 0.5 mg, the provider overstated his costs for the drug and was, therefore, overpaid." *Id.* For 2007,[8] the ZPIC stated that it had reviewed 3,045 claims with "total amount billed" $8,212,900.00; "total amount allowed" $6,426,649.34; "total amount paid" $5,138,601.38; and "overpayment amount" $3,118,816.93. *Id.* at 128.

The ZPIC recommended that CMS issue a National Coverage Determination (NOD) for claims for HCPCS codes J2778 and J3490 (Lucentis injections) "that reiterates the drug manufacturer's labeling and administration instructions." Exh. MAC-1, at 128. The ZPIC also recommended that Medicare issue a national educational policy "instructing physicians on how to properly bill for Lucentis." *Id.* The ZPIC stated that it was also "considering developing a National Medicare Fraud Alert to notify CMS, other ZPICs and PSCs, and law enforcement of the alleged activities." *Id.* The memorandum also includes a table reflecting the monetary impact on the Medicare program for Lucentis injections billed in 2008. *Id.* at 128-29.

The ZPIC then summarized its findings, stating that it had reviewed "all claims" from February 1, 2007, through December 31, 2007, "where J3490 was billed for an amount greater than or equal to $2200 and paid [an] amount greater than $1624" and "all

[8] The memorandum states that claims for 2008 had not been reviewed as part of the investigation, but that the same outcome for 2008 was expected.

claims" from January 1, 2008, through December 31, 2008, for HCPCS code J2778. Exh. 1, at 130. The ZPIC repeated that each Lucentis vial was used to treat three individuals and, "[k]nowing the unit price may change per quarter," it had "applied the appropriate unit price per quarter as identified by the Average Sale Price (ASP) as required by current regulations." *Id.* The ZPIC summarized Lucentis "pricing information" in each quarter of 2007 and 2008, based on an "allowance per 0.1 mg." *Id.* at 131. The ZPIC stated that it determined the overpayment based on the algorithm that included a "revised paid amount" calculated as "[(Unit price X 5)/3] X 0.80." *Id.* at 131. The "overpayment amount" was therefore the "paid amount - revised paid amount." *Id.*

Contractor Overpayment Determination

On June 30, 2009, the ZPIC (PSC) issued a notice of "preliminary overpayment" of $8,981,514.42 for 2007 and 2008. Exh. 1, at 120-24. This included an overpayment of $3,118,821.91 for 2007, and $5,862,692.51 for 2008. *Id.* at 122. The ZPIC also stated that the appellant was not "without fault," and was liable for the non-covered charges and overpayment under sections 1879 and 1870 of the Act. *Id.* at 124; *see* Exh. 5 (spreadsheet). The ZPIC further advised that FCSO would issue a demand letter regarding the specifics of the overpayment and repayment process, and that the appellant should not make payment or appeal until it heard from FCSO. *Id.* at 122.

Subsequently, on August 5, 2009, FCSO issued a revised initial determination and notice of

overpayment of $8,982,706.98.[9] *Id.* at 113-17. The appellant, through counsel, requested redetermination. *Id.* at 87-108, 112.

Redetermination

On October 13, 2009, the contractor issued an unfavorable redetermination decision, upholding the overpayment. Exh. MAC- 1, at 75-86;[10] *see also* Exh. 2 (overpayment detail). The contractor first stated that "medical necessity is not at issue in this case. Medical records were not the source of this review." *Id.* at 79. Instead, the contractor stated that "[w]hat resulted in the overpayment were the invoices reflecting what the provider purchased, the actual expense to the practice." *Id.* The contractor then stated that it would determine overpayment responsibility under section 1870 of the Act. *Id.* The contractor indicated that the appellant had participated in Medicare since October 1, 1988, and

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[9] It is not clear why this total differs from the total overpayment calculated by the ZPIC.

[10] The record contains a memorandum captioned "Case Rationale," prepared by a ZPIC investigator and dated September 24, 2009. Exh. 1, at 109-111. In relevant part, the memorandum states the "date investigation opened" as November 29, 2007, and that the appellant "was paid consistently month after month, for his specialty, 40% more than the next highest paid provider in the State of Florida." *Id.* at 109. The memorandum also states that "[m]edical records ultimately were not needed for the overpayment calculation." *Id.* The memorandum also references correspondence from the drug manufacturer Genentech, which "confirm[ed] the complete product indication and safety information." *Id.* at 110; *see id.* at 132 ("As stated in the prescribing information, each vial of Lucentis should only be used for the treatment of a single eye.")

was presumed to have knowledge of contractor issuances since that time. *Id.* at 80. The contractor reviewed the contents of the drug manufacturer label for Lucentis and determined that, "based on the evidence provided," the appellant was liable for the overpayment under section 1870 of the Act. *Id.* at 81. The appellant requested reconsideration, with a supporting memorandum of law. Exh. 1, at 46-48, 49-76.

Reconsideration

On January 29, 2010, the Qualified Independent Contractor (QIC) issued an unfavorable reconsideration decision for services billed under HCPCS codes 67028, J2778, and J3490. Exh. 1, at 31. The QIC divided its findings/analyses into two categories: (1) Medicare had already paid the allowed amount for some services and could not make additional payment (Category A); and (2) the appellant's invoices did "not equal the number of vials need[ed] even if three doses were obtained from each vial purchased" (Category B). *Id.* at 33. The QIC later noted that the Medicare Part B allowance for Lucentis was based on the Average Sales Price (ASP), which "was 407.79 per unit which for Lucentis is 0.1 mg." *Id.* at 39. The QIC found that "[t]aken together, the ASP for 0.5mg administered as per the package insert provides for an allowable of $2,038.95 per dose. The administration of Lucentis and the ASP for the 0.5mg dose are not exclusive of each other." *Id.* at 40.

The QIC rejected the appellant's comparison of Lucentis to Botox, also provided in a single vial, finding that "Botox itself is reimbursed per unit

which may vary dose to dose. This is also supported by the fact that Botox is now also supplied as a 200 unit vial." Exh. 1, at 41. The QIC also stated that multi-dosing from one vial of Lucentis "may expose the patient to additional safety risks [a]lthough this is not an off-label use of Lucentis . . . ." *Id.* The QIC concluded that it "cannot equate Botox which is supplied and administered as a single use, multiple dose vial with Lucentis which is supplied and administered as a single use, single dose vial." *Id.* The QIC then concluded that, "[d]ue to the inconsistencies between the number of injections given and the number of vials of Lucentis purchase[d], Medicare cannot allow for any additional payment" for services in Category B. *Id.* The QIC agreed that the appellant was not without fault for the overpayment, which could therefore be recouped. *Id.* at 42-44, *citing* section 1870(b) of the Act; Medicare Financial Management Manual (MFMM) (Pub. 100-06) Ch. 3, §§ 90, 90.1. On March 30, 2010, the appellant requested an ALJ hearing, with supporting memorandum of law. Exh. 1, at 1-2, 3-27.

ALJ Decision

On June 13, 2011, the ALJ issued an unfavorable decision, based on the administrative record and without a hearing, as requested by the appellant. Dec. at 2. The ALJ summarized that the case involved Lucentis injections (HCPCS code J2778), intravitreal injection of a pharmacological agent (HCPCS code 67028), and unclassified drugs (HCPCS code J3490) to 746 beneficiaries, for a total of 8,487 claims, and dates of service February 1, 2007,

through December 1, 2007, and January 2, 2008, through December 23, 2008. *Id.* at 1-2.

In his findings of fact, the ALJ reviewed the Lucentis drug manufacturer label indications, including that Lucentis was provided in a single-use vial and was "designed to treat one eye of one beneficiary." Dec. at 3. The ALJ also found that "[e]ach vial contains enough solution for 4 actual doses because extra solution is provided to account for loss of product when the dose is being prepared and administered appropriately." *Id.* The ALJ noted that the appellant "used the extra solution in each vial to treat additional patients," at approximately three doses per vial. *Id.* The ALJ reviewed the appellant's invoices, noted that the appellant's dosing practice "gave Appellant huge cost savings," and found that multi-dosing from the vial resulted in the "cost for the drug [being] reduced." *Id.* The ALJ also found that the appellant had not notified the beneficiaries of the multi-dosing practice "to obtain their informed consent." *Id.* The ALJ noted that there was no evidentiary support for the appellant's argument that it had a patient infection rate consistent with or lower than reported in literature. *Id.* The ALJ then reviewed the ZPIC and QIC denials and found that the appellant had not disclosed to beneficiaries the financial benefit obtained from the multi-dosing process. *Id.* at 3-5.

In "Principles of Law," the ALJ set forth multiple statutory, regulatory, and administrative authority, including contractor LCDs L26327 and L29266, with respective effective dates of February 29, 2008, and February 2, 2009. Dec. at 6-24. The ALJ began his

analysis by stating that, after a review of all record evidence, the appellant had not established that the Lucentis injections and related services were reasonable and necessary under section 1862 of the Act. *Id.* at 24. The ALJ then considered the appellant's arguments under six categories. *Id.* at 24-34.

1. Medical Necessity and Reasonableness

The ALJ determined that the services were not reasonable and necessary. Dec. at 24-28. The ALJ quoted MBPM provisions that the use of a drug or biological must be "safe and effective and otherwise reasonable and necessary" for Medicare coverage. *Id.* at 25, *quoting* MBPM Ch. 15, § 50.4. Further, "[d]rugs or biologicals approved for marketing by the [FDA] are considered safe and effective for these purposes when used for indication specified on the labeling." *Id.* The ALJ reasoned that the intent of Medicare drug coverage "is to provide safe and effective medications and treatments to Medicare beneficiaries." *Id.* The ALJ stated that "Appellant's multi-dosing technique may have compromised the safety of Medicare beneficiaries with no medical benefit to the beneficiaries." *Id.* The ALJ stated that "[s]ingle use vials are specifically designed to be used one time only, to best ensure patient health and safety." *Id.*

After reviewing Lucentis labeling information, the ALJ stated that "Appellant disregarded all instructions advising that each vial should be used only one time, in one eye of a single patient" and that the vial and injection supplies should then be discarded. Dec. at 26. The ALJ found that this

deviation from the FDA labeling instructions "violated both Medicare and FDA guidelines." *Id.* The ALJ further found that the appellant's practices violated Medicare's policy for reimbursing a provider for the unused portion of a single use vial or package, stating that the 0.5 mg dose specified in the FDA label and LCD "constitutes the full billing unit and maximum amount that a provider can bill for a single-use vial. A provider cannot bill multiple 0.5 mg doses from a single-use vial." *Id.* at 26-27, *citing* Medicare Claims Processing Manual (MCPM) (Pub. 100-04), Ch. 17, § 40. The ALJ also determined that the appellant's dosage and billing practices for Lucentis violated medical necessity provisions of the Medicare Program Integrity Manual (MPIM). *Id.* at 27-28, *citing* MPIM Ch. 13, § 13.5.1. The ALJ concluded that the appellant had not met medical necessity standards, as he "did not comply with the requirements of the FDA, the local coverage determination or Medicare policies." *Id.* at 28. The ALJ also concluded that "Appellant has not proven his dosing technique was medically reasonable and necessary." *Id.* at 28.

2. Average Sales Price

The ALJ considered the appellant's argument that Medicare authority requires that Medicare pay for a drug at the ASP based rate without considering actual cost, so long as the drug meets Medicare coverage requirements. Dec. at 28, *citing Hays v. Sebelius*, 589 F.3d 1279 (D.C. Cir. 2009). The ALJ determined that *Hays* was inapposite, because the appellant's drug administration practice was not reasonable and necessary; "the least costly

alternative method of reimbursement was not applied to the present case," but "Medicare reimbursed [the appellant] for each single-use vial he purchased with the standard 106% ASP rate;" and the appellant was "actually doing the inverse of what the physicians in the *Hays* case did," in that the "billing does not reflect what is actually being done, and thus is incorrect and misleading." *Id.* The ALJ determined, instead, that the case more closely resembled *U.S. ex rel. Westmoreland v. Amgen, Inc.*, a federal False Claims Act (FCA) case concerning allegations of manufacturer "overfill" in drug containers. *Id.* at 30, *citing U.S. ex rel. Westmoreland v. Amgen, Inc.*, 738 F. Supp. 2d 267 (D.Mass. 2010). *Id.* at 30. The ALJ concurred with the *Westmoreland* Court's reasoning denying the defendants' motion to dismiss, including that manufacturers are required to deduct "price concessions" in calculating the ASP and that the Office of Inspector General (OIG) had previously "adjusted" the ASP for a different drug by this manufacturer to account for the effect on cost. *Id.; citing* 42 C.F.R. § 414.804(a) (2)(i)(D). The ALJ then re-calculated the ASP for Lucentis based on 4 doses from one vial ($101.9475 for J2778).[11] *Id.* at 31.

3. Cost of the Drug

The ALJ considered the appellant's acquisition-cost arguments that a July 2009 LCD revision permitted multi-dosing from a single vial with a reduced partial payment to the physician;

[11] However, in his conclusions of law the ALJ instead recalculated the ASP based on 3 doses per vial. *See* Dec. at 35. The contractor also based the overpayment on the appellant extracting three doses per vial.

reimbursement is not related to the physician's acquisition cost; and Medicare incurred no additional expense resulting from the appellant's multi-dosing practice. Dec. at 31. The ALJ determined, however, that the appellant's practice of using a single-use vial for multiple doses also "represented no additional expense to the physician." *Id., citing* MBPM Ch. 15, § 50.3. The ALJ concluded that the appellant "overbilled Medicare for the actual cost of the drug," as the only expense was "the cost of the single-use vial's first dose." *Id.* at 31-32. The ALJ determined that the second, third, and fourth doses represented no additional expense to the appellant, the appellant had "overstated its expense . . . when he billed in this manner," and the appellant "was [therefore] overpaid." *Id.* at 32. The ALJ concluded that the appellant had not complied with LCD or MBPM authority and "thus overbilled Medicare." *Id.* The ALJ stated that "[o]nly the first dose of each single-use vial is eligible for reimbursement, as that is the only dose that met the guidelines stated in the LCD." *Id.*

4. Avastin

The ALJ considered the appellant's argument that Medicare reimburses the drug Avastin, produced in single-use vial by the same manufacturer, "at a multi-dosing rate" and that Lucentis should therefore be treated similarly. Dec. at 32. The ALJ stated that Avastin was used to treat age-related macular degeneration (AMD) as an "off-label" use, since Avastin was approved by the FDA for treatment of metastatic colorectal cancer, non-squamous non-small cell lung cancer, and metastatic breast cancer.

Id. The ALJ also stated that the contractor issued LCD L29959 (2009) authorizing payment for the off-label use to treat AMD. *Id.* The ALJ stated that Avastin was currently marketed in single use vials of 100mg/4ml and 400 mg/16ml per vial, with reimbursement set at "$50 per a 1.25mg dose of Avastin." *Id.* The ALJ also stated that a 100mg single-use vial currently cost $600.

The ALJ found that the current reimbursement rate for Avastin was consistent with the QIC's reconsideration regarding Lucentis and undercut the appellant's argument. Dec. at 32. The ALJ stated that the appellant would likely agree that "the correct billing practice would be to bill $50 for a single dose, not $600 for a single dose." *Id.* In language identical to that used on page 31 of the decision in discussing the ASP,[12] the ALJ then calculated a revised ASP and cost per dose for Lucentis by assuming four 0.5 mg doses per vial and determining that a standard 0.5mg dose would be reimbursed at $101.9475 per 0.1 mg.

5. *U.S. ex rel. Westmoreland v. Amgen, Inc.*

The ALJ stated that the instant case was most closely aligned, factually, with the False Claims Act litigation, *U.S. ex rel. Westmoreland v. Amgen*, 738 F. Supp. 2d 267 (D. Mass. 2010). Dec. at 33. The ALJ quoted a portion of the *Westmoreland* Court's reasoning in denying the defendant's motion to dismiss, stating that the relator had adequately alleged factual support for its complaint. *Id.* For example, the Court noted the relator's allegation that

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[12] *See supra* at n.9 and accompanying text.

"[e]xcess overfill is in effect free doses of [the drug] Aranesp, which create the potential for providers to profit from Medicare reimbursement." *Id.* The Court further noted that the manufacturer's own spreadsheets reflected calculations of profit to be made from overfill. *Id.* The Court then stated that the "essential crux of Relator's allegations is not that the amount of overfill was illegal in and of itself, but rather that Amgen: (1) gave excess Aranesp to providers for which the providers did not pay; (2) advocated that providers bill Medicare for the free doses; and (3) induced providers to purchase Aranesp and make false certifications of compliance with the anti-kickback statute. . . . Such allegations are sufficient to state a claim that the Defendants gave kickbacks in the form of overfill to providers, and thus caused them falsely and expressly to certify compliance with the anti-kickback statute." *Id.* The ALJ made no coverage or reimbursement findings for Lucentis injections based on the *Westmoreland* analysis.

6. Conclusions of Law

The ALJ concluded that "[f]or all the above reasons," the QIC reconsideration was affirmed. Dec. at 33-34. The ALJ found that the record did not establish that the Lucentis injections and related services were reasonable and necessary under section 1862(a) of the Act for the dates of service and "[r]eimbursement was appropriately denied . . ." *Id.* The ALJ stated that "[a]lternatively, the undersigned reduces the average sales price of each dose to $679.65 [$135.93 per 0.1 mg] to reflect the Appellant's actual billing practices." *Id.* at 34-35. The

ALJ also found the appellant liable for non-covered charges under section 1879 of the Act. *Id.* at 35.

Request for Review

The appellant timely filed its request for review, dated August 15, 2011, with accompanying memorandum of law (22 pages) and included a request to present oral argument. Exh. MAC-1, at 1. The appellant presented two general arguments of ALJ error, with multiple sub-arguments, as follows:

> A. The appellant's treatment of the beneficiaries was reasonable and necessary.
>
> 1. The appellant's administration of Lucentis complied with MBPM Ch. 15, § 50.4.1.
>
> 2. Multi-dosing of Lucentis does not violate medical necessity standards in MPIM Ch. 13, § 13.5.1 or the contractor LCD.
>
> 3. The ALJ erred in the "refusal to acknowledge Medicare's Coverage of Avastin for AMD."
>
> *Id.* at 3-12.
>
> B. The appellant was properly reimbursed for Lucentis based upon the ASP "for each unit of product administered."
>
> 1. Drug product reimbursement is fixed based on the ASP, and the Secretary has no authority to reduce reimbursement rates based a physician's drug acquisition cost. The ALJ erred in rejecting the application of *Hays*.
>
> 2. The ALJ erred in determining that "additional product constitutes non-reimbursable 'overfill'" because "prior to

January 1, 2011, it was Medicare Policy to reimburse for 'overfill.'"

3. The ALJ erred in relying on *U.S. ex rel. Westmoreland*.

Id. at 12-22.

Appellant's Supplementary Submission

On October 17, 2012, the Council advised the appellant that the Council did not intend to hold oral argument and provided the appellant an additional 30 days to submit supplemental briefing. Exh. MAC-4, at 1. On November 15, 2012, the appellant filed a "supplemental submission" with the Council, consisting of a memorandum brief (22 pages) and Exhibits A through J. Exh. MAC-5. The appellant generally expanded on arguments in the request for review and more directly argued that Medicare covers Lucentis injections as "incident to" a physician's service. *See id.* at 3-4, 10-12. The appellant concluded as follows:

1. The Lucentis injections are a covered service under Medicare Part B.

2. The Lucentis injections were reasonable and necessary for treatment of the beneficiaries' AMD, and each beneficiary received the standard dose of 0.5 mg.

3. Medicare statutes and regulations establish drug reimbursement based upon ASP.

4. No written policy by CMS and/or its contractors during the dates of service prohibited the appellant from billing for multiple administrations of Lucentis from a single-use vial.

Id. at 21-22. The appellant also argued that, if the Council found that the appellant had been overpaid, the appellant is entitled to overpayment waiver under the "without fault" provisions of section 1870 of the Act. *Id.* at 22.

Council Order to Develop the Record

On February 20, 2013, the Council issued an "Order to Develop the Record," in which the Council requested CMS and/or its contractors and the appellant to file additional submissions responding to nine questions. Exh. MAC-6.[13] The questions are as follows:

> 1. Do the injections of Lucentis (Ranibizumab) at issue satisfy the coverage, limitations, and utilization standards set forth in contractor Local Coverage Determination (LCDs) L26237 and L29266 during the dates of service? If not, why not, and how does that affect Medicare reimbursement to the appellant?
>
> 2. Is there any dispute as to whether the Lucentis injections were provided for indications set forth in the LCDs (diagnoses of established exudative senile macular degeneration or neovascular (wet) age-related macular degeneration (ARMD) in patients without ocular or periocular infections)?
>
> 3. Is there any evidentiary basis to support that multi-dosing from a single vial of Lucentis

[13] As noted above, the Council also directed that "CMS and the appellant shall provide each other with a copy of any filing with the Council." *Id.* at 2.

resulted in, or contributed to, medical complications for any beneficiary?

4. What effect does the Food and Drug Administration (FDA) label for a single vial of Lucentis have on the physician's prescription and use of the vial contents in treating a single patient or more than one patient?

5. How did CMS or contractor authority in effect during the dates of service require a physician to account to CMS for expense incurred when billing for the recommended 0.5mg dose of Lucentis for each beneficiary? What effect does Medicare Benefit Policy Manual (MBPM) (Pub. 100-02) Ch. 15, § 50.3 concerning an "expense to the physician" have on Medicare reimbursement for each claim at issue?

6. What was CMS's published policy, if any, concerning physician billing Medicare for drug "overfill" or "wastage" during the dates of service?

7. To what extent can Medicare contractors deviate from the Average Sales Price (ASP) established by CMS in determining Medicare reimbursement? Is the determination of the ASP an initial determination that is subject to review? *See* 42 C.F.R. §§ 405.924, 405.926.

8. What is the relevance of the discussion concerning "Botox" in the Medicare Claims Processing Manual (Pub. 100-04) (MCPM) Ch. 17, § 40 to billing Medicare for multiple doses of Lucentis from a single vial?

9. How do the reasonable and necessary provisions of section 1862(a)(1)(A) of the Social Security Act (Act) apply in analyzing the overpayments at issue? Do the limitation on liability provisions in section 1879 of the Act apply? Is the appellant entitled to waiver of overpayment under section 1870 of the Act?

CMS Response and Appellant Responses

On March 22, 2013, the ZPIC submitted a nine page facsimile in response to the Council's Order. Exh. MAC-7 (Excluded). As previously noted, the ZPIC's submission did not address the Council's questions and does not indicate that a copy was provided to any other entity or to the appellant. The ZPIC's submission is therefore struck from the administrative record, and the Council does not consider it in reaching this decision.

On March 27, 2013, the FCSO Medical Director submitted the MAC's response (8 pages, Exhs. A-D). Exh. MAC-8. On April 12, 2013, the appellant submitted its response with supplementary legal memorandum (25 pages) and Exhibits A-P. Exh. MAC-9. On April 24, 2013, the Council provided the MAC with copies of the appellant's submission and advised both CMS and the appellant that the administrative record was now closed. Exh. MAC-10.

APPLICABLE LEGAL AUTHORITIES

ALJs and the Council are bound by all statutes and regulations pertaining to the Medicare program, as well as National Coverage Determinations and Rulings issued by CMS. 42 C.F.R. §§ 405.1060, 405.1063. ALJs and the Council are not bound by contractor LCDs or CMS manual authority, but are

required to afford "substantial deference" to that authority or to explain the reasons for not doing so in their decision. 42 C.F.R. § 405.1062.

Medicare Coverage—Outpatient Drugs

Medicare covers "drugs and biologicals" as a subset of "medical and other health services" under Part B. Section 1861(s) of the Act. These terms include drugs provided to a Medicare beneficiary in a physician's office that are not normally self-administered by the patient, are furnished "incident to" the physician's service, and are commonly furnished in a physician's office either without charge or are "included in the physician's bills . . ." Section 1861(s)(2)(A) of the Act; *see also* 42 C.F.R. §§ 410.10(b), 410.26, 410.29.

CMS emphasizes that the Part B benefit for outpatient drugs is "limited," but that such drugs are covered when they meet the definition of a drug, are not typically self-administered, meet all general requirements for coverage "incident to" a physician's service, "are reasonable and necessary for the diagnosis or treatment of the illness or injury for which they are administered according to accepted standards of medical practice," are not excluded from coverage, and "have not been determined by the FDA to be less then effective." MBPM Ch. 15, § 50 (10-01-03). With respect to the "incident to" requirement, the MBPM states that "[t]he charge, if any, for the drug or biological must be included in the physician's bill, and the cost of the [drug] must represent an expense to the physician." *Id.* at § 50.3.

With respect to "Reasonableness and necessity," the MBPM states:

> Use of the drug or biological must be safe and effective and otherwise reasonable and necessary. Drugs or biological approved for marketing by the Food and Drug Administration (FDA) are considered safe and effective for purposes of this requirement when used for indications specified on the labeling. Therefore, the program may pay for the use of an FDA approved drug or biological, if:
>
> - It was injected on or after the date of the FDA's approval;
> - It is reasonable and necessary for the individual patient; and
> - All other applicable coverage requirements are met.

Id. at § 50.4.1.

The MBPM explains that an "unlabeled use of a drug is a use that is not included as an indication on the drug's label as approved by the FDA." MBPM Ch. 15, § 50.4.2. However, "FDA approved drugs used for indications other than what is indicated on the official label may be covered under Medicare if the carrier determines the use to be medically accepted, taking into consideration the major drug compendia, authoritative medical literature and/or accepted standards of medical practice." *Id.*

In the absence of CMS national coverage policy, a Medicare contractor may issue an LCD on whether to cover a particular item or service as "reasonable and necessary" under section 1862(a) of the Act. MPIM Ch. 13, § 13.1.3 (Eff. 10-26-06). In part, a

contractor may determine in an LCD that an item or services is reasonable and necessary for coverage if that item or service is "safe and effective," "not experimental or investigational," and "appropriate" if "furnished in accordance with accepted standards of medical practice . . . ." *Id.* at § 13.5.1. "Contractor LCDs shall be based on the strongest evidence available," including published scientific literature, general acceptance by the medical community "as supported by sound medical evidence" based on scientific data or research studies published in peer-reviewed medical journals, consensus of expert medical opinion, or medical opinion derived from consultants within the health care field. *Id.* § 13.7.1. The MPIM also makes clear that, in the event no LCD is applicable, the same standards are applied in individual adjudications. *Id.* § 13.3 ("A service may be covered by a contractor if it meets all of the conditions listed in § 13.5.1, Reasonable and Necessary Provisions in LCDs below"). The Medicare contractor in this case, FCSO, issued an LCD for Ranibizumab (Lucentis) (L26237), for HCPCS code J2778, with effective date February 29, 2008.[14]

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[14] The Medicare contractor also issued "Local Coverage Determination (LCD): Ranibizumab (Lucentis) (L29266)," for HCPCS code J2778, with effective date February 2, 2009, and "Local Coverage Article for J2778: Ranibizumab (Lucentis) article clarification (A49317)," effective July 22, 2009, which provides that billing for multiple doses from a single-use vial of Lucentis represents an overpayment and a voluntary reimbursement of the overpayment is expected. Exh. MAC-9, at Hl-H3. The last date of service at issue here is December 23, 2008, which is before either of these policies was published.

Medicare Part B Drug Reimbursement

"CMS establishes a single, national payment limit for [Medicare contractor] payment for each Medicare-covered drug . . . ." Medicare Claims Processing Manual (MCPM) (Pub. 100-04) Ch. 17, § 20.1 (effective 01-01-05). As of January 1, 2005, "the payment limit for Part B drugs and biologicals will be based on the Average Sales Price (ASP). Drugs will be paid based on the lower of the submitted charge or the ASP." *Id.* CMS provides an ASP file to each Medicare contractor, and drugs are "priced based on date of service. These drug payment limits will be distributed to contractors by CMS. CMS will update and provide this file quarterly. Carriers/DMERCs/SADMERC shall develop payment limits when CMS does not supply a payment limit for the drug on the file." *Id.*

The MCPM also indicates that, as of January 1, 2003, Medicare contractors "pay drug claims on the basis of the prices shown on the SDP [Single Drug Pricer] files, if present." MCPM Ch. 17, § 20.2. CMS provides the SDP file to Medicare contractors with drugs identified by HCPCS code, and the "HCPCS drug-pricing file (HCPF)" includes the following:

- Every HCPCS drug code for every drug for which claims are submitted to local carriers (excluding DMERCs);
- With respect to each such HCPCS code, *the unit of measure by which such HCPCS code is defined*;
- With respect to each HCPCS code *and unit of measure, the Medicare allowed amount*.

Id. (emphasis supplied).

CMS has also established reimbursement standards for "discarded drugs and biologicals" that are packaged in single-use vials. MCPM Ch. 17, § 40. In pertinent part, that policy in effect through June 30, 2007 stated:

> The CMS encourages physicians to schedule patients in such a way that they can use drugs most efficiently. However, if a physician must discard the remainder of a vial or other package after administering it to a Medicare patient, the program covers the amount of drug discarded along with the amount administered.

On May 25, 2007, CMS issued Transmittal 1248, which modified the first quoted paragraph, effective July 1, 2007. *See* Exh. MAC-8, Attachment C. The revised version follows, with the changes in bold italic type:

> The CMS encourages physicians, hospitals and other providers to schedule patients in such a way that they can use drugs ***or biologicals*** most efficiently, ***in a clinically appropriate manner***. However, if a physician, hospital or other provider must discard the remainder of a ***single use*** vial or other ***single use*** package after administering a dose/quantity of the drug or biological to a Medicare patient, the program provides payment for the amount of drug *or biological* discarded along with the amount administered, ***up to the amount of the***

drug or biological as indicated on the vial or package label.

Both versions include the following examples.

EXAMPLE 1:

A physician schedules three Medicare patients to receive Botulinum Toxin Type A on the same day within the designated shelf life of the product. Currently, Botox is available only in a 100-unit size. Once Botox is reconstituted in the physician's office, it has a shelf life of only four hours. Often, a patient receives less than a 100 unit dose. The physician administers 30 units to each patient. The remaining 10 units are billed to Medicare on the account of the last patient. Therefore, 30 units are billed on behalf of the first patient seen and 30 units are billed on behalf of the second patient seen. Forty units are billed on behalf of the last patient seen because the physician had to discard 10 units at that point.

EXAMPLE 2:

A physician must administer 15 units of Botulinum Toxin Type A to a Medicare patient, and it is not practical to schedule another patient who requires Botulinum Toxin. For example, the physician has only one patient who requires Botulinum Toxin, or when the physician sees the patient for the first time and did not know the patient's condition. The physician bills for 100 units on behalf of the patient *and Medicare pays for 100 units*.

Id. (emphasis added).[15]

DISCUSSION

The Council first clarifies that this case is an administrative appeals proceeding to determine whether the appellant is entitled to reimbursement for covered services provided to Medicare beneficiaries during the dates of service at issue, consistent with authority then in effect. While the administrative record and ALJ decision contain references, for example, to the federal False Claims Act, the case before the Council does not involve civil or criminal proceedings or related authority.[16]

The Council conducts a *de novo* review of the record to determine whether the appellant has met its burden of proof, by a preponderance of the evidence, that the services provided meet relevant Medicare coverage and reimbursement policies in effect on the dates of service. For the reasons set forth below, the Council finds that the appellant

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[15] Additional guidance on using the JW modifier to bill for discarded drugs is in the MCPM, Ch. 17, § 100.2.9.

[16] The Council finds that the ALJ's reliance upon *U.S. ex rel. Westmoreland v. Amgen, Inc.*, 738 F. Supp. 2d 267 (D. Mass. 2010), a civil action brought pursuant to the federal False Claims Act, is misplaced. Dec. at 33. The *Westmoreland* Court considered the defendant's motion to dismiss the *qui tam* relator's claim pursuant to Rules 12(b) and 9(b) of the Federal Rules of Civil Procedure (FRCP). The instant Medicare administrative proceeding concerns whether the appellant has met its burden of proving, by a preponderance of the evidence, that the services meet Medicare coverage and reimbursement requirements under applicable statutes, regulations, and administrative authority. Given the different legal standards and case procedural postures, *Westmoreland* is inapposite.

failed to meet this burden of proof. A portion of the services provided and billed to Medicare by the appellant were not reasonable and necessary and are not covered by Medicare.

I. The Appellant has not shown that it is Medically Reasonable and Necessary to Extract and Administer More than a Single Dose of Lucentis from a Single Use Vial; Thus, Injections Are Medically Reasonable and Necessary Only When the Contents of a Single Vial Are Used To Treat a Single Eye of a Single Beneficiary; Any Excess Use is not Medically Reasonable and Necessary and Is Not Covered by Medicare

In alternative conclusions, the ALJ found that the Lucentis injections were not reasonable and necessary and are not covered by Medicare, and that reimbursement should be made based on three doses per vial. Dec. at 24-28, 34-35. These inconsistent and mutually exclusive alternative findings are not capable of effectuation. If the injections are not medically reasonable and necessary, then no payment may be made for any injection.

The Council concludes that the ALJ erred by stating that none of the Lucentis injections administered by the appellant are medically reasonable and necessary. We conclude that Lucentis injections were medically reasonable and necessary to the extent the drug was administered consistent with its FDA-approved label. However, the appellant has not shown that it was medically reasonable and necessary to extract and administer more than a single dose of Lucentis from a single use vial. Thus, when the appellant departed from the product

labeling by using a single vial of Lucentis to treat more than one beneficiary or more than one eye, such administration was not medically reasonable and necessary and is not covered by Medicare.

As noted above, CMS guidance requires the same showing of medical necessity to establish Medicare coverage for an item or service regardless of whether the contractor is reviewing claims individually or developing an LCD applicable across the contractor's jurisdiction. *See* MPIM, Ch. 13, § 13.3. *See also Almy v. Sebelius*, 679 F.3d 297, 304-05 (4th Cir. 2012), *cert. denied* 133 S.Ct. 841 (2013). The MPIM provides:

> Contractors shall consider a service to be reasonable and necessary if the contractor determines that the service is:
>
> • Safe and effective; *and*
>
> Appropriate, including the duration and frequency that is considered appropriate for the service, in terms of whether it is:
>
> • Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition. . . .

MPIM, Ch. 13, § 13.5.1. In the present case, the appellant's practice of using a single-use vial of Lucentis to treat multiple beneficiaries or multiple eyes is not appropriate because it departs from accepted standards of practice. Evidence of such standards is found in the FDA-approved label instructions, as well as in Centers for Disease Control and Prevention (CDC) guidelines.

The Lucentis drug manufacturer label indicates that Lucentis received FDA approval in 2006 only when packaged in a single-use vial. Exh. 4, at 58.[17] The FDA defines a single-use vial as "a vial where a single dose of a parenteral drug product can be removed, and then the vial. and its remaining contents can be disposed." FDA Data Standards Manual, Drug Registration and Listing System, CDER Data Element Number C-DRG-00907, Rev. 4/30/2009.[18]

Under "Indications and Usage," the FDA label states that Lucentis is "indicated for the treatment of patients with neovascular (wet) age-related macular degeneration." *Id.* Under "Dosage and Administration," the label states that Lucentis is "for ophthalmic intravitreal injection only" and that "LUCENTIS 0.5 mg (0.05 ml)" should be dosed once monthly by intravitreal injection. *Id.*

More importantly, under "Dosage Forms and Strengths," the label states: "10mg/ml solution in a single-use vial for intravitreal injection." *Id.* The label also states that the entire contents of the single-use vial are 0.2 ml and should be drawn into the syringe in preparation for the injection, with the excess drug "expelled" from the syringe until the recommended dosage of 0.05 mL is obtained. *Id.* at 59

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[17] Contractor LCD L26237 states that Lucentis "was approved by the Food and Drug Administration (FDA) on June 30, 2006 for treatment of patients with exudative senile macular degeneration." LCD L26327, "LCD Information."

[18] *See*, www.fda.gov.Drugs/DevelopmentApprovalProcess/FormsSubmissionRequirements/ElectronicSubmissions/DataStandardsManualmonographs, (accessed June 25, 2013).

(§ 2.3). Under "Administration," the label provides that the injection should take place under aseptic conditions and *"[e]ach vial should only be used for the treatment of a single eye. If the contralateral eye requires treatment, a new vial should be used"* and the manufacturer-provided injection apparatus "should be changed before LUCENT'S is administered to the other eye." *Id. (*§ 2.4) (emphasis added).

Similarly, the Medicare contractor issued LCD L26237 establishing coverage and reimbursement standards for Lucentis, effective February 29, 2008. Under "Indications and Limitations of Coverage and/or Medical Necessity," the LCD repeats the drug label information and provides that Lucentis "is supplied as a preservative-free, sterile solution in a single-use glass vial. Each vial should only be used for the treatment of a single eye. If the contralateral eye requires treatment, a new vial should be used." Under "Limitations," the LCD provides that the use of Lucentis injections "in any condition other than neovascular AMD is considered investigational/not medically necessary."

Further, in a May 5, 2009 letter responding to an inquiry from FCSO's Director of Policy, the manufacturer of Lucentis confirmed that the product's labeling does not "support the practice of administering the contents of one vial of Lucentis to more than one eye or more than one patient." Exh. 1, at 132. The manufacturer further explained that each "vial contains overfill to account for loss of product when the dose is being prepared and administered appropriately according to the FDA-

approved labeling. The vial is designed to contain enough liquid so that a single 0.5 mg (0.05 mL) dose can be administered." *Id.*

The standard for appropriate administration of Lucentis as set forth in the product labeling and reinforced by LCD L26237, as well as the manufacturer's explanatory letter, is also consistent with general guidelines for injection safety promulgated by the CDC. In 2012, the CDC published a position statement in which summarizing its position on single-dose/single use vials:

> The Centers for Disease Control and Prevention's guidelines call for medications labeled as "single dose" or "single use" to be used for only one patient. This practice protects patients from life-threatening infections that occur when medications get contaminated from unsafe use.

See http://www.cdc.gov/injectionsafety/PDF/CDC-SDVPosition05022012.pdf (last visited June 17, 2013). The CDC specifies:

> Unsafe injection practices include, but are not limited to, reuse of syringes for multiple patients or to access shared medications, *administration of medication from a single-dose/single-use vial to multiple patients,* and failure to use aseptic technique when preparing and administering injections.

Id. (emphasis added). The policy statement notes that "CDC injection safety guidelines are not new. They have been part of Standard Precautions since

2007." *Id.* (citing http:// www.cdc.gov/injectionsafety/ IP07_standardPrecaution.html).

We acknowledge that CMS and the CDC have both permitted an exception to this single use guideline when drug shortages of critical medicines threaten the general public welfare. Exh. MAC-1, tab I. Both agencies have limited this exception to instances when the applicable USP standards have been followed to ensure the safe repackaging and storage of drugs delivered in a single-use vial. The appellant has not shown that a shortage of Lucentis caused him to repackage a single-use vial. Nor has appellant shown that each individual dose extracted and administered in 2007-2008 was repackaged and stored in accord with the applicable USP standards.

Appellant's argument that the FDA label language requires the use of a second single-use vial only to treat the contralateral eye of a single patient, but not multiple eyes in multiple patients, is not persuasive. This language does not expand or alter the limitation on extracting only one dose from a single-use vial, i.e., each vial should only be used for the treatment of a single eye. If anything, this language only emphasizes to a practitioner that the use of a single-dose vial applies even when both eyes in the same patient are treated.

We note also that, in response to the Council's Order to Develop the Record, the FCSO Medical Director noted that the Co-Chair of FCSO's Contractor Advisory Committee is a practicing ophthalmologist. *See* Exh. MAC-8, at 8. According to the FCSO response, the Advisory Committee Co-Chair is unaware of any accepted practice within the

medical community to deviate from the standard of care represented by the product labeling when administering Lucentis. *Id.* The appellant has expressed concerns about the reliability of this representation, but has produced no direct evidence of its own concerning the standard of care.

Based on the authorities just discussed, the Council concludes that, to be considered "appropriate" within the meaning of section 13.5.1 of the MPIM, Lucentis must be administered in accordance with the instructions found in the FDA-approved product label. A single-use vial may only be used to treat a single eye. Deviation from the procedures specified in the product label is inconsistent with accepted standards of medical practice and is therefore not medically reasonable and necessary.

The Council does not find persuasive the appellant's contentions that CMS and/or contractor guidance with respect to two other drugs, i.e. Botox and Triescence, compel a conclusion that it is medically reasonable and necessary to treat multiple beneficiaries using a single vial of Lucentis. With regard to Botox, the appellant points to CMS guidance in the MCPM regarding Medicare reimbursement for "discarded drugs." The guidance explains that if a provider or supplier is unable to use the full contents of a vial of Botox in treating a patient or patients, it may bill Medicare for the discarded amount. *See* MCPM, Ch. 17, § 40.

The comparison to Botox based on the MCPM guidance is inapposite to Lucentis. First and most significantly, the FDA-approved label for Botox does

not specify that the contents of a vial of Botox may only be used to treat a single beneficiary or a single anatomic site. Instead, the Botox label specifies that, once reconstituted, the product must be kept refrigerated and used within four hours. Thus, the example in the MCPM contemplates that a provider or supplier may appropriately (i.e. consistent with the product labeling) treat multiple beneficiaries using the contents of a single vial of Botox, provided the drug is consumed within four hours of being reconstituted. Payment is made on a unit basis for the amount of the drug in the vial, whether discarded as "wastage" or used. By contrast, as discussed above, the product labeling for Lucentis contemplates that the entire contents of a vial is required to administer a single dose to a single beneficiary. Thus, when administered in accordance with the product labeling, there is no excess amount of Lucentis to account for as "wastage" or overfill. The ASP allowance for a single 0.5 mg dose represents payment in full for all of the drug intended to be extracted and administered from a single-use vial. By manufacturer design and FDA labeling, the excess is meant to be discarded.

The appellant's argument based on contractor guidance regarding Triesence is similarly unavailing. Triesence is a synthetic corticosteroid for ophthalmic injection. *See* Exh, MAC-9, Attachment C. Its product labeling, like that for Lucentis, provides that each vial should only be used to treat a single eye. In contrast to the Lucentis label, however, the Triesence label does not instruct that the entire contents of the vial must be drawn into the syringe to prepare a single dose.

The appellant points to a Policy Article for Triesence, A48266, issued by FCSO, which includes the following quotation from the MCPM:

> The CMS encourages physicians, hospitals and other providers to schedule patients in such a way that they can use drugs or biologicals most efficiently, in a clinically appropriate manner. However, if a physician, hospital or other provider must discard the remainder of a single use vial or other single use package after administering a dose/quantity of the drug or biological to a Medicare patient, the program provides payment for the amount of drug or biological discarded along with the amount administered, up to the amount of the drug or biological as indicated on the vial or package label.

Exh. MAC-9, Attachment C (Article A48266 *citing* MCPM, Ch. 17, § 40). The appellant asks the Council to infer from this language that Article A48266 endorses the practice of treating multiple beneficiaries using a single vial of Triesence. The Article does not support such an inference.

This language does nothing more than repeat the MCPM language quoted *supra* at 21. Article A48266 nowhere states that providers or suppliers should administer Triesence in a manner incompatible with the instructions found in its labeling. Indeed, the referenced MCPM guidance reinforces that drugs and biologicals must be administered "in a clinically appropriate manner." As discussed previously in the context of Lucentis, it would not be "clinically

appropriate" to disregard the product labeling by using a single vial of Triesence to treat more than one beneficiary or more than one eye. At most, Article 48266 may stand for the proposition that a provider or supplier may bill Medicare for the excess medication in a vial of Triesence that is not consumed in treating a single eye. However, again Medicare payment for a 0.5mg dose of Lucentis represents full payment for the amount of drug discarded along with the amount administered, up to the amount of the useful drug indicated on the FDA label.

The appellant argues, additionally, that neither CMS nor FCSO may dictate how the appellant practices medicine. *See* Exh. MAC-9, at 7. While the Council agrees with the appellant's general proposition, the Council does not agree that, by taking the position that Medicare will not pay for Lucentis when it is not administered in accordance with its FDA-approved label, CMS is interfering with the appellant's medical practice. The appellant remains free to practice medicine as it sees fit. Nothing in CMS's position prevents the appellant from continuing to use a single vial of Lucentis to treat multiple beneficiaries. However, just as CMS cannot constrain the appellant's medical practice, the appellant's medical decision to administer Lucentis in a manner incompatible with the product label cannot obligate Medicare to pay for an item or service that is not medically reasonable and necessary as defined in the statute, regulations, and guidance. This overarching exclusion from coverage applies notwithstanding any other provision of the statute. Section 1862(a)(1)(1) of the Act.

In summary, the Council concludes that the appellant has not shown that it was medically reasonable and necessary to extract and administer more than a single dose of Lucentis from a single use vial. In other words, it is only medically reasonable and necessary to use one single-use vial of Lucentis to treat one eye of one beneficiary. To the extent the appellant administered the contents of a single vial of Lucentis to more than one beneficiary, or treated more than one eye, those injections are not medically reasonable and necessary and are not covered by Medicare. Medicare will cover and pay for one dose of Lucentis per each vial purchased by the appellant. Any amount paid by Medicare in excess of this amount represents an overpayment to the appellant.[19] As discussed below, Medicare is authorized to recoup such overpayment.

II. The Appellant is Liable for the Non-Covered Costs and Must Repay the Resulting Overpayment

The ALJ found that the appellant was liable for the non-covered costs related to the Lucentis injections, pursuant to section 1879 of the Act. The ALJ's decision did not address whether recovery of the resulting overpayment may be waived pursuant to section 1870(b) of the Act. The Council agrees with

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[19] Based upon the Council's analysis explained above, we find it unnecessary to address the appellant's arguments with regard to Medicare pricing of Lucentis. Nor do we find it necessary to reexamine the assumptions the contractor used to calculate the amount of the overpayment, which give the benefit of the doubt to the appellant that he only extracted three doses from each vial. The appellant's evidence suggests that it was possible to extract more than 4 doses per vial. Exh. MAC-9 at 81 (1075 doses extracted from 250 vials).

the ALJ's conclusion that the appellant's liability for the non-covered costs may not be waived pursuant to section 1879 of the Act. We further conclude that the appellant is not "without fault" in receiving the resulting overpayment. Accordingly, recoupment of the overpayment will not be waived under section 1870(b) of the Act.

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

In the present case, there is no evidence that any beneficiary received an Advance Beneficiary Notice (ABN) or was otherwise informed that the injections

at issue would not likely be covered by Medicare. Therefore, the beneficiaries are not liable for the cost of any non-covered services. By contrast, the appellant, as a Medicare supplier, is deemed to have constructive notice of the requirements for Medicare coverage, as published in the regulations and CMS guidance discussed above. Further, as a medical practitioner, the appellant's physician(s) are deemed to have knowledge of acceptable standards of medical practice. Under the prevailing standards of practice embodied in the FDA label and CDC guidance, the appellant knew or should have known that it was not medically reasonable and necessary to extract and administer more than a single dose of Lucentis from a single use vial under the circumstances presented in this case. Therefore, the appellant knew, or could reasonably be expected to know, that the Lucentis injections at issue would not be covered by Medicare. Accordingly, the appellant's liability for the non-covered services is not waived, and an overpayment exists.

Having determined that an overpayment exists, the Council next considers whether recoupment of the overpayment may be waived pursuant to section 1870(b) of the Act. Section 1870(b) of the Act provides that recoupment of an overpayment to a provider or supplier may be waived if the provider or supplier was without fault in receiving the overpayment. CMS guidance published in the MFMM explains that a provider or supplier is considered to be without fault—

if it exercised reasonable care in billing for, and accepting, the payment; i.e.,

> • It made full disclosure of all material facts; and
>
> • On the basis of the information available to it, including, but not limited to, the Medicare instructions and regulations, it had a reasonable basis for assuming that the payment was correct, or, if it had reason to question the payment; it promptly brought the question to the FI or carrier's attention.

MFMM, IOM 100-06, Ch. 3, § 90. The MFMM goes on to explain that a provider or supplier is not without fault if it billed, or Medicare paid for, services that the provider or supplier should have known were not covered:

> In general, the provider should have known about a policy or rule, if:
>
> • The policy or rule is in the provider manual or in Federal regulations,
>
> • The [contractor] provided general notice to the medical community concerning the policy or rule, or
>
> • The [contractor] gave written notice of the policy or rule to the particular provider.
>
> Generally, a provider's allegation that it was not at fault with respect to payment for noncovered services because it was not aware of the Medicare coverage provisions is not a basis for finding it without fault if any of the above conditions is met.

MFMM, Ch. 3, § 90.1.H.

As we have discussed above, the appellant knew or should have known that its administration of

Lucentis was not consistent with accepted standards of practice and, accordingly, did not meet Medicare coverage guidelines. The appellant is not deemed to be without fault and recovery of the overpayment will not be waived.

DECISION

It is the decision of the Medicare Appeals Council that the appellant has not shown that it was medically reasonable and necessary to extract and administer more than a single dose of Lucentis from a single use vial. Where the appellant treated more than one beneficiary or more than one eye using the contents of a single vial of Lucentis, such treatment was not medically reasonable and necessary and is not covered by Medicare.

Further, the appellant knew, or could reasonably be expected to know, that such treatments were not medically reasonable and necessary. Therefore, the appellant's liability for the non-covered costs may not be waived pursuant to section 1879 of the Act. To the extent Medicare paid for Lucentis injections that are not covered as explained above, the appellant was overpaid. The appellant is not considered to be without fault within the meaning of section 1870(b) of the Act. Accordingly, recoupment of the overpayment will not be waived.

The ALJ's decision is modified in accordance with the foregoing discussion.

Medicare Appeals Council

[handwritten: signature]
Clausen J. Krzywicki
Administrative Appeals Judge

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Leslie A. Sussan, Member
Departmental Appeals Board

Date: Jun 28, 2013

Appendix G

Relevant Statutory and Regulatory Provisions Involved

42 U.S.C. §1395*l*(a)(1)

(a) Amounts

Except as provided in section 1395mm of this title, and subject to the succeeding provisions of this section, there shall be paid from the Federal Supplementary Medical Insurance Trust Fund, in the case of each individual who is covered under the insurance program established by this part and incurs expenses for services with respect to which benefits are payable under this part, amounts equal to—

(1) in the case of services described in section 1395k(a)(1) of this title—80 percent of the reasonable charges for the services; except that (A) an organization which provides medical and other health services (or arranges for their availability) on a prepayment basis (and either is sponsored by a union or employer, or does not provide, or arrange for the provision of, any inpatient hospital services) may elect to be paid 80 percent of the reasonable cost of services for which payment may be made under this part on behalf of individuals enrolled in such organization in lieu of 80 percent of the reasonable charges for such services if the organization undertakes to charge such individuals no more than 20 percent of such reasonable cost plus any amounts payable by them as a result of subsection (b) of this section,

(B) with respect to items and services described in section 1395x(s)(10)(A) of this title, the amounts paid shall be 100 percent of the reasonable charges for such items and services, (C) with respect to expenses incurred for those physicians' services for which payment may be made under this part that are described in section 1395y(a)(4) of this title, the amounts paid shall be subject to such limitations as may be prescribed by regulations, (D) with respect to clinical diagnostic laboratory tests for which payment is made under this part (i) on the basis of a fee schedule under subsection (h)(1) of this section or section 1395m(d)(1) of this title, the amount paid shall be equal to 80 percent (or 100 percent, in the case of such tests for which payment is made on an assignment-related basis) of the lesser of the amount determined under such fee schedule, the limitation amount for that test determined under subsection (h)(4)(B) of this section, or the amount of the charges billed for the tests, or (ii) on the basis of a negotiated rate established under subsection (h)(6) of this section, the amount paid shall be equal to 100 percent of such negotiated rate,, (E) with respect to services furnished to individuals who have been determined to have end stage renal disease, the amounts paid shall be determined subject to the provisions of section 1395rr of this title, (F) with respect to clinical social worker services under section 1395x(s)(2)(N) of this title, the amounts paid shall be 80 percent of the lesser of (i) the actual charge for the services or (ii) 75 percent of the

amount determined for payment of a psychologist under clause (L), (G) with respect to facility services furnished in connection with a surgical procedure specified pursuant to subsection (i)(1)(A) of this section and furnished to an individual in an ambulatory surgical center described in such subsection, for services furnished beginning with the implementation date of a revised payment system for such services in such facilities specified in subsection (i)(2)(D) of this section, the amounts paid shall be 80 percent of the lesser of the actual charge for the services or the amount determined by the Secretary under such revised payment system, (H) with respect to services of a certified registered nurse anesthetist under section 1395x(s)(11) of this title, the amounts paid shall be 80 percent of the least of the actual charge, the prevailing charge that would be recognized (or, for services furnished on or after January 1, 1992, the fee schedule amount provided under section 1395w–4 of this title) if the services had been performed by an anesthesiologist, or the fee schedule for such services established by the Secretary in accordance with subsection (*l*) of this section, (I) with respect to covered items (described in section 1395m(a)(13) of this title), the amounts paid shall be the amounts described in section 1395m(a)(1) of this title, and (J) with respect to expenses incurred for radiologist services (as defined in section 1395m(b)(6) of this title), subject to section 1395w–4 of this title, the amounts paid shall be 80 percent of the lesser of the actual charge for the services or the amount

provided under the fee schedule established under section 1395m(b) of this title, (K) with respect to certified nurse-midwife services under section 1395x(s)(2)(L) of this title, the amounts paid shall be 80 percent of the lesser of the actual charge for the services or the amount determined by a fee schedule established by the Secretary for the purposes of this subparagraph (but in no event shall such fee schedule exceed 65 percent of the prevailing charge that would be allowed for the same service performed by a physician, or, for services furnished on or after January 1, 1992, 65 percent (or 100 percent for services furnished on or after January 1, 2011) of the fee schedule amount provided under section 1395w–4 of this title for the same service performed by a physician), (L) with respect to qualified psychologist services under section 1395x(s)(2)(M) of this title, the amounts paid shall be 80 percent of the lesser of the actual charge for the services or the amount determined by a fee schedule established by the Secretary for the purposes of this subparagraph, (M) with respect to prosthetic devices and orthotics and prosthetics (as defined in section 1395m(h)(4) of this title), the amounts paid shall be the amounts described in section 1395m(h)(1) of this title, (N) with respect to expenses incurred for physicians' services (as defined in section 1395w–4(j)(3) of this title) other than personalized prevention plan services (as defined in section 1395x(hhh)(1) of this title), the amounts paid shall be 80 percent of the payment basis determined under section 1395w–4(a)(1) of

this title, (O) with respect to services described in section 1395x(s)(2)(K) of this title (relating to services furnished by physician assistants, nurse practitioners, or clinic nurse specialists), the amounts paid shall be equal to 80 percent of (i) the lesser of the actual charge or 85 percent of the fee schedule amount provided under section 1395w–4 of this title, or (ii) in the case of services as an assistant at surgery, the lesser of the actual charge or 85 percent of the amount that would otherwise be recognized if performed by a physician who is serving as an assistant at surgery, (P) with respect to surgical dressings, the amounts paid shall be the amounts determined under section 1395m(i) of this title, (Q) with respect to items or services for which fee schedules are established pursuant to section 1395u(s) of this title, the amounts paid shall be 80 percent of the lesser of the actual charge or the fee schedule established in such section, (R) with respect to ambulance services, (i) the amounts paid shall be 80 percent of the lesser of the actual charge for the services or the amount determined by a fee schedule established by the Secretary under section 1395m(*l*) of this title and (ii) with respect to ambulance services described in section 1395m(*l*)(8) of this title, the amounts paid shall be the amounts determined under section 1395m(g) of this title for outpatient critical access hospital services, (S) with respect to drugs and biologicals (including intravenous immune globulin (as defined in section 1395x(zz) of this title)) not paid on a cost or prospective payment basis as otherwise provided in this part

(other than items and services described in subparagraph (B)), the amounts paid shall be 80 percent of the lesser of the actual charge or the payment amount established in section 1395u(*o*) of this title (or, if applicable, under section 1395w–3, 1395w–3a, or 1395w–3b of this title), (T) with respect to medical nutrition therapy services (as defined in section 1395x(vv) of this title), the amount paid shall be 80 percent (or 100 percent if such services are recommended with a grade of A or B by the United States Preventive Services Task Force for any indication or population and are appropriate for the individual) of the lesser of the actual charge for the services or 85 percent of the amount determined under the fee schedule established under section 1395w–4(b) of this title for the same services if furnished by a physician, (U) with respect to facility fees described in section 1395m(m)(2)(B) of this title, the amounts paid shall be 80 percent of the lesser of the actual charge or the amounts specified in such section, (V) notwithstanding subparagraphs (I) (relating to durable medical equipment), (M) (relating to prosthetic devices and orthotics and prosthetics), and (Q) (relating to 1395u(s) items), with respect to competitively priced items and services (described in section 1395w–3(a)(2) of this title) that are furnished in a competitive area, the amounts paid shall be the amounts described in section 1395w–3(b)(5) of this title, (W) with respect to additional preventive services (as defined in section 1395x(ddd)(1) of this title), the amount paid shall be (i) in the case of such

services which are clinical diagnostic laboratory tests, the amount determined under subparagraph (D) (if such subparagraph were applied, by substituting "100 percent" for "80 percent"), and (ii) in the case of all other such services, 100 percent of the lesser of the actual charge for the service or the amount determined under a fee schedule established by the Secretary for purposes of this subparagraph, (X) with respect to personalized prevention plan services (as defined in section 1395x(hhh)(1) of this title), the amount paid shall be 100 percent of the lesser of the actual charge for the services or the amount determined under the payment basis determined under section 1395w–4 of this title, (Y) with respect to preventive services described in subparagraphs (A) and (B) of section 1395x(ddd)(3) of this title that are appropriate for the individual and, in the case of such services described in subparagraph (A), are recommended with a grade of A or B by the United States Preventive Services Task Force for any indication or population, the amount paid shall be 100 percent of (i) except as provided in clause (ii), the lesser of the actual charge for the services or the amount determined under the fee schedule that applies to such services under this part, and (ii) in the case of such services that are covered OPD services (as defined in subsection (t)(1)(B)), the amount determined under subsection (t), and (Z) with respect to Federally qualified health center services for which payment is made under section 1395m(*o*) of this title, the amounts paid shall be 80 percent of the

lesser of the actual charge or the amount determined under such section

42 U.S.C. §1395w-3a

(a) Establishment of competitive acquisition programs

(1) Implementation of programs

(A) In general

The Secretary shall establish and implement programs under which competitive acquisition areas are established throughout the United States for contract award purposes for the furnishing under this part of competitively priced items and services (described in paragraph (2)) for which payment is made under this part. Such areas may differ for different items and services.

(B) Phased-in implementation

The programs—

(i) shall be phased in among competitive acquisition areas in a manner consistent with subparagraph (D) so that the competition under the programs occurs in—

(I) 10 of the largest metropolitan statistical areas in 2007;

(II) an additional 91 of the largest metropolitan statistical areas in 2011; and

(III) additional areas after 2011 (or, in the case of national mail order for items and services, after 2010); and

(ii) may be phased in first among the highest cost and highest volume items and services or those items and services that the Secretary determines have the largest savings potential.

(C) Waiver of certain provisions

In carrying out the programs, the Secretary may waive such provisions of the Federal Acquisition Regulation as are necessary for the efficient implementation of this section, other than provisions relating to confidentiality of information and such other provisions as the Secretary determines appropriate.

(D) Changes in competitive acquisition programs

(i) Round 1 of competitive acquisition program

Notwithstanding subparagraph (B)(i)(I) and in implementing the first round of the competitive acquisition programs under this section—

(I) the contracts awarded under this section before July 15, 2008, are terminated, no payment shall be made under this subchapter on or after July 15, 2008, based on such a contract, and, to the extent that any damages may be applicable as a result of the termination of such contracts, such damages shall be payable from the Federal Supplementary Medical

Insurance Trust Fund under section 1395t of this title;

(II) the Secretary shall conduct the competition for such round in a manner so that it occurs in 2009 with respect to the same items and services and the same areas, except as provided in subclauses (III) and (IV);

(III) the Secretary shall exclude Puerto Rico so that such round of competition covers 9, instead of 10, of the largest metropolitan statistical areas; and

(IV) there shall be excluded negative pressure wound therapy items and services.

Nothing in subclause (I) shall be construed to provide an independent cause of action or right to administrative or judicial review with regard to the termination provided under such subclause.

(ii) Round 2 of competitive acquisition program

In implementing the second round of the competitive acquisition programs under this section described in subparagraph (B)(i)(II)—

(I) the metropolitan statistical areas to be included shall be those metropolitan statistical areas selected

by the Secretary for such round as of June 1, 2008;

(II) the Secretary shall include the next 21 largest metropolitan statistical areas by total population (after those selected under subclause (I)) for such round; and

(III) the Secretary may subdivide metropolitan statistical areas with populations (based upon the most recent data from the Census Bureau) of at least 8,000,000 into separate areas for competitive acquisition purposes.

(iii) Exclusion of certain areas in subsequent rounds of competitive acquisition programs

In implementing subsequent rounds of the competitive acquisition programs under this section, including under subparagraph (B)(i)(III), for competitions occurring before 2015, the Secretary shall exempt from the competitive acquisition program (other than national mail order) the following:

(I) Rural areas.

(II) Metropolitan statistical areas not selected under round 1 or round 2 with a population of less than 250,000.

(III) Areas with a low population density within a metropolitan statistical area that is otherwise

selected, as determined for purposes of paragraph (3)(A).

(E) Verification by OIG

The Inspector General of the Department of Health and Human Services shall, through post-award audit, survey, or otherwise, assess the process used by the Centers for Medicare & Medicaid Services to conduct competitive bidding and subsequent pricing determinations under this section that are the basis for pivotal bid amounts and single payment amounts for items and services in competitive bidding areas under rounds 1 and 2 of the competitive acquisition programs under this section and may continue to verify such calculations for subsequent rounds of such programs.

(F) Supplier feedback on missing financial documentation

(i) In general

In the case of a bid where one or more covered documents in connection with such bid have been submitted not later than the covered document review date specified in clause (ii), the Secretary—

(I) shall provide, by not later than 45 days (in the case of the first round of the competitive acquisition programs as described in subparagraph (B)(i)(I)) or 90 days (in the case of a subsequent round of such programs) after the

covered document review date, for notice to the bidder of all such documents that are missing as of the covered document review date; and

(II) may not reject the bid on the basis that any covered document is missing or has not been submitted on a timely basis, if all such missing documents identified in the notice provided to the bidder under subclause (I) are submitted to the Secretary not later than 10 business days after the date of such notice.

(ii) Covered document review date

The covered document review date specified in this clause with respect to a competitive acquisition program is the later of—

(I) the date that is 30 days before the final date specified by the Secretary for submission of bids under such program; or

(II) the date that is 30 days after the first date specified by the Secretary for submission of bids under such program.

(iii) Limitations of process

The process provided under this subparagraph—

(I) applies only to the timely submission of covered documents;

(II) does not apply to any determination as to the accuracy or completeness of covered documents submitted or whether such documents meet applicable requirements;

(III) shall not prevent the Secretary from rejecting a bid based on any basis not described in clause (i)(II); and

(IV) shall not be construed as permitting a bidder to change bidding amounts or to make other changes in a bid submission.

(iv) Covered document defined

In this subparagraph, the term "covered document" means a financial, tax, or other document required to be submitted by a bidder as part of an original bid submission under a competitive acquisition program in order to meet required financial standards. Such term does not include other documents, such as the bid itself or accreditation documentation.

(2) Items and services described

The items and services referred to in paragraph (1) are the following:

(A) Durable medical equipment and medical supplies

Covered items (as defined in section 1395m(a)(13) of this title) for which payment would otherwise be made under section 1395m(a) of this title, including items used

in infusion and drugs (other than inhalation drugs) and supplies used in conjunction with durable medical equipment, but excluding class III devices under the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.] and excluding certain complex rehabilitative power wheelchairs recognized by the Secretary as classified within group 3 or higher (and related accessories when furnished in connection with such wheelchairs).

(B) Other equipment and supplies

Items and services described in section 1395u(s)(2)(D) of this title, other than parenteral nutrients, equipment, and supplies.

(C) Off-the-shelf orthotics

Orthotics described in section 1395x(s)(9) of this title for which payment would otherwise be made under section 1395m(h) of this title which require minimal self-adjustment for appropriate use and do not require expertise in trimming, bending, molding, assembling, or customizing to fit to the individual.

(3) Exception authority

In carrying out the programs under this section, the Secretary may exempt—

(A) rural areas and areas with low population density within urban areas that are not competitive, unless there is a

significant national market through mail order for a particular item or service; and

(B) items and services for which the application of competitive acquisition is not likely to result in significant savings.

(4) Special rule for certain rented items of durable medical equipment and oxygen

In the case of a covered item for which payment is made on a rental basis under section 1395m(a) of this title and in the case of payment for oxygen under section 1395m(a)(5) of this title, the Secretary shall establish a process by which rental agreements for the covered items and supply arrangements with oxygen suppliers entered into before the application of the competitive acquisition program under this section for the item may be continued notwithstanding this section. In the case of any such continuation, the supplier involved shall provide for appropriate servicing and replacement, as required under section 1395m(a) of this title.

(5) Physician authorization

(A) In general

With respect to items or services included within a particular HCPCS code, the Secretary may establish a process for certain items and services under which a physician may prescribe a particular brand or mode of delivery of an item or service within such code if the physician determines that use of the particular item or service

would avoid an adverse medical outcome on the individual, as determined by the Secretary.

(B) No effect on payment amount

A prescription under subparagraph (A) shall not affect the amount of payment otherwise applicable for the item or service under the code involved.

(6) Application

For each competitive acquisition area in which the program is implemented under this subsection with respect to items and services, the payment basis determined under the competition conducted under subsection (b) of this section shall be substituted for the payment basis otherwise applied under section 1395m(a) of this title, section 1395m(h) of this title, or section 1395u(s) of this title, as appropriate.

(7) Exemption from competitive acquisition

The programs under this section shall not apply to the following:

(A) Certain off-the-shelf orthotics

Items and services described in paragraph (2)(C) if furnished—

(i) by a physician or other practitioner (as defined by the Secretary) to the physician's or practitioner's own patients as part of the physician's or practitioner's professional service; or

(ii) by a hospital to the hospital's own patients during an admission or on the date of discharge.

(B) Certain durable medical equipment

Those items and services described in paragraph (2)(A)—

(i) that are furnished by a hospital to the hospital's own patients during an admission or on the date of discharge; and

(ii) to which such programs would not apply, as specified by the Secretary, if furnished by a physician to the physician's own patients as part of the physician's professional service.

42 U.S.C. §1395y(a)

(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—

(1)(A) which, except for items and services described in a succeeding subparagraph or additional preventive services (as described in section 1395x(ddd)(1) of this title), are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member,

(B) in the case of items and services described in section 1395x(s)(10) of this title,

which are not reasonable and necessary for the prevention of illness,

(C) in the case of hospice care, which are not reasonable and necessary for the palliation or management of terminal illness,

(D) in the case of clinical care items and services provided with the concurrence of the Secretary and with respect to research and experimentation conducted by, or under contract with, the Medicare Payment Advisory Commission or the Secretary, which are not reasonable and necessary to carry out the purposes of section 1395ww(e)(6) of this title,

(E) in the case of research conducted pursuant to section 1320b–12 of this title, which is not reasonable and necessary to carry out the purposes of that section,

(F) in the case of screening mammography, which is performed more frequently than is covered under section 1395m(c)(2) of this title or which is not conducted by a facility described in section 1395m(c)(1)(B) of this title, in the case of screening pap smear and screening pelvic exam, which is performed more frequently than is provided under section 1395x(nn) of this title, and, in the case of screening for glaucoma, which is performed more frequently than is provided under section 1395x(uu) of this title,

(G) in the case of prostate cancer screening tests (as defined in section 1395x(*oo*) of this

title), which are performed more frequently than is covered under such section,

(H) in the case of colorectal cancer screening tests, which are performed more frequently than is covered under section 1395m(d) of this title,

(I) the frequency and duration of home health services which are in excess of normative guidelines that the Secretary shall establish by regulation,

(J) in the case of a drug or biological specified in section 1395w–3a(c)(6)(C) of this title for which payment is made under part B of this subchapter that is furnished in a competitive area under section 1395w–3b of this title, that is not furnished by an entity under a contract under such section,

(K) in the case of an initial preventive physical examination, which is performed more than 1 year after the date the individual's first coverage period begins under part B of this subchapter,

(L) in the case of cardiovascular screening blood tests (as defined in section 1395x(xx)(1) of this title), which are performed more frequently than is covered under section 1395x(xx)(2) of this title,

(M) in the case of a diabetes screening test (as defined in section 1395x(yy)(1) of this title), which is performed more frequently than is covered under section 1395x(yy)(3) of this title,

(N) in the case of ultrasound screening for abdominal aortic aneurysm which is performed more frequently than is provided for under section 1395x(s)(2)(AA) of this title,

(O) in the case of kidney disease education services (as defined in paragraph (1) of section 1395x(ggg) of this title), which are furnished in excess of the number of sessions covered under paragraph (4) of such section, and

(P) in the case of personalized prevention plan services (as defined in section 1395x(hhh)(1) of this title), which are performed more frequently than is covered under such section;

(2) for which the individual furnished such items or services has no legal obligation to pay, and which no other person (by reason of such individual's membership in a prepayment plan or otherwise) has a legal obligation to provide or pay for, except in the case of Federally qualified health center services;

(3) which are paid for directly or indirectly by a governmental entity (other than under this chapter and other than under a health benefits or insurance plan established for employees of such an entity), except in the case of rural health clinic services, as defined in section 1395x(aa)(1) of this title, in the case of Federally qualified health center services, as defined in section 1395x(aa)(3) of this title, in the case of services for which payment may be made under section

1395qq(e) of this title, and in such other cases as the Secretary may specify;

(4) which are not provided within the United States (except for inpatient hospital services furnished outside the United States under the conditions described in section 1395f(f) of this title and, subject to such conditions, limitations, and requirements as are provided under or pursuant to this subchapter, physicians' services and ambulance services furnished an individual in conjunction with such inpatient hospital services but only for the period during which such inpatient hospital services were furnished);

(5) which are required as a result of war, or of an act of war, occurring after the effective date of such individual's current coverage under such part;

(6) which constitute personal comfort items (except, in the case of hospice care, as is otherwise permitted under paragraph (1)(C));

(7) where such expenses are for routine physical checkups, eyeglasses (other than eyewear described in section 1395x(s)(8) of this title) or eye examinations for the purpose of prescribing, fitting, or changing eyeglasses, procedures performed (during the course of any eye examination) to determine the refractive state of the eyes, hearing aids or examinations therefor, or immunizations (except as otherwise allowed under section 1395x(s)(10) of this title and subparagraph (B), (F), (G), (H), (K), or (P) of paragraph (1));

(8) where such expenses are for orthopedic shoes or other supportive devices for the feet, other than shoes furnished pursuant to section 1395x(s)(12) of this title;

(9) where such expenses are for custodial care (except, in the case of hospice care, as is otherwise permitted under paragraph (1)(C));

(10) where such expenses are for cosmetic surgery or are incurred in connection therewith, except as required for the prompt repair of accidental injury or for improvement of the functioning of a malformed body member;

(11) where such expenses constitute charges imposed by immediate relatives of such individual or members of his household;

(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;

(13) where such expenses are for—

(A) the treatment of flat foot conditions and the prescription of supportive devices therefor,

(B) the treatment of subluxations of the foot, or

(C) routine foot care (including the cutting or removal of corns or calluses, the trimming of nails, and other routine hygienic care);

(14) which are other than physicians' services (as defined in regulations promulgated specifically for purposes of this paragraph), services described by section 1395x(s)(2)(K) of this title, certified nurse-midwife services, qualified psychologist services, and services of a certified registered nurse anesthetist, and which are furnished to an individual who is a patient of a hospital or critical access hospital by an entity other than the hospital or critical access hospital, unless the services are furnished under arrangements (as defined in section 1395x(w)(1) of this title) with the entity made by the hospital or critical access hospital;

(15)(A) which are for services of an assistant at surgery in a cataract operation (including subsequent insertion of an intraocular lens) unless, before the surgery is performed, the appropriate quality improvement organization (under part B of subchapter XI of this chapter) or a carrier under section 1395u of this title has approved of the use of such an assistant in the surgical procedure based on the existence of a complicating medical condition, or

(B) which are for services of an assistant at surgery to which section 1395w–4(i)(2)(B) of this title applies;

(16) in the case in which funds may not be used for such items and services under the Assisted Suicide Funding Restriction Act of 1997 [42 U.S.C. 14401 et seq.];

(17) where the expenses are for an item or service furnished in a competitive acquisition area (as established by the Secretary under section 1395w–3(a) of this title) by an entity other than an entity with which the Secretary has entered into a contract under section 1395w–3(b) of this title for the furnishing of such an item or service in that area, unless the Secretary finds that the expenses were incurred in a case of urgent need, or in other circumstances specified by the Secretary;

(18) which are covered skilled nursing facility services described in section 1395yy(e)(2)(A)(i) of this title and which are furnished to an individual who is a resident of a skilled nursing facility during a period in which the resident is provided covered post-hospital extended care services (or, for services described in section 1395x(s)(2)(D) of this title, which are furnished to such an individual without regard to such period), by an entity other than the skilled nursing facility, unless the services are furnished under arrangements (as defined in section 1395x(w)(1) of this title) with the entity made by the skilled nursing facility;

(19) which are for items or services which are furnished pursuant to a private contract described in section 1395a(b) of this title;

(20) in the case of outpatient physical therapy services, outpatient speech-language pathology services, or outpatient occupational therapy services furnished as an incident to a physician's professional services (as described in section 1395x(s)(2)(A) of this title), that do not meet the standards and conditions (other than any licensing requirement specified by the Secretary) under the second sentence of section 1395x(p) of this title (or under such sentence through the operation of subsection (g) or (*ll*)(2) of section 1395x of this title) as such standards and conditions would apply to such therapy services if furnished by a therapist;

(21) where such expenses are for home health services (including medical supplies described in section 1395x(m)(5) of this title, but excluding durable medical equipment to the extent provided for in such section) furnished to an individual who is under a plan of care of the home health agency if the claim for payment for such services is not submitted by the agency;

(22) subject to subsection (h) of this section, for which a claim is submitted other than in an electronic form specified by the Secretary;

(23) which are the technical component of advanced diagnostic imaging services described in section 1395m(e)(1)(B) of this title for which payment is made under the fee schedule established under section 1395w–4(b) of this title and that are furnished by a supplier (as defined in section 1395x(d) of this title), if such supplier is not accredited by an accreditation organization

designated by the Secretary under section 1395m(e)(2)(B) of this title;

(24) where such expenses are for renal dialysis services (as defined in subparagraph (B) of section 1395rr(b)(14) of this title) for which payment is made under such section unless such payment is made under such section to a provider of services or a renal dialysis facility for such services; or

(25) not later than January 1, 2014, for which the payment is other than by electronic funds transfer (EFT) or an electronic remittance in a form as specified in ASC X12 835 Health Care Payment and Remittance Advice or subsequent standard.

Paragraph (7) shall not apply to Federally qualified health center services described in section 1395x(aa)(3)(B) of this title. In making a national coverage determination (as defined in paragraph (1)(B) of section 1395ff(f) of this title) the Secretary shall ensure consistent with subsection (*l*) of this section that the public is afforded notice and opportunity to comment prior to implementation by the Secretary of the determination; meetings of advisory committees with respect to the determination are made on the record; in making the determination, the Secretary has considered applicable information (including clinical experience and medical, technical, and scientific evidence) with respect to the subject matter of the determination; and in the determination, provide a clear statement of the basis for the determination (including responses to comments received from the public), the

assumptions underlying that basis, and make available to the public the data (other than proprietary data) considered in making the determination.

42 C.F.R. §414.904

(a) Method of payment. Payment for a drug furnished on or after January 1, 2005 is based on the lesser of—

(1) The actual charge on the claim for program benefits; or

(2) 106 percent of the average sales price, subject to the applicable limitations specified in paragraph (d) of this section or subject to the exceptions described in paragraph (e) of this section.

(3) For purposes of this paragraph—

(i) CMS calculates an average sales price payment limit based on the amount of product included in a vial or other container as reflected on the FDA-approved label.

(ii) Additional product contained in the vial or other container does not represent a cost to providers and is not incorporated into the ASP payment limit.

(iii) No payment is made for amounts of product in excess of that reflected on the FDA-approved label.

(b) Multiple source drugs—

(1) Average sales prices. The average sales price for all drug products included within the same multiple source drug billing and payment code is

the volume-weighted average of the manufacturers' average sales prices for those drug products.

(2) Calculation of the average sales price.

(i) For dates of service before April 1, 2008, the average sales price is determined by—

(A) Computing the sum of the products (for each National Drug Code assigned to the drug products) of the manufacturer's average sales price and the total number of units sold; and

(B) Dividing that sum by the sum of the total number of units sold for all NDCs assigned to the drug products.

(ii) For dates of service on or after April 1, 2008, the average sales price is determined by—

(A) Computing the sum of the products (for each National Drug Code assigned to such drug products) of the manufacturer's average sales price, determined by the Secretary without dividing such price by the total number of billing units for the National Drug Code for the billing and payment code and the total number of units sold; and

(B) Dividing the sum determined under clause (A) by the sum of the products (for each National Drug Code assigned to such drug products) of the total number of units sold and the total number of

billing units for the National Drug Code for the billing and payment code.

(iii) For purposes of this subsection and subsection (c), the term billing unit means the identifiable quantity associated with a billing and payment code, as established by CMS.

(c) Single source drugs—

(1) Average sales price. The average sales price is the volume-weighted average of the manufacturers' average sales prices for all National Drug Codes assigned to the drug or biological product.

(2) Calculation of the average sales price.

(i) For dates of service before April 1, 2008, the average sales price is determined by—

(A) Computing the sum of the products (for each National Drug Code assigned to the drug product) of the manufacturer's average sales price and the total number of units sold; and

(B) Dividing that sum by the sum of the total number of units sold for all NDCs assigned to the drug product.

(ii) For dates of service on or after April 1, 2008, the average sales price is determined by—

(A) Computing the sum of the products (for each National Drug Code assigned to such drug products) of the manufacturer's average sales price,

determined by the Secretary without dividing such price by the total number of billing units for the National Drug Code for the billing and payment code and the total number of units sold; and

(B) Dividing the sum determined under clause (A) by the sum of the products (for each National Drug Code assigned to such drug products) of the total number of units sold and the total number of billing units for the National Drug Code for the billing and payment code.

(d) Limitations on the average sales price—

(1) Wholesale acquisition cost for a single source drug. The payment limit for a single source drug product is the lesser of 106 percent of the average sales price for the product or 106 percent of the wholesale acquisition cost for the product.

(2) Payment limit for a drug furnished to an end-stage renal disease patient.

(i) Effective for drugs and biologicals furnished in 2005, the payment for such drugs and biologicals, including erythropoietin, furnished to an end-stage renal disease patient that is separately billed by an end-stage renal disease facility and not paid on a cost basis is acquisition cost as determined by the Inspector General report as required by section 623(c) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 inflated by the percentage increase in the Producer Price Index.

(ii) Except as provided in paragraph (a) of this section, the payment for drugs and biologicals, furnished to an end-stage renal disease patient that is separately billed by an end-stage renal disease facility, is based on 106 percent of the average sales price.

(iii) Effective for drugs and biologicals furnished in CY 2006 and subsequent calendar years, the payment for such drugs and biologicals furnished in connection with renal dialysis services and separately billed by freestanding and hospital-based renal dialysis facilities not paid on a cost basis is the amount determined under section 1847A of the Act.

(3) Widely available market price and average manufacturer price. If the Inspector General finds that the average sales price exceeds the widely available market price or the average manufacturer price by the applicable threshold percentage specified in paragraph (d)(3)(iii) or (iv) of this section, the Inspector General is responsible for informing the Secretary (at such times as specified by the Secretary) and the payment amount for the drug or biological will be substituted subject to the following adjustments:

(i) The payment amount substitution will be applied at the next average sales price payment amount calculation period after the Inspector General informs the Secretary (at such times specified by the Secretary) about billing codes for which the average sales price has exceeded the average

manufacturer price by the applicable threshold percentage, and will remain in effect for 1 quarter after publication.

(ii) Payment at 103 percent of the average manufacturer price for a billing code will be applied at such times when all of the following criteria are met:

(A) The threshold for making price substitutions, as defined in paragraph (d)(3)(iii) of this section is met.

(B) 103 percent of the average manufacturer price is less than the 106 percent of the average sales price for the quarter in which the substitution would be applied.

(C) Beginning in 2013, the drug and dosage form described by the HCPCS code is not identified by the FDA to be in short supply at the time that ASP calculations are finalized.

(iii) The applicable percentage threshold for average manufacturer price comparisons is 5 percent and is reached when—

(A) The average sales price for the billing code has exceeded the average manufacturer price for the billing code by 5 percent or more in 2 consecutive quarters, or 3 of the previous 4 quarters immediately preceding the quarter to which the price substitution would be applied; and

(B) The average manufacturer price for the billing code is calculated using the same set of National Drug Codes used for the average sales price for the billing code.

(iv) The applicable percentage threshold for widely available market price comparisons is 5 percent.

(e) Exceptions to the average sales price—

(1) Vaccines. The payment limits for hepatitis B vaccine furnished to individuals at high or intermediate risk of contracting hepatitis B (as determined by the Secretary), pneumococcal vaccine, and influenza vaccine and are calculated using 95 percent of the average wholesale price.

(2) Infusion drugs furnished through a covered item of durable medical equipment. The payment limit for an infusion drug furnished through a covered item of durable medical equipment is calculated using 95 percent of the average wholesale price in effect on October 1, 2003 and is not updated in 2006.

(3) Blood and blood products. In the case of blood and blood products (other than blood clotting factors), the payment limits are determined in the same manner as the payment limits were determined on October 1, 2003.

(4) Payment limit in a case where the average sales price during the first quarter of sales is unavailable. In the case of a drug during an initial period (not to exceed a full calendar quarter) in which data on the prices for sales of

the drug are not sufficiently available from the manufacturer to compute an average sales price for the drug, the payment limit is based on the wholesale acquisition cost or the applicable Medicare Part B drug payment methodology in effect on November 1, 2003.

(5) Treatment of certain drugs. Beginning with April 1, 2008, the payment amount for—

(i) Each single source drug or biological described in section 1842(o)(1)(G) that is treated as a multiple source drug because of the application of section 1847A(c)(6)(C)(ii) is the lower of—

(A) The payment amount that would be determined for such drug or biological applying section 1847A(c)(6)(C)(ii); or

(B) The payment amount that would have been determined for such drug or biological if section 1847A(c)(6)(C)(ii) were not applied.

(ii) A multiple source drug described in section 1842(o)(1)(G) (excluding a drug or biological that is treated as a multiple source drug because of the application of section 1847A(c)(6)(C)(ii)) is the lower of—

(A) The payment amount that would be determined for such drug or biological taking into account the application of section 1847A(c)(6)(C)(ii); or

(B) The payment amount that would have been determined for such drug or

biological if section 1847A(c)(6)(C)(ii) were not applied.

(f) Except as otherwise specified (see paragraph (e)(2) of this section) for infusion drugs, the payment limits are updated quarterly.

(g) The payment limit is computed without regard to any special packaging, labeling, or identifiers on the dosage form or product or package.

(h) The payment amount is subject to applicable deductible and coinsurance.

(i) If manufacturer ASP data is not available prior to the publication deadline for quarterly payment limits and the unavailability of manufacturer ASP data significantly changes the quarterly payment limit for the billing code when compared to the prior quarter's billing code payment limit, the payment limit is calculated by carrying over the most recent available manufacturer ASP price from a previous quarter for an NDC in the billing code, adjusted by the weighted average of the change in the manufacturer ASPs for the NDCs that were reported for both the most recently available previous quarter and the current quarter.

(j) Biosimilar biological products. Effective January 1, 2016, the payment amount for a biosimilar biological drug product (as defined in § 414.902) for all NDCs assigned to such product is the sum of the average sales price of all NDCs assigned to the biosimilar biological products included within the same billing and payment code as determined under section 1847A(b)(6) of the Act and 6 percent of the amount determined under section 1847A(b)(4) of

the Act for the reference drug product (as defined in § 414.902).