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<b>NATIONAL ASSOCIATION FOR</b>	)	
<b>HOME CARE &amp; HOSPICE, INC.</b>	)	
	)	
<b>Plaintiff,</b>	)	
	)	
<b>v.</b>	)	<b>Case No. 1:14-CV-950 (CRC)</b>
	)	
<b>SYLVIA MATHEWS BURWELL, in her</b>	)	
<b>official capacity as Secretary of the</b>	)	
<b>United States Department of Health and</b>	)	
<b>Human Services, et al.,</b>	)	
	)	
<b>Defendants</b>	)	
	)	

## I. INTRODUCTION

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meet Medicare coverage standards. This additional requirement is not authorized under the Medicare statute.

The Defendants' challenged rule has led to the wholesale and improper denial of Medicare coverage for services to beneficiaries who otherwise meet the longstanding standards for payment. The challenged rule wrongly triggers the denial of Medicare payment based upon a review of the sufficiency of the physician narrative alone even where the full patient record demonstrates that the beneficiary is entitled to Medicare coverage. In other words, an allegedly "insufficient" physician narrative triggers a total denial of Medicare where the beneficiary's full clinical record demonstrates that coverage standards have been met.

Defendants' argument that the statute permits the discretion to broadly define "document" to include a requirement that the patient's physician explain "why" the patient meets Medicare coverage standards ignores the clear statutory language setting out the parameters of permitted physician documentation. Further, explaining why a physician believes a patient meets Medicare coverage standards is not documenting, it is a physician opining.

The law focuses solely on physician documentation of "what" occurred, not "why" the physician opines that a patient meets Medicare coverage standards. Compliance with the specific statutory documentation directive permits the claim determination process to be based on the whole patient record. Only through full record reviews do Medicare beneficiaries and their providers of home health services receive the fair consideration of the claim for payment intended by Congress. Only through that full review can Medicare avoid a payment denial that is in conflict with the true clinical condition and needs of the home health patient.

Defendants' illegal rule creates that conflict. Summary Judgment in plaintiff's favor achieves the ends intended by Congress and restores full record reviews in Medicare home health claim determinations.

Defendant's tortured reading of the authorizing statute leads to a result that is the opposite of what Congress intended. Instead of helping to prevent overutilization in the home health benefit by requiring that a physician have a face-to-face encounter with his/her patient, the Defendants' implementation leads to wrongful denial of Medicare coverage to individuals truly meeting Medicare coverage standards. As such, Defendants' rule violates the plain language of the law or is otherwise an arbitrary and capricious interpretation of it.

## **II. BACKGROUND**

This matter concerns the validity and application of a rule issued in 2011, implementing section 6407 of the Patient Protection and Affordable Care Act (hereinafter "ACA"). Section 6407 requires a Medicare beneficiary receiving home health services to have a face-to-face encounter with a physician in order to qualify for Medicare coverage of home health services.

The Defendants implemented a simple and understandable statutory requirement for documenting a physician/patient encounter by adding a complex, unnecessary, and unauthorized requirement. Specifically, Section 6407 simply requires that "the physician must document that the physician himself or herself... has had a face-to-face encounter with the individual within a reasonable timeframe as determined by the Secretary."

In rulemaking, the Defendants added an unauthorized, burdensome, and wholly confusing requirement. Under 42 CFR 424.22(a)(1)(v), the Defendants also require that the physician

“must document that the face-to-face patient encounter...has occurred...**and** including an explanation of why the clinical findings of such encounter support that the patient is homebound and in need of either intermittent skilled nursing services or therapy services as defined in Sec. 409.42(a) and (c) of this chapter, respectively.” (emphasis added)

The added “explanation” is administered by the Defendants in the form of a narrative statement from the physician. If a claim for home health services payment does not have a “sufficient” narrative, the claim is denied payment by Medicare. A claim may include a narrative, but if it is “insufficient” a full claim denial is issued irrespective of whether the entire patient care record supports a grant of coverage.

These payment denials have occurred in the tens of thousands in recent months with the Defendants’ auditing of 2011 and later claims on a post-payment basis. It is notable that even though it is the home health agency that faces the liability for cost of a noncompliant physician narrative statement, the home health agency cannot compose or participate in the composition of the statement. 42 CFR 424.22; CMS IOM 100-02 Section 30.5.1.1

<http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c07.pdf>.

To compound the difficulties attendant to the unauthorized physician narrative requirement, the Defendants have also devised and administered the requirement in a manner that renders it nearly impossible to achieve compliance as its application is wholly confusing to physicians, home health agencies, and patients along with Medicare administrative contractors. This has led the contractors to evaluate claims in a manner that is inconsistent, arbitrary, and inaccurate. Ultimately, the unauthorized and confusing narrative requirement has resulted in retroactive claim denials on claims where the overall health care record of the

patient establishes that the patient is, in fact, homebound and in need of skilled care consistent with 42 CFR 409.42.

This saga began almost immediately following the 2010 passage of the ACA. Plaintiff and others conveyed concerns to Defendants and their staff about the validity and workability of the requirement for a physician's narrative as part of the face-to-face encounter requirements. To alleviate some of the concerns, the Defendants delayed the enforcement of the rule from January 1, 2011 to April 1, 2011. However, the problems with the rule and its application hit crisis levels in late 2013 and early 2014 as Defendants' contractors expanded the retroactive review of claims and issued tens of thousands of claim denials on the basis of an "insufficient" physician narrative.

On July 7, 2014 the Defendants issued a Notice of Proposed Rulemaking that addressed many, but not all, of the concerns expressed by Plaintiff in this litigation. 79 Fed. Reg. 38366 (July 7, 2014). Among other changes, the Defendants proposed to eliminate the physician narrative. In their proposed rulemaking, Defendants explained that:

The home health industry continues to voice concerns regarding the implementation of the Affordable Care Act face-to-face encounter documentation requirement. The home health industry cites challenges that HHAs face in meeting the face-to-face encounter documentation requirements regarding the required narrative, including a perceived lack of established standards for compliance that can be adequately understood and applied by the physicians and HHAs. In addition, the home health industry conveys frustration with having to rely on the

physician to satisfy the face-to-face encounter documentation requirements without incentives to encourage physician compliance. Correspondence received to date has expressed concern over the “extensive and redundant” narrative required by regulation for face-to-face encounter documentation purposes when detailed evidence to support the physician certification of homebound status and medical necessity is available in clinical records. In addition, correspondence stated that the narrative requirement was not explicit in the Affordable Care Act provision requiring a face-to-face encounter as part of the certification of eligibility and that a narrative requirement goes beyond Congressional intent. 79 Fed. Reg. at 38376.

As a result, the Defendants state: “Therefore, in an effort to simplify the face-to-face encounter regulations, reduce burden for HHAs and physicians, and to mitigate instances where physicians and HHAs unintentionally fail to comply with certification requirements,” ... “[t]he narrative requirement in regulation at 424.22(a)(1)(v) would be eliminated.” Id at 38776.

Defendants issued a Final Rule eliminating the physician narrative requirement effective January 1, 2015. 79 Fed. Reg. 66032 (November 6, 2014). However, despite the rescission of the rule, this matter remains a live controversy as the Defendants refuse to address the past harm that the rule and its administration have caused along with the potential of applying the rescinded narrative requirement in future claims reviews covering the April 1, 2011 to December 31, 2014 period and continue to defend it in this matter.

### **III. THE DEFENDANTS’ PHYSICIAN NARRATIVE RULE IS IN CONFLICT WITH THE AUTHORIZING STATUTE, 42 USC 1395f(a)(2)(C)**

The Defendants’ requirement that physicians both document that a face-to-face encounter occurred during the prescribed time period **and** provide as explanation as to why the patient meets Medicare homebound status and is in need of qualifying skilled nursing services or therapy is in direct conflict with the plain language of Medicare law and represents a vast overreach of the Defendants’ power to define physician documentation requirements related to the face-to-face encounter law. Therefore, under the analytic framework established by the U.S. Supreme Court in *Chevron U.S.A., Inc., v. Natural Res. Def. Council, Inc.*, 467 U.S. 837 (1984), the challenged rule is invalid. Further, that invalidity exists whether the rule is evaluated under the “plain language” standard known as Chevron Step 1 or under the “arbitrary and capricious” standard known as Chevron Step 2 analysis. Accordingly, Plaintiff respectfully asks this court to grant its Motion for Summary Judgment and deny the Defendants’ cross-motion.

#### **A. The Challenged Regulation Violates the Plain Language of Medicare Act**

A challenge to the agency’s construction of a statute that it administers is subject to the principles articulated in *Chevron U.S.A., Inc., v. Natural Res. Def. Council, Inc.*, 467 U.S. 837 (1984), which require this Court to employ a two-part inquiry. In assessing the validity of an agency’s interpretation of a statute, the court must first determine “whether Congress has directly spoken to the precise question at issue.” *Pharm. Research & Mfrs. of Am. v.*

*Thompson*, 251 F.3d 219, 223-24 (D.C. Cir. 2001), quoting *Chevron*, 467 U.S. at 842. If it has, “that is the end of the matter; for the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress.” *Id.*, quoting *Chevron*, 467 U.S. at 842-43. If, however, “the statute is silent or ambiguous with respect to the specific issue,” the Court should proceed to the second step of *Chevron* analysis, asking “whether the agency’s answer is based on a permissible construction of the statute.” *Id.* at 224, quoting *Chevron*, 467 U.S. at 843. In short, plaintiffs’ “burden is to show that the statute unambiguously supports its interpretation.” *Univ. of Tex. M.D. Anderson Cancer Ctr. v. Sebelius*, 650 F.3d 685, 690 (D.C. Cir. 2011) (emphasis in original). Federal agencies must interpret implementing legislation in a reasonable manner and may not promulgate rules that are arbitrary and capricious in substance or contrary to the authorizing statute. *United States v. Mead Corp.*, 533 U.S. 218, 227 (2001). The judiciary is the final authority on issues of statutory construction and must reject any construction that is at odds with clear congressional intent. *Chevron*, 467 U.S. at 843 n. 9.

Here, the court’s inquiry can end at Step 1. The statute establishing the Medicare requirement of a face-to-face physician encounter as a condition of payment for home health services does not permit the physician narrative that the Defendants require in their rule. Instead, the requirement in 42 CFR 424.22(a)(1)(v) that the physician provide a narrative explaining “why the clinical findings of such encounter support that the patient is homebound and in need of either intermittent skilled nursing care or therapy services” creates a wholly separate physician obligation distinct from the documentation prescribed and authorized by the plain language of the statute. In fact, that obligation is not one of documentation. Instead,

it is an obligation to compose an unique narrative as to the physician's opinion on a patient's eligibility for Medicare home health benefits along with the rationale for such an opinion.

The plain language of the statutory provision at issue does not permit the Defendants to demand this added element of a physician narrative composition as part of the singular requirement that the physician document that a timely face-to-face encounter with the patient has occurred. Defendants attempt to support adding such a problematic requirement on physicians by ignoring the ordinary meaning of the words within the statute, the basic concepts of grammar and sentence construction, the context of the provision within the statutory scheme of the Medicare program as a whole, and the relevant legislative history.

Section 6407 of the PPACA added the face-to-face physician encounter requirement, as an amendment to 42 U.S.C. 1395f(a)(2)(C). That amendment provides, in relevant part, that:

”in the case of a certification made by a physician after January 1, 2010, prior to making such certification the physician must document that the physician himself or herself, ...has had a face-to-face encounter... with the individual within a reasonable timeframe as determined by the Secretary,”

A similar provision is included under 42 U.S.C. 1395n(a)(2)(C) governing home health benefits under Medicare Part B. The only difference is that the Part B provision provides that the physician encounter occurred “during the 6-month period preceding such certification, or other reasonable timeframe as determined by the Secretary.” The Part B provision includes identical language relative to the documentation of the encounter.

The plain and clear statutory language limits the physician documentation responsibility to documenting that the encounter occurred within the Secretary's prescribed timeframe. It also limits the Defendants authority to fill any gap in the law to the timeframe allowed for the encounter. However, the Defendants rule (rescinded as of services beginning January 1, 2015) provided a second, additional requirement that is found nowhere in the authorizing statute.

In 42 CFR 424.22(a)(1)(v), the Defendants require that:

1. the physician document that the encountered occurred within a prescribed timeframe,  
**and**
2. the physician provide "an explanation of why the clinical findings of such encounter support that the patient is homebound and in need of either intermittent skilled nursing services or therapy services as defined in Sec. 409.42(a) and (c) of this chapter, respectively."

The additional "explanation" is otherwise known as the physician narrative. Defendants base their claim that the addition of the physician narrative is a reasonable interpretation of the word "document." *Defendants' Memorandum* at passim. Specifically, the Defendants claim that it is within the authority to define "document" relative to "why" an individual meets Medicare coverage standards.

However, that position is not rational. By isolating the word "document," the Defendants' position ignores crucial and controlling qualifying language that the documentation is limited to whether the physician "has had a face-to-face encounter... with the individual within a reasonable timeframe as determined by the Secretary." 42 USC

1395f(a)(2)(C). Also, the Defendant is not requiring the physician to document anything.

Instead, the Defendants are requiring that a physician create a unique composition setting out the physician's opinion and the rationale for such. Such a requirement is not consistent with the concept that a physician "document" something that has occurred let alone a requirement that a physician compose a narrative.

This unauthorized added narrative requirement is highlighted in the Defendants' own rule as it includes a conjunctive "and" between the requirements that the physician document that the encounter occurred and that the physician provide a narrative on homebound status and the need for skilled nursing or therapy services. Adding a condition in the regulations that is not contained in the statutory language creates a conflict that is inconsistent with the plain language of the statute. *St. Bernard's Hospital, Inc. v. Thompson*, 193 F.Supp.2d 1097 (E.D. AR. 2002). The plain language of the statute authorizes the first requirement (documentation that the encounter occurred), but not the second (the uniquely composed physician narrative reflecting his/her opinion on Medicare coverage eligibility).

The tools for statutory construction to be used in a step-one analysis in *Chevron* analysis "include examination of the statute's text, legislative history, and structure." *Bell Atl. Tel. Cos. V. FCC*, 131 F3d 1044, 1047 (D.C. Cir. 1997); *Southern Cal. Edison Co. v. FERC*, 116 F.d 507. 515 (D.C. Cir. 1997). The words are expected "to carry their ordinary, contemporary, common meaning." *Pioneer Inv. Servs. Co. v. Brunswick Assocs. L.P.*, 507 U.S. 380, 388 (1993). Here, the text of the statute unambiguously limits physician documentation to that which documents that the encounter occurred during the Secretary's prescribed time frame. Not only does that statutory text provide for a clear limit on the physician documentation, it also limits the Secretary's interpretative and discretionary

authority. That authority is strictly limited to defining the timeframe during which the encounter has occurred. No such authority is given to add further subjects that must be documented by the physician.

The proper interpretation of a statute starts with the words themselves used in the pertinent provision. That analysis proceeds with an evaluation of the sentence as a whole in which the word or words at issue appear. Finally, the interpretation is determined by examining the overall context of the pertinent provision. Under each of these steps, the plain language of Section 6407 of the PPACA, as codified in 42 USC.§1395f(a)(2)(C) and 1395n(a)(2)(C), supports only Plaintiff's interpretation—the physician narrative requirement in 42 CFR 424.22(a)(1)(v) is not permitted.

In the statutory provision, the word “document” is used as a verb. The Webster's Dictionary, <http://www.merriam-webster.com/dictionary/document>, defines the verb “document” as:

- “to create a record of (something) through writing, film, photography, etc.
- to prove (something) by using usually written evidence”

Here, the “something” is the face-to-face encounter. In contrast to the Defendants' view, it is not a “why,” it is a “what.” The sentence where “document” appears provides full illumination as to what the “something” is that the physician is required to document. It provides:

”in the case of a certification made by a physician after January 1, 2010, prior to making such certification the physician must document that the physician himself or herself, ...**has had a face-to-face encounter**... with the individual within a reasonable timeframe as determined by the Secretary,” (emphasis added)

With respect to what the physician must document, in this sentence “physician,” “document” is the verb, and the object is the “has had an encounter.” The word “must” qualifies the verb, “document” making the action mandatory. The matter to be documented is that the physician “has had an encounter” with the individual patient. In other words, the physician must document that the encounter occurred as is set out in the first part of Defendants’ implementing rule, 42 CFR 424.22(a)(1)(v). The only further qualification on the requirement is that the physician must that the encounter occurred within the timeframe prescribed by the Secretary. No where in that provision is there any reference at all to the the second part of the Defendants’ rule, the physician narrative of his/her opinion on coverage eligibility.

“[O]ne of the most basic interpretive canons [is] that [a] statute should be construed [to give effect] to all of its provisions, so that no part will be inoperative or superfluous, void or insignificant. “ See, *United States v. Mathis*, 660 F. Supp. 2d 27 (2009) (quoting *Corley v. United States*, 129 S. CT. 1558, 1560 (2009); See also, *TRW Inc. v. Andrews*, 534 U.S. 19, 31 (2001) (“it is a cardinal principle of statutory construction that a statute ought, upon the whole, to be construed that, if it can be prevented, no clause, sentence, or word shall be superfluous, void, or insignificant.”) (internal quotations omitted). Every word of the statutory provision must be effectuated to secure the appropriate construction. *North Broward Hospital d/b/a Broward General Medical Center, et al v. Shalala*, 997 F. Supp. 41 (D.C.D.C. 1998).

Here, the Defendants seek to place the word “document” in a silo in order to permit them to claim that the word is ambiguous and susceptible to countless and varied meanings in order to avoid a finding that the provision at issue is plain and ordinary in its composition and

construction. However, the word “document” must be read in combination with the words in the entire sentence. In doing so, it is clear that “a physician”...”must document” that he or she “has had a face-to-face encounter”...”with the individual within a reasonable timeframe as determined by the Secretary.” By removing the word “document” from the Defendants’ protective silo, the meaning of the whole provision becomes clear and obvious.

The sum total of the physician documentation responsibilities is that the patient encounter occurred within the prescribed timeframe. Anything more is beyond the statutory requirement. At no point does the language itself permit any additional documenting. More importantly, at no point does the provision permit a requirement that the physician compose a narrative on his/her opinion regarding the patient’s Medicare coverage status.

Interpreting the statutory provision is a simple exercise in defining words and diagramming sentence structure just as most students do in elementary school. In doing so, the clarity and absence of ambiguity in what the physician “must document” stands out. It is limited to documenting that the encounter occurred within the allowed timeframe.

The statutory structure overall provides crucial confirming insight as to the provision at issue. In context, the documenting of the physician’s face-to-face encounter with the patient is a piece in an elaborate program integrity structure. The same statutory provision also requires that the physician must present a written certification that the individual is homebound, under a plan of care established by the physician, and in need of intermittent skilled nursing services and/or physical therapy or speech language pathology. 42 USC 1395f(a)(2)(C) [Part A benefits]; 42 USC 1395n(a)(2)(A) [Part B benefits]. As such, Congress did not authorize the narrative requirement imposed by the Defendants as stronger program integrity provisions in the form of a physician certification already are in place.

That certification is a serious element of physician accountability and a tool to achieve program integrity. A false certification subjects the physician to a myriad of civil and criminal anti-fraud laws. Imprisonment is a certain risk in false certifications. See, e.g. 42 USC 1302 et seq. Congress was well aware of this protection of Medicare when enacting Section 6407 of the ACA. In that respect, Congress added a simple element to the physician certification—that a face-to-face encounter occur. It did not add the burdensome, confusing, and now discredited physician narrative requirement included in the Defendants’ original rule.<sup>1</sup>

Further, Medicare coverage decisions are based on the whole record review as the total condition of the patient must be considered in determining eligibility for payment. 42 CFR 409.40 et seq.

Also, Congress is well aware as to how it can require a physician face-to-face encounter for purposes of establishing Medicare coverage certification accountability. In the hospice benefit, under 42 USC 1395f(a)(7)(D)(i), a physician must certify that the patient is terminally ill and that “a hospice physician or nurse practitioner has a face-to-face encounter with the individual to determine continued eligibility of the individual for hospice care prior to the 180th-day recertification and each subsequent recertification under subparagraph (A)(ii) and attests that such visit took place (in accordance with procedures established by the Secretary). (emphasis added). The Secretary had previously required a physician narrative focused on the basis for certifying that the patient is terminally ill. 42 CFR 418.22(b)(3). The

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<sup>1</sup> Defendants argue that the narrative requirement presents the “best basis for determining truthfulness.” Memorandum at 11. However, this post-hoc rationalization is belied by the reality that the Defendants’ challenged policy puts partial patient information ahead of full facts about the patient. The physician narrative may present an abbreviated documentation that makes Medicare’s administration easier, but it does so at the expense of a comprehensive documentation review. Full content review is always a better manner of determining the truth, honesty or accuracy of a physician’s certification than a partial one. *Mackenzie Medical Supply, Inc. v. Leavitt*, 506 F.3d 341 (4<sup>th</sup> Cir. 2007) (Medicare medical equipment coverage better determined based on full record review rather than just the physician certificate of medical necessity)

2010 statutory amendment triggered a minor modification in the narrative requirement intended to assure that it was signed and dated. It is notable that the hospice face-to-face provision is structured wholly different from the home health provision which focuses on requiring an encounter rather than requiring the physician to explain the basis for the terminal illness prognosis of the patient.

Legislative history on the pertinent provision is sparse. The Senate Finance Committee *Chairman's Mark: America's Healthy Future Act* indicates that the purpose of the provision is focused on making sure the physician has some direct engagement with the patient before initiating home health services. However, the focus is not on the "why" the individual qualifies for home health services as argued by the Defendants. The report states:

"Additionally, as a condition of payment, physicians must have a face-to-face encounter with the patient before making a referral for home health..."

*See S. Comm.on Finance, Chairman's Mark: America's Healthy Future Act of 2009, at 190 (September 22, 2009).*<sup>2</sup>

This statement is fully consistent with Plaintiff's reading of the plain language of the authorizing provision in the statute. It is about whether the face-to-face encounter occurred. That is only what the law requires be documented.

Additional legislative history is further found in reports issued by two governmental bodies that routinely advise Congress on necessary changes to Medicare law and its administration.

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<sup>2</sup> Defendants' Memorandum incorrectly references the Chairman's Mark on page 9 of their Memorandum. The quoted portion pertains to what ultimately was enacted as Section 6406 of the Affordable Care Act regarding documentation of patient referrals rather than section 6407 which is at issue herein. Nonetheless, Plaintiff agrees that section 6407 was intended as a program integrity measure as well.

Both the Medicare Payment Advisory Commission (MedPAC) and the Office of Inspector General of the Department of Health and Human Services (OIG) regularly make recommendations to Congress on Medicare. In fact, prior to the passage of the ACA in 2010, both bodies addressed the issue of physician involvement with patients receiving Medicare home health services.

In a 1996 OIG report, “MEDICARE HOME HEALTH: Eliminating Fraud, Waste, and Abuse,” OEI-09-96-00290, California Operation Restore Trust Steering Committee, U.S. Department of Health and Human Services, July 1996, the OIG noted that the Medicare administration recommended that the certifying physician have an established relationship with patient prior to certification, that standards be set for the physician to see the patient under established time lines. <http://oig.hhs.gov/oei/reports/oei-09-96-00290.pdf>. The OIG focused on the encounter not on an elaboration of the physician’s opinion regarding the patient’s entitlement to Medicare coverage. *See also*, “The Physician’s Role in Medicare Home Health 2001”, <http://oig.hhs.gov/oei/reports/oei-02-00-00620.pdf>

The Medicare Payment Advisory Commission (MedPAC) also recommended a physician encounter, but did not recommend or suggest the use of a physician opinion narrative.. [http://www.medpac.gov/chapters/Mar09\\_Ch02E.pdf](http://www.medpac.gov/chapters/Mar09_Ch02E.pdf).

Defendants themselves had earlier indicated that a requirement for “direct” patient contact with the physician” was under consideration in 2008.

<http://www.gpo.gov/fdsys/pkg/FR-2008-07-07/html/E8-14949.htm>

It is notable that in no instance did the any federal agency or congressional advisory body indicate an interest in or desire for a physician narrative such as that at issue here. The

focus was simply on having the patient see the physician prior to the initiation of home health services, a focus directly consistent with the statute passed by Congress.

Accordingly, the plain language of section 6407 of the ACA, the overall context of physician certification contained in pre-existing law, and the legislative history of physician involvement in home health services consistently demonstrates that the physician face-to-face encounter and documentation that it occurred is the charge that Congress mandated in Section 6407. The Defendants' addition of a confusing, burdensome and unmanageable narrative requirement extended far beyond the scope of their authority.<sup>3</sup>

**B. The Defendants' Challenged Regulation Also Fails under Chevron Step 2 As It Is Unreasonable, Irrational, and Arbitrary and Capricious**

While the plain language of 42 USC 1395f(a)(2)(C) limits the nature and content of the documentation required to support compliance with the physician face-to-face requirements, the challenged rule also fails under the Chevron Step 2 test as it is unreasonable, arbitrary and capricious.

If the outcome of a rule is absurd, irrational, and unreasonable, the rule is considered arbitrary and capricious. *United States v. Ron Pair Enters, Inc.* 489 U.S. 235, 242 (1989); *Appleton v. First National Bank of Ohio*, 62 F.3d 791, 801 (6<sup>th</sup> Cir. 1995); *Walker v. Bain*.

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<sup>3</sup> It is highly notable that the production of a compliant physician narrative is well beyond the control of the patient's home health agency (HHA) while all liability for noncompliance rests with the HHA not the physician. An HHA can validate through objective evidence that a physician has had a timely patient encounter. The HHA cannot compose the required narrative or even determine if it is "sufficient" given the hazy guidance from the Defendants. As such, Congress could not have authorized an HHA to produce something it could not control.

257 F.3d 660, 667 (6<sup>th</sup> Cir. 2001); *Robbins v. Chronister*, 402 F.3d 1047, 1050 (10<sup>th</sup> Cir. 2005). Here, the rule results in Medicare contractors denying coverage and payment for services provided to patients who meet all substantive conditions for payment simply because the reviewer is not satisfied with the word choices and grammar used by the patient's physician in composing his or her supporting narrative.

One example highlights the absurdity of the narrative requirement as constructed and applied by Defendants. The patient's physician supplied a narrative that stated:

"The veteran never leaves his home or his bed. He is a total care patient who is dependent in all ADLs [Activities of Daily Living] and IADLs [Instrumental Activities of Daily Living]." *Complaint* Paragraph 38.

The Medicare contractor, in reviewing the whole record of the patient, concluded that,

"The skilled nursing visits were warranted based on the submitted documentation. The patient met homebound criteria and the skilled nursing visits were reasonable and necessary...However, the provided documentation does not support that a complete Face-to-Face evaluation was performed as the homebound eligibility was an insufficient description of how the patient's clinical condition warranted homebound status." *Complaint* Paragraph 36-37.

This Medicare decision can be simply summarized: subjective concerns with the words and grammar chosen by the patient's physician trump the reality of the patient's condition and care needs. In this situation, the Medicare contractor admits that the patient clearly meets the

homebound status requirements for coverage, but still issues a claim denial because of perceived flaws in the physician narrative. Such an outcome is wholly irrational.

Unfortunately, this is not an isolated case. *Complaint* Paragraph 34-35. It is an example of the common outcome of a policy that permits perceived insufficiency in the physician narrative to preempt reality of a patient's clinical condition, homebound status, and skilled care needs when determining Medicare coverage. The full facts about a patient should control the outcome, not partial information in the form of a narrative composed under ambiguous and incomplete guidance.

A determination that a rule is arbitrary and capricious starts with a facial review of the rule and proceeds with an evaluation of its operation and application to gain full context. With respect to the challenged rule, ambiguities and inconsistencies triggered mass confusion in its operation and application among home health agencies, physicians, and Medicare contractors..

“There are cases where an agency’s failure to state its reasoning or to adopt an intelligible standard is so glaring that we can declare with confidence that the agency action was arbitrary and capricious.” *Checkosky v. S.E.C.* 23 F.3d 452, 463 (D.C. Cir.1994). An amorphous rule is, by definition, arbitrary and capricious,. *Select Specialty Hospital-Bloomington, Inc. et al v. Burwell*, No. 12-5355 at 12 (D.C. Cir. 2014) (Medicare rule defining a “new” hospital for purposes of entitling qualified facilities to payment of certain capital-related costs), citing, *Coburn v. McHugh*, 679 F.3d 924, 934 (D.C. 2012) (noting agency decisions that lack “coherence” and “make it impossible for this court to determine whether [such decisions] survive arbitrary and capricious review under the APA” fail the test of “reasoned

decisionmaking”). <http://www.gpo.gov/fdsys/granule/USCOURTS-caDC-12-05355/USCOURTS-caDC-12-05355-0/content-detail.html>.

“[W]hen ambiguity begets ambiguity, making it such that we cannot discern the decisional standard, much less the correctness of its application, we have little choice but to declare the decision arbitrary and capricious—especially as our review is constrained to the rationale provided by the Board, *see SEC v. Chenery Corp.*, 332 U.S. 194, 196 (1947), however unintelligible it may be.” *Select Specialty Hospital* at 12.

One need look no further than the Defendants’ own admissions that the physician narrative rule was so plagued with confusion and ambiguity that it warranted rescission. <http://www.gpo.gov/fdsys/pkg/FR-2014-11-06/pdf/2014-26057.pdf>. In acknowledging the mass confusion with the rule, the Defendants took the rare step of dropping a rule it had only recently promulgated. Unfortunately, the Defendants did not see fit to correct the harm that the wholly confusing rule had inflicted up to that point.

The HHS Office of Inspector General also found unusually high levels of noncompliance with the ambiguous documentation standards. <http://oig.hhs.gov/oei/reports/oei-01-12-00390.asp>.

Members of Congress reported concerns with the face-to-face physician encounter documentation requirements as well. For example, in a September 17, 2013 letter, numerous members of the House of Representatives stated, “the current regulations contain complicated, confusing, and overlapping documentation requirements that exceed the intent of the law passed by Congress.” *Affidavit of Mary K. Carr*.

Data from Medicare contractors illuminates the state of confusion rampant within the home health services community. One Medicare contractor, PGBA, reported that in the period

January to December 2013, it reviewed 28,703 claims and denied 9676 on the basis of the face-to-face requirements, an astounding 33.7% denial rate for a paperwork requirement. *Affidavit of Mary K. Carr*. The same Medicare contractor reported that of the 5,285 denials issued in October to December 2014, 72.1% were based on the face-to-face requirements. Even a year later, the paperwork standards remained so confusing and ambiguous that nearly three-quarters of the claim denials were related.

It also is notable that the Administrative Record in the rulemaking process is totally devoid of any evidence that the challenged rule was reasonable and that it could actually work in application to restrict fraud, waste and abuse. Instead, the Defendants simply imposed the requirement without any evidence that it would be effective.<sup>4</sup> To support its exercise of interpretive discretion, a federal agency must “articulate a satisfactory explanation for its action including a rational connection between the facts found and the choice made.” *Motor Vehicles Mfrs. Ass’n v. State Farm Mutual Auto Ins. Co.*, 463 U.S. 29, 43 (1983).

Here, the Defendants chose an interpretation at odds with all the inputs and concern voiced by stakeholders in the public comment rulemaking process. AR at 0072-2322; 2482-3031; 3168-3794; and 3937-4494. These commenters repeatedly noted that the narrative requirement would cause serious problems including barriers to care access, alienation of physicians who should focus on care not paperwork, and across-the-board confusion with compliance standards. A central concern voiced was that neither the home health agency nor the patient, the two parties with direct interest in the payment of the Medicare claim, had any control over the outcome of the physician narrative. Only the physician could compose the

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<sup>4</sup> Defendants merely stated that “[w]e believe that our proposed documentation requirements meet the Congressional intent for more physician involvement in determining the patient’s eligibility and managing the care plan.” Defendants’ Memorandum at 12, citing 75 Fed. Reg. at 70431. Belief alone is not a sufficient rationale.

narrative, yet it was the home health services coverage that was in issue not any physician's Medicare claim.

For the first time in this litigation, the Defendants attempt to rely on 42 USC 1395l(e) and 1395g(a) in a half-hearted, but futile effort to validate the Defendants' authority to promulgate and implement the challenged rule. *Defendants' Memorandum* at 15. Each of these provisions purportedly provide the Defendants with authority to require any documentation that they wish. However, this argument fails. In construing legislative authority to issue interpretive regulations, the specific authorization governs and prevails over any general authorizing power. *Long Island Care at Home v. Coke*, 551 U.S. 158, 170 (2007), citing, *Morales v. Trans World Airlines, Inc.*, 504 U. S. 374, 384–385 (1992) ; *Simpson v. United States*, 435 U. S. 6, 15 (1978). Here, section 1395f(a)(2)(C) provides very specific and limited authorization regarding allowable physician documentation requirements. Defendants have far exceeded that allowance with the challenged narrative requirement. They cannot now rely on generic powers to overcome the specific and limited authorization contained in the face-to-face encounter documentation provision.

Even if the Defendants' reliance on 1395l(e) and 1395(g) was well founded, the rule still fails under a *Chevron* Step 2 analysis as set out above. The irrational and absurd outcome of denying Medicare coverage for patient's home health services where the patient meets standards for homebound status and skilled care need based on a subjective and singular review of a physician composed narrative intended to explain the patient's homebound status and skilled care needs renders the challenged rule invalid.

#### **IV. CONCLUSION**

For the foregoing reasons, Plaintiff respectfully requests that this Court grant its Motion for Summary Judgment and deny Defendants' cross motion.

Respectfully submitted,

/s/ William A. Dombi  
William A. Dombi  
D.C. Bar No. 445832  
Center for Health Care Law  
228 7thSt, SE  
Washington, D.C. 20003  
Phone: 202-547-5262  
Fax: 202-547-7126  
[wad@nahc.org](mailto:wad@nahc.org)  
Attorney for Plaintiff

#### **CERTIFICATE OF SERVICE**

I hereby certify that on this 7<sup>th</sup> day of May, 2015, a true and correct copy of the attached document was filed and served pursuant to the Court's electronic filing procedures using the Court's CM/ECF System.

/s/ William A. Dombi  
William A. Dombi  
D.C. Bar No. 445832  
Center for Health Care Law  
228 7<sup>th</sup> St, SE  
Washington, D.C. 20003  
Phone: 202-547-5262  
Fax: 202-547-7126  
[wad@nahc.org](mailto:wad@nahc.org)  
Attorney for Plaintiff