U.S. DISTRICT COURT DISTRICT OF VERMONT FILED

UNITED STATES DISTRICT COURT FOR THE DISTRICT OF VERMONT CLERK GLENDA JIMMO, et al., Plaintiffs, V. Case No. 5:11-cv-17

OPINION AND ORDER GRANTING IN PART AND DENYING IN PART PLAINTIFFS' MOTION FOR RESOLUTION OF NONCOMPLIANCE WITH SETTLEMENT AGREEMENT

SYLVIA MATHEWS BURWELL, Secretary

of Health and Human Services.

Defendant.

(Doc. 94)

This matter comes before the court on Plaintiffs' motion for resolution of noncompliance with Settlement Agreement (Plaintiffs' "motion to enforce") (Doc. 94), in which Plaintiffs assert that Defendant Sylvia Mathews Burwell, Secretary of Health and Human Services (the "Secretary"), has breached the parties' settlement agreement dated October 16, 2012 (the "Settlement Agreement"), which the court entered as a judgment on January 24, 2013 (the "Judgment"). As grounds for their motion to enforce, Plaintiffs point to the Secretary's refusal to make certain revisions to the Medicare Benefit Policy Manual (the "MBPM") and her allegedly deficient educational campaign designed to implement the Settlement Agreement.

The Secretary opposes Plaintiffs' motion, asserting that the court lacks jurisdiction to adjudicate the pending motion because Plaintiffs' notices of noncompliance are not timely. In the alternative, if jurisdiction exists, the Secretary asserts that Plaintiffs fail to establish a breach of the Settlement Agreement and their proposed remedial measures extend beyond the court's limited jurisdiction.

The court heard oral argument on May 26, 2016, at which point it took the pending motion under advisement. Plaintiffs are represented by David J. Berger, Esq., Matthew R. Reed, Esq., the Center for Medicare Advocacy, Inc., and Vermont Legal Aid, Inc. The Secretary is represented by Assistant United States Attorney M. Andrew Zee, Assistant United States Attorney Steven Y. Bressler, and Special Assistant United States Attorney Tamra Moore.

I. Factual and Procedural Background.

A. The Jimmo Class Action.

On January 18, 2011, six individual Medicare beneficiaries (the "Individual Plaintiffs") and seven national organizations (the "Organizational Plaintiffs") (collectively, "Plaintiffs") filed a class action suit in the District of Vermont against the Secretary, alleging, among other things, that the Secretary "impose[d] a covert rule of thumb that operate[d] as an additional and illegal condition of coverage and result[ing] in the termination, reduction, or denial of coverage for thousands of Medicare beneficiaries annually." (Doc. 13 at 2, ¶ 1.) Plaintiffs alleged this covert rule of thumb improperly imposed an "Improvement Standard," whereby coverage for certain home health care services was denied if a beneficiary's condition had not improved. *Id.* at ¶ 2. Plaintiffs further alleged that because of the Improvement Standard, Medicare contractors and adjudicators were denying Medicare coverage merely because a patient was unlikely to improve, or in retrospect failed to improve, even when the patient needed skilled care to maintain his or her condition or prevent or slow further deterioration.

The Secretary moved to dismiss Plaintiffs' claims on a number of grounds, including that they failed to allege a plausible ground for relief. The court granted the motion to dismiss in part and denied it in part. *See Jimmo v. Sebelius*, 2011 WL 5104355, at *1 (D. Vt. Oct. 25, 2011). Thereafter, without admitting liability or any wrongdoing, after several months of arms-length negotiations, the Secretary agreed to settle Plaintiffs' claims in accordance with the terms and conditions of the Settlement Agreement. The court approved the Settlement Agreement at a January 24, 2013 fairness hearing under Fed. R. Civ. P. 23(b)(2).

B. The Settlement Agreement.

Pursuant to the Settlement Agreement, the parties agreed to a "maintenance coverage standard" which provides that "[s]killed nursing services would be covered where such skilled nursing services are necessary to maintain the patient's current condition or prevent or slow further deterioration so long as the beneficiary requires skilled care for the services to be safely and effectively provided." (Doc. 82-1 at 13, § IX.7.a.)¹ The parties agreed to implement the maintenance coverage standard in two ways that are relevant to Plaintiffs' pending motion to enforce.

First, the Settlement Agreement required certain revisions to the MBPM in order "to clarify the coverage standards for the skilled nursing facility (SNF), home health (HH), and outpatient therapy (OPT) benefits when a patient has no restoration or improvement potential but when that patient needs skilled SNF, HH, or OPT services" and to state that Medicare coverage "does not turn on the presence or absence of an individual's potential for improvement from the nursing care, but rather on the beneficiary's need for skilled care." *Id.* at 8-9, 12, §§ IX.1, IX.7. The Secretary further agreed to "revise or eliminate any [MBPM] provisions . . . that [the Secretary] determines are in conflict" with the agreed-upon maintenance coverage standard for nursing services. *Id.* at 9, § IX.3.

The Settlement Agreement provides that the Secretary:

will take any recommendations from Plaintiffs' Counsel under advisement and will make a good faith effort to utilize Plaintiffs' Counsel's reasonable recommendations that are limited to the coverage standards as clarified in Sections IX.6 through IX.8 and that are consistent with those coverage standards as well as all other statutory and regulatory requirements.

Id. at 10, § IX.4. Under the Settlement Agreement, the Secretary "retain[s] final authority as to the ultimate content of [MBPM] provisions." Id. at 9, § IX.2.

¹ To receive Medicare benefits for home health care services, a beneficiary must be: (a) confined to the home; (b) under the care of a physician; (c) in need of skilled services; and (d) under a plan of care. 42 C.F.R. § 409.42(a)-(d). "Nothing in [the] Settlement Agreement modifies, contracts, or expands the existing eligibility requirements for receiving Medicare coverage[.]" (Doc. 82-1 at 9, § IX.2.)

Second, the Settlement Agreement required the Secretary to engage in certain educational activities designed to implement the changes to the MBPM and to educate stakeholders regarding the maintenance coverage standard. Specifically, the Settlement Agreement requires the Secretary to "engage in a nationwide educational campaign" through the Centers for Medicare and Medicaid Services ("CMS"), and in this "Educational Campaign," "use written materials and interactive forums with providers and contractors, to communicate the SNF, home health, and OPT maintenance coverage standards and the [inpatient rehabilitation facility] coverage standards[.]" Doc. 82-1 at 14, § IX.9. The Settlement Agreement provides that "CMS shall retain final authority as to the ultimate content of the written educational materials" and the "PowerPoint slides" used in the Educational Campaign. *Id.* at 16, § IX.12.

The Settlement Agreement states that:

The Parties recognize that Defendant's obligations are met under the Settlement Agreement once it has complied with the terms of this Settlement Agreement, and that Defendant is not guaranteeing to Plaintiffs that certain results will be achieved once the steps set forth in this Settlement Agreement have been implemented.

Id. at 23, § IX.18.

The Settlement Agreement further provides that the court will retain jurisdiction for thirty-six months after the conclusion of the Educational Campaign to "enforc[e] the provisions of the Settlement Agreement in the event that one of the Parties claims that there has been a breach of any of those provisions[.]" *Id.* at 6, § VI.3. Under the Settlement Agreement, before an aggrieved party may file a motion with the court alleging noncompliance, it must follow the dispute resolution process described in § VIII of the Settlement Agreement. The first step is to provide written notice detailing the alleged noncompliance, which must include:

(a) a reference to all specific provisions of the Settlement Agreement that are involved; (b) a statement of the issue; (c) a statement of the remedial action sought by the Initiating Party; and (d) a brief statement of the specific facts, circumstances, and any other arguments supporting the position of the Initiating Party; and (e) if there is a good faith basis for

expedited resolution, the circumstances that make expedited resolution appropriate, and the proposed date for a reasonable expedited response.

Doc. 82-1 at 7, § VIII.1. Notice of noncompliance "must be provided promptly." *Id.*Under the Settlement Agreement, "[n]otice that is not provided promptly because of a lack of diligence on the part of the Initiating Party shall not serve as a basis for the [c]ourt to exercise jurisdiction[.]" *Id.* In its Judgment, the court retained "jurisdiction over this matter for the limited purposes and time period set forth in Section VI of the [Settlement] Agreement." (Doc. 92 at 2.)

C. The Parties' Efforts to Implement the Settlement Agreement.

The Secretary made substantial revisions to chapters seven and eight of the MBPM, although many of the revisions were unrelated to the maintenance coverage standard or the Settlement Agreement and were instead made "pursuant to CMS's general authority to provide guidance on Medicare policy and implementation." (Doc. 94-5 at 2.) The Secretary issued an article regarding the revised MBPM provisions, which was disseminated to Medicare Administrative Contractors, Medicare Advantage Organizations, Qualified Independent Contractors ("QICs"), Qualified Improvement Organizations, the Chief Administrative Law Judge, the Chair of the Departmental Appeals Board, providers, suppliers, and others. The article was also posted on CMS's website.

The Secretary issued a Health Plan Management System memorandum, a Program Transmittal, and a Transmittal of Policy Systems memorandum, about the revised MBPM provisions and revised the relevant 1-800-MEDICARE customer service scripts to reflect them. The Secretary posted the Program Transmittal on CMS's website.

The Secretary conducted five open door forums and two national conference calls for the purpose of communicating the MBPM revisions and the maintenance coverage standard. The open door forums involved over 3,900 participants. During the national calls, the Secretary utilized a PowerPoint presentation that was provided to Plaintiffs' counsel in advance for comment and review. The December 19, 2013 national call was one hour in length, and approximately 3,428 participants were on the call. The Secretary

used CMS's regular communication channel and its website to provide notice that the calls would take place and posted an audio recording and written transcript of the call on CMS's website. The parties also discussed implementation of the Settlement Agreement during biannual meetings that occurred in January 2014, September 2014, April 2015, and September 2015.

Pursuant to the Settlement Agreement, the Secretary conducted a random sampling of 100 decisions by QICs to identify potential errors and found that fifty-six QIC decisions contained potential errors. The Secretary then determined that twenty-one of the fifty-six decisions reflected actual errors, although not all of the identified errors involved the incorrect application of the maintenance coverage standard. Another sampling identified thirty-two QIC decisions with potential errors, with four of those errors involving the incorrect application of the maintenance coverage standard.

Since publication of the MBPM revisions on December 6, 2013, Plaintiffs have repeatedly raised concerns regarding the adequacy of the revisions to reflect the maintenance coverage standard and the Secretary's allegedly deficient Educational Campaign.² In conjunction with their concerns, Plaintiffs have submitted to the Secretary additional proposed revisions to the MBPM, provided examples of alleged continued application of an Improvement Standard to deny Medicare coverage, and have proposed

We have a couple of suggestions and requests that we think might improve the process.

First, we were struck by the fact that the Ombudsman call will not include an opportunity for questions. It's been apparent from the other calls that attendees do have a lot of questions, and so we request that that opportunity be provided in this instance as well. If that is not possible, could an e-mail address be provided so that attendees could e-mail their questions after the call?

Second, in general, could CMS provide an e-mail address where anyone could send a question about the relief and the process? This would be part of the ongoing "education campaign" (small caps). Again, we believe that the questions that have been generated on the calls demonstrate that such a need exists. Those questions and answers could then be used to develop FAQ postings that would alleviate some of the confusion.

² For example, on January 10, 2014, Plaintiffs raised the following concerns:

Frequently Asked Questions to be posted on CMS's website. The Secretary has responded to most of Plaintiffs' proposals, but has not agreed to adopt the vast majority of them, contending they are either unnecessary or are not required by the Settlement Agreement.

Plaintiffs, through counsel, also formed a *Jimmo* Implementation Council (the "Council"), a multi-disciplinary group of providers and advocates to monitor progress with the implementation of the Settlement Agreement. The Council conducted a survey of sixty interested providers, advocates, and other stakeholders, which revealed that "46% were not aware of the Education[al] Campaign provided by CMS and only 36% participated in the education efforts." (Doc. 94-50 at 4.) When asked about how the *Jimmo* settlement could be best implemented, "more education from CMS was most frequently mentioned." *Id*.

In an August 3, 2015 email, the Secretary, through counsel, stated that she had no new information to report regarding additional outreach or education. Three days later, on August 6, 2015, Plaintiffs' counsel served the Secretary with two notices of noncompliance: one addressing Plaintiffs' proposed MBPM revisions and the other identifying alleged deficiencies in the Secretary's Educational Campaign. On September 25, 2015, the Secretary responded to the notices of noncompliance. The parties then unsuccessfully attempted to resolve their differences. On November 10, 2015, the Secretary advised Plaintiffs' counsel in an email that the Secretary would engage in no additional educational activities.

On March 1, 2016, Plaintiffs filed their motion to enforce. In support of their motion, Plaintiffs submitted several coverage decisions which they contend demonstrate the persistence of confusion over the maintenance coverage standard and application of an Improvement Standard. They also submitted the declarations of certain stakeholders who opine that the Secretary did not adequately disseminate the maintenance coverage standard and conducted a confusing and inadequate Educational Campaign, and that little has changed as a result of the *Jimmo* class action settlement. As relief, Plaintiffs ask the court to require the Secretary "to revise or eliminate the specific language in the MBPM

that conflicts with the maintenance nursing coverage standard." (Doc. 94-1 at 25.) Plaintiffs also request that the court require the Secretary "to carry out additional educational activities to address the inaccuracies and inadequacies of the original [Educational] Campaign." *Id.*

II. Legal Analysis and Conclusions.

A. Whether the Court has Jurisdiction to Hear the Motion.

As a threshold issue, the Secretary contends that the court lacks jurisdiction to adjudicate the motion to enforce because Plaintiffs did not provide "timely" and "prompt" notice of alleged noncompliance as required by the Settlement Agreement. The Secretary points out that the allegedly deficient MBPM revisions were completed on December 6, 2013 and the Educational Campaign was completed on January 23, 2014. She asserts that Plaintiffs allowed over nineteen months to elapse before filing their notices of noncompliance. Plaintiffs counter that the record establishes they were diligent in pursuing their concerns and attempting to resolve them with the Secretary before invoking this court's jurisdiction.

Because "[f]ederal courts are courts of limited jurisdiction[,] [t]hey possess only that power authorized by Constitution and statute, which is not to be expanded by judicial decree[.]" Kokkonen v. Guardian Life Ins. Co. of Am., 511 U.S. 375, 377 (1994) (internal citations omitted). For that reason, the court does not "automatically retain jurisdiction to hear a motion to enforce a settlement agreement simply by virtue of having disposed of the original case." Hendrickson v. United States, 791 F.3d 354, 358 (2d Cir. 2015) (internal quotation marks omitted). "[T]o retain ancillary jurisdiction over enforcement of a settlement agreement . . . a district court's order of dismissal must either (1) expressly retain jurisdiction over the settlement agreement, or (2) incorporate the terms of the settlement agreement in the order." Id.

The court retained jurisdiction for thirty-six months after the conclusion of the Educational Campaign to enforce the Settlement Agreement in the event that one of the parties claims that there has been a breach thereof. The Settlement Agreement requires a party seeking enforcement to do so in a timely manner. Plaintiffs satisfy this standard.

They raised their concerns regarding the Secretary's alleged breaches of the Settlement Agreement promptly after they occurred and repeatedly thereafter. Consistent with the Settlement Agreement, Plaintiffs attempted to resolve their concerns with the Secretary until August 3, 2015, when the Secretary advised Plaintiffs through counsel that she had no new information with respect to additional outreach or education. Three days later, Plaintiffs served two Notices of Noncompliance. On September 25, 2015, the Secretary responded in writing to Plaintiffs' Notices of Noncompliance. The parties engaged in negotiations until November 10, 2015, when the Secretary informed Plaintiffs that no further action would be taken on the Notices of Noncompliance. Plaintiffs' motion to enforce was filed less than four months thereafter.

Because Plaintiffs provided the Secretary with prompt notice of the alleged noncompliance with the Settlement Agreement, diligently pursued their concerns, and served their notices of noncompliance in a timely manner, the court retains jurisdiction to resolve the pending motion to enforce.

B. Standard of Review for Motion to Enforce.

"[A] motion to enforce a settlement agreement is fundamentally 'a claim for breach of contract, part of the consideration of which was dismissal of an earlier federal suit[.]" *Id.* (quoting *Kokkonen*, 511 U.S. at 381). In turn, "[s]ettlement agreements are contracts and must therefore be construed according to general principles of contract law." *Red Ball Interior Demolition Corp. v. Palmadessa*, 173 F.3d 481, 484 (2d Cir. 1999). If a settlement agreement is clear and unambiguous, the court "must take care not to alter or go beyond the express terms of the agreement, or to impose obligations on the parties that are not mandated by the unambiguous terms of the agreement itself." *Id.*; *see also Cruden v. Bank of N.Y.*, 957 F.2d 961, 976 (2d Cir. 1992) ("A court may neither rewrite, under the guise of interpretation, a term of the contract when the term is clear and unambiguous, nor redraft a contract to accord with its instinct for the dispensation of equity upon the facts of a given case") (internal citation omitted).

Because the federal government is one of the contracting parties, the Settlement Agreement is "governed exclusively by federal [common] law." *Boyle v. United Techs.*

Corp., 487 U.S. 500, 504 (1988). Federal common law "generally adopts the relevant state law rule unless there is a significant conflict between the state rule and a federal interest." *Palmieri v. Allstate Ins. Co.*, 445 F.3d 179, 188-89 (2d Cir. 2006). In this case, there is no apparent conflict with state law.

Pursuant to Vermont law, courts "look to the plain language of a contract to discern the intent of the parties." *In re Cole*, 2008 VT 58, ¶ 13, 184 Vt. 64, 71, 954 A.2d 1307, 1311; *see also Bixler v. Bullard*, 769 A.2d 690, 695 (Vt. 2001) ("[T]he language and acts of a party to a contract are to receive such construction as the other party was fairly justified in giving to them"). In every contract governed by Vermont law, there is implied covenant of good faith and fair dealing which is "not a contractual term that the parties are free to bargain in or out [of] as they see fit." *Carmichael v. Adirondack Bottled Gas Corp. of Vt.*, 635 A.2d 1211, 1216 (Vt. 1993). The Vermont Supreme Court has described the implied covenant as follows:

The definition of the "covenant of good faith and fair dealing" is broad. An underlying principle implied in every contract is that each party promises not to do anything to undermine to destroy the other's rights to receive the benefits of the agreement. The implied covenant of good faith and fair dealing exists to ensure that parties to a contract act with "faithfulness to an agreed common purpose and consistency with the justified expectations of the other party." . . . The implied promise by its nature protects against "a variety of types of conduct characterized as involving 'bad faith' because they violate community standards of decency, fairness or reasonableness." As the Restatement [(Second) of Contracts] points out,

[a] complete catalogue of types of bad faith is impossible, but the following types are among those which have been recognized in judicial decisions: evasion of the spirit of the bargain, lack of diligence and slacking off, willful rendering of imperfect performance, abuse of a power to specify terms, and interference with or failure to cooperate in the other party's performance.

Id. at 1216-17 (internal citations omitted).

In their pending motion, Plaintiffs seek enforcement of the Secretary's obligation to revise the MBPM and to conduct the Educational Campaign. Although Plaintiffs acknowledge that the Secretary has completed both of these obligations, they contend

that she has evaded the spirit of the Settlement Agreement in doing so and has thereby deprived them of the benefit of their bargain. The Secretary argues that Plaintiffs cannot establish a breach based on obligations not contained in the Settlement Agreement or merely because they are dissatisfied with the results of their agreement.

C. Whether the MBPM Revisions Violate the Settlement Agreement.

Plaintiffs concede that the Secretary made substantial changes to Chapters 7 and 8 of the MBPM, but claim that most of the changes either did not pertain to the maintenance coverage standard or did not clarify sections that arguably gave rise to the Improvement Standard. They further argue that the Secretary failed to make a good faith effort to implement Plaintiffs' recommendations to revise the MBPM as required by the Settlement Agreement. Plaintiffs assert that while the Secretary added the maintenance coverage standard to the general principles set forth in MBPM, she "did not revise or clarify any of the specific sections that govern coverage requirements for skilled nursing services to provide for maintenance nursing, [MBPM] 40.1.2.1 through [MBPM] 40.1.2.14." (Doc. 94 at 2.) The Secretary does not deny that she made no specific revisions to these sections of the MBPM to reflect the maintenance coverage standard. She contends she had no obligation to do so in the absence of a direct conflict with the maintenance coverage standard and, even in that instance, the Settlement Agreement left it to her discretion as to what, if any, revisions should be made. Two provisions of the MBPM are the subject of the pending motion to enforce.

1. MBPM § 40.1.2.1 and the "Three Week Rule."

First, Plaintiffs cite the Secretary's refusal to eliminate a reference to a "3 week rule" in MBPM § 40.1.2.1 governing skilled observation and assessment. This section provides:

Where a patient was admitted to home health care for skilled observation because there was a reasonable potential of a complication or further acute episode, but did not develop a further acute episode or complication, the skilled observation services are still covered for 3 weeks or so long as there remains a reasonable potential for such a complication or further acute episode.

Id.; MBPM, Ch. 7 § 40.1.2.1. Plaintiffs argue that there is no statutory support for the "3 week rule," and that it falsely suggests that skilled observation services are limited to that time period unless the patient is at risk for future complications. They assert this language conflicts with the maintenance coverage standard which does not contain a three week limitation. They further contend that the "3 week rule" imposes an impermissible "rule of thumb" that the Settlement Agreement was intended to eliminate.

The Secretary responds that because the "3 week rule" is only one measure and because MBPM § 40.1.2.1 also provides that skilled observations will be covered "so long as there remains a reasonable potential for such a complication or further acute episode[,]" there is no direct conflict with the maintenance coverage standard. *Id.*

MBPM § 40.1.2.1 neither refers to the maintenance coverage standard nor incorporates it. As a result, it can reasonably be interpreted as endorsing standards for determining coverage for skilled observation and assessment other than the maintenance coverage standard. None of this is surprising because MBPM § 40.1.2.1 predates the parties' Settlement Agreement and the Secretary has refused to revise it. In an effort to implement the terms and conditions of the Settlement Agreement, the Secretary could have clarified how the maintenance coverage standard applies to MBPM § 40.1.2.1 and how it modifies the "3 week rule." It is a much closer question, however, whether the Secretary breached the Settlement Agreement by failing to make those revisions.

Because coverage for skilled nursing services can comply with both the maintenance coverage standard and § 40.1.2.1, there is no direct conflict between the two standards and they can be read in tandem. See F.C.C. v. NextWave Pers. Commc'ns Inc., 537 U.S. 293, 304 (2003) ("[W]hen two statutes are capable of co-existence, it is the duty of the courts, absent a clearly expressed congressional intention to the contrary, to regard each as effective") (internal quotation marks omitted). Moreover, although the "3 week rule" appears to have no basis in the applicable regulations or law, it is modified by § 40.1.2.1's further provision that coverage remains available "so long as there remains a

³ At oral argument, the only statutory or regulatory support the Secretary cited for the "3 week rule" pertained to an unrelated issue.

reasonable potential for . . . a complication or further acute episode." As a result, while the "3 week rule" has the potential to become an impermissible rule of thumb, this outcome is not certain. She further contends she never agreed to eliminate "rules of thumb" from the MBPM.⁴

Although the Secretary's refusal to revise § 40.1.2.1 to reflect the maintenance coverage standard is likely to cause confusion, in the absence of a direct conflict between the two provisions, the Settlement Agreement permits her to refrain from certain clarifying revisions and authorizes no recourse if she decides not to make them. The court is not empowered to revise the parties' agreement to impose a more onerous burden even if it would enhance the implementation of the maintenance coverage standard. *See Greenlaw v. United States*, 554 U.S. 237, 243-44 (2008) (describing "the principle of party presentation" whereby "as a general rule, our adversary system is designed around the premise that the parties . . . are responsible for advancing the facts and arguments entitling them to relief") (internal quotation marks and alterations omitted).

Because there is no direct conflict between the cited provision of § 40.1.2.1 and the maintenance coverage standard, the court must DENY Plaintiffs' motion to enforce insofar as it pertains to the skilled observation and assessment provision of MBPM § 40.1.2.1.

2. MBPM § 40.1.2.1 and the Maintenance Coverage Standard.

Plaintiffs also challenge a portion of MBPM § 40.1.2.1 that states:

⁴ As the Secretary correctly points out, the Settlement Agreement does not prohibit rules of thumb or require her to eliminate them from the MBPM. However, the Secretary arguably has an independent duty to remove impermissible rules of thumb from the MBPM. See 42 C.F.R. § 409.44(a) (explaining that, under the home health benefit, Medicare coverage of skilled services is based on the "unique medical condition of the individual beneficiary"); MBPM, Ch. 7, § 20.3 (prohibiting the use of utilization screens or "rules of thumb" to make coverage decisions); 42 C.F.R. § 409.44(b)(3)(iii) (providing that the determination of whether a skilled service is reasonable and necessary "must be based solely upon the beneficiary's unique condition and individual needs, without regard to whether the illness or injury is acute, chronic, terminal, or expected to last a long time"); Home Health Prospective Payment System Rate Update for Calendar Year 2011, 75 Fed. Reg. 70372, 70395 (Nov. 17, 2010) ("Rules of thumb' in the Medicare medical review process are prohibited. . . . Medical denial decisions must be based on a detailed and thorough analysis of the beneficiary's total condition and individual need for care.").

Such signs and symptoms as abnormal/fluctuating vital signs, weight changes, edema, symptoms of drug toxicity, abnormal/fluctuating lab values, and respiratory changes on auscultation may justify skilled observation and assessment. Where these signs and symptoms are such that there is a reasonable potential that skilled observation and assessment by a licensed nurse will result in changes to the treatment of the patient, then the services would be covered. However, observation and assessment by a nurse is not reasonable and necessary for the treatment of the illness or injury where fluctuating signs and symptoms are part of a longstanding pattern of the patient's condition which has not previously required a change in the prescribed treatment.

(Doc. 94-8); MBPM, Ch. 7 § 40.1.2.1 (emphasis supplied).

Plaintiffs argue that the Settlement Agreement requires MBPM § 40.1.2.1 to be revised to clarify that, based on the maintenance coverage standard, it does not preclude observation and assessment "to address a long standing pattern of their condition, particularly when their treatment plan does not require changes to meet their needs or maintain their condition[.]" (Doc. 94 at 2-3.) As currently drafted, Plaintiffs contend § 40.1.2.1 erroneously suggests that the need for skilled care requires an acute episode and thus is "always episodic, temporary, [and] short-term." (Doc. 94-6 at 2.) Plaintiffs further argue that the section fails to reflect that a patient may obtain covered skilled nursing observation and assessment to maintain or prevent deterioration of his or her condition.

The Secretary responds that the challenged provision accurately indicates that when a patient's fluctuating signs and symptoms are part of a long standing pattern that remains unchanged, skilled observation and assessment services will not be reasonable and necessary, and that CMS's regulation governs when observation and assessment constitute skilled services. *See* 42 C.F.R. § 409.33(a)(2)(i). 5 She points out that "CMS"

⁵ 42 C.F.R. § 409.33(a)(2)(i) states:

Observation and assessment of the patient's changing condition—(i) When observation and assessment constitute skilled services. Observation and assessment constitute skilled services when the skills of a technical or professional person are required to identify and evaluate the patient's need for modification of treatment or for additional medical procedures until his or her condition is stabilized.

did not agree to 'eliminate' the so-called 'Improvement Standard,' nor did it promise that the measures set forth in the [Settlement] Agreement would eliminate it." (Doc. 102 at 3.) Indeed, she denies that the Improvement Standard exists.⁶

Although not a model of clarity, § 40.1.2.1 neither expressly contains an Improvement Standard nor negates the application of the maintenance coverage standard. As a result, the Secretary did not violate the Settlement Agreement by refusing to revise this provision of the MBPM.

Finally, while Plaintiffs point to the Secretary's alleged repeated failure to clarify the application of the maintenance coverage standard in the MBPM, the Settlement Agreement required only that the Secretary take Plaintiffs' recommendations for MBPM revisions "under advisement" and make a "good faith effort to utilize" them. (Doc. 82-1 at 10, § IX.4.) The Secretary has proffered sufficient evidence that she fulfilled this duty, and Plaintiffs make no colorable claim of bad faith. The court therefore DENIES Plaintiffs' motion to enforce insofar as it pertains to revisions to the MBPM.

3. The Educational Campaign.

Plaintiffs allege that although the Secretary "checked off all the boxes set out in the Educational Campaign portion of the [Settlement] Agreement" (Doc. 103 at 4), she did not make a good faith effort to carry out the Educational Campaign with respect to both the MBPM revisions and the maintenance coverage standard. Plaintiffs also point to

⁶ While it is true that the Settlement Agreement contains no concessions by the Secretary regarding the existence of the Improvement Standard, the Secretary agreed to a maintenance coverage standard which renders the use of an Improvement Standard to deny coverage impermissible. Under § IX.7 of the Settlement Agreement, the maintenance coverage standard for nursing services "does not turn on the presence or absence of an individual's *potential for improvement* from the nursing care, but rather on the beneficiary's need for skilled care." (Doc. 82-1 at 12) (emphasis supplied). Section IX.1 defines the "maintenance coverage standard as the coverage standard "when a patient has no restoration or *improvement potential* but when the patient needs skilled [services]" and provides that "[s]killed nursing services would be covered where such skilled nursing services are necessary to maintain the patient's current condition or prevent or slow further deterioration" even if the patient is unlikely to improve "so long as the beneficiary requires skilled care for the services to be safely and effectively provided." *Id.* at 9, 13 (emphasis supplied). An Improvement Standard, when used as a rule of thumb, is clearly impermissible. *See supra* note 4, at 12-13.

a number of specific alleged deficiencies in the manner in which the Secretary conducted the Educational Campaign.

For example, Plaintiffs point out that they did not have the opportunity to adequately comment on the Secretary's PowerPoint presentation because the MBPM revisions were not published until December 6, 2013. During the national call, the Secretary briefed the PowerPoint presentation, and then took questions from eighteen participants before terminating the call. Plaintiffs assert that when the Secretary terminated the call there were many participants waiting to ask questions about the Settlement Agreement and revisions to the MBPM. Plaintiffs point out that the Ombudsman call did not include any opportunity for questions, and that when they asked the Secretary to schedule another call, she refused this request. They suggested that the Secretary provide an email address for questions and post Frequently Asked Questions regarding the *Jimmo* settlement on CMS's website. Those requests were also denied.

With respect to the national calls, Plaintiffs contend that the Secretary did not effectively communicate about the calls in advance to give interested parties effective notice. The Settlement Agreement, however, only required the Secretary to "make a good faith effort to notify Plaintiffs' Lead Counsel, in advance of the National Calls[.]" (Doc. 82-1 at 19, § IX.15.) It is undisputed that the Secretary notified Plaintiffs' counsel about the calls, and provided a copy of the PowerPoint presentation utilized during the calls three weeks before the calls took place. Although not required to by the Settlement Agreement, the Secretary also noticed Medicare providers and suppliers about the national calls through her regular communications channel. These efforts were sufficient to comply with the Settlement Agreement.

Plaintiffs similarly claim that Open Door Forums ("ODFs") conducted by the Secretary pursuant to the Settlement Agreement were "problematic" because the Secretary "did not allow questions" and the publicity surrounding the ODFs "often failed to connect." (Doc. 94-1 at 11.) However, the Settlement Agreement did not require the Secretary to publicize the ODFs or ensure that the ODFs "connected" with their audience. It required only that the Secretary announce the manual revisions and reference the

national calls during an ODF. As the Secretary points out, she announced each ODF through targeted email, and each ODF had hundreds of participants.

Plaintiffs submit declarations from stakeholders averring that the Secretary's training regarding the maintenance coverage standard was both minimal and inadequate, that there was no follow-up, and that CMS has made little effort to address the confusion in the Medicare community regarding the import of the *Jimmo* settlement. Plaintiffs argue that there remains substantial confusion among Medicare providers, suppliers, contractors, adjudicators, and beneficiaries with respect to the maintenance coverage standard. In support of this claim, Plaintiffs cite the results of a random sampling of QIC coverage decisions which they contend demonstrate an unreasonably high error rate. They also rely on a number of individual adverse coverage decisions which they assert demonstrate that the Improvement Standard persists.⁷

Finally, Plaintiffs submit several declarations, including one from a retired administrative law judge from the Office of Medicare Hearings and Appeals who avers that after the *Jimmo* settlement, the Improvement Standard continued to be reflected in the decisions appealed to him, and that the Secretary has "paid only lip service" to the court's Judgment and has "not effectively implemented the letter or the spirit of the *Jimmo* settlement." (Doc. 94-1 at 14.)

Plaintiffs acknowledge that the Secretary did not guarantee results or the absence of mistakes, but contend that the evidence supports a conclusion that the Secretary's Educational Campaign was flawed to such an extent that it deprived them of the benefit of their bargain because "the evidence overwhelmingly indicates that the word did not get out" regarding the maintenance coverage standards. *Id.* at 11. Plaintiffs propose that the

⁷ In support of this contention, Plaintiffs cite thirty-nine individual adverse decisions in which the Secretary allegedly "failed to take the patient's unique condition into consideration or to recognize that the services were needed to maintain the beneficiary's condition or to slow deterioration." *Id.* at 17. In some of the cases cited by Plaintiffs, Medicare providers stated that they had not heard of the *Jimmo* Settlement Agreement or the maintenance coverage standard.

Secretary be required to take additional steps to ensure that the Settlement Agreement has its intended effect.⁸ *Id.* at 25.

In response, the Secretary sets forth in some detail the efforts she undertook to disseminate the maintenance coverage standard. She argues that what Plaintiffs actually seek is *results* and that, under the Settlement Agreement, she did not guarantee "that certain results [would] be achieved[.]" (Doc. 82-1 at 23, § IX.18.) Consequently, she asserts that adverse coverage decisions in which Medicare providers incorrectly deny coverage to beneficiaries based on the alleged "Improvement Standard" do not constitute a breach of the Settlement Agreement and, in any event, it is within her discretion to address when and how to address noncompliance. *See id.* at 22, § IX.22.e.2 ("The manner in which CMS addresses [noncompliance issues] will be within its discretion."). The Secretary notes that beneficiaries who are incorrectly denied coverage may appeal those decisions through the administrative process.

Because it is undisputed that the Secretary completed each component of the Educational Campaign, the only issue is whether the *manner* in which she conducted the campaign constitutes a breach of the Settlement Agreement. Although a close question, Plaintiffs have sustained their burden to establish that the Secretary failed to fulfill the letter and spirit of the Settlement Agreement with respect to at least one essential component of the Educational Campaign.

Plaintiffs have provided persuasive evidence that at least some of the information provided by the Secretary in the Educational Campaign was inaccurate, nonresponsive, and failed to reflect the maintenance coverage standard. The most compelling example of this is the Secretary's "Summary of the questions posed and answers provided during

⁸ Plaintiffs suggest addressing the alleged inadequacies of the Educational Campaign with:

¹⁾ Frequently Asked Questions, drafted by [P]laintiffs' counsel and edited by CMS, posted on CMS'[s] website, and updated no less than semi-annually[;]

²⁾ National Calls for providers and suppliers, and for contractors and adjudicators; [and]

³⁾ A dedicated e-mail address for providers to pose questions directly to CMS. (Doc. 94-1 at 26.)

the December 16, 2013 *Jimmo vs. Sebelius* National Call for contractors and adjudicators" (the "Summary") (Doc. 94-15). The Summary does not mention the maintenance coverage standard, does not provide the parties' agreed upon definition of it, and reflects virtually no effort to educate participants regarding the impact of the *Jimmo* settlement and the implementation of the maintenance coverage standard. Examples of its deficiencies are set forth below.

a. The Summary: Non-responsive answers.

When asked by contractors "how to distinguish claims where the goal is restorative from claims where the goal is maintaining or preventing decline in [the patient's] condition[,]" the Secretary did not answer this question and explain how the distinction should be drawn. Instead, she responded: "CMS believes that treatment goals should be clearly articulated in the patient's medical record. Goals should be established clearly from the beginning, in terms of maintenance or restoration. If clinical conditions change, treatment goals may change." *Id.* at 3.

When asked whether a patient can "now qualify for maintenance therapy for life assuming that therapy is necessary to prevent or slow deterioration[,]" the Secretary did not answer this question in the affirmative or negative, but instead stated that "[n]one of the existing requirements or limitations of coverage have changed." *Id.* (emphasis omitted).

When asked "[w]hen and how will the review of past claims be conducted[,]" the Secretary responded: "That aspect of the settlement agreement is relatively clear in the agreement language itself. CMS hasn't set up [a] formal timeline. The settlement agreement lays out biannual meetings at which the plaintiffs will bring additional claims." *Id.* (emphasis omitted).

When asked for guidance for determining when maintenance services would be covered for a patient that "continues to deteriorate," the Secretary advised contractors to conduct "a thorough review of the clinical record as a whole" to determine "when such a review does not support the need for skilled care." *Id.* at 2 (emphasis omitted). She did not direct them to the maintenance coverage standard which clearly provides that:

"Skilled nursing services would be covered where such skilled nursing services are necessary to maintain the patient's current condition or prevent or slow further deterioration so long as the beneficiary requires skilled care for the services to be safely and effectively provided." (Doc. 82-1 at 13, § IX.7.a.)

b. The Summary: Incorrect Information.

The Summary also reflects the provision of arguably incorrect information. When asked by contractors for "some examples from the settlement of where a claim was denied inappropriately[,]" and "what sort of language would be appropriate for them to use when denying claims[,]" the Secretary replied as follows:

As stated at the beginning of my presentation, the court has not decided this case and actual claims review of cases will not begin until the second phase of the settlement agreement. As far as inappropriate examples, in some instances, contractor denials have used certain terms such as "no improvement potential," "patient plateaued"—which can serve as shorthand justifications for denying. The basis for denial should be that the beneficiary did not need skilled care. Make sure that you are not using inaccurate, shorthand terms when writing denial language—use appropriate language to describe the reason for denial (e.g., no longer need for skilled care, patient not complicated/treatment not complicated).

(Doc. 94-15 at 3.) The problem with the Secretary's response is threefold.

First, the Secretary's response may erroneously suggest that she is unaware of any claims raised in the *Jimmo* settlement of improper denials based on an Improvement Standard. *See Anderson v. Sebelius*, 2010 WL 4273238, at *8 (D. Vt. Oct. 25, 2010) (rejecting the use of an Improvement Standard and requiring the Secretary "to reexamine the need for skilled services for observation and assessment from the perspective of the condition of Plaintiff at the time the services were ordered, free from any presumption that if hindsight reveals Plaintiff's condition was stable throughout the covered period, coverage for skilled services should be denied"); *Papciak v. Sebelius*, 742 F. Supp. 2d 765, 770 (W.D. Pa. 2010) (granting plaintiff's motion for summary judgment where "the question of whether services were necessary for a maintenance program was not considered by the Secretary, and thus the Secretary failed to apply the proper legal standard"); *Rizzi v. Shalala*, 1994 WL 686630, at *5 (D. Conn. Sept. 29, 1994) (opining

that "the revised guidelines prohibit any arbitrary presumptions or use of illegal 'rules of thumb' to deny patients with chronic or stable illnesses home health coverage"); *Folland v. Sullivan*, 1992 WL 295230, at *7 (D. Vt. Sept. 1, 1992) (concluding the "ALJ's interpretation of [claimant's] condition [was] flawed because it impermissibly relies on the benefit of hindsight, which of course is always 20-20" and "[t]he fact that skilled care has stabilized a claimant's health does not render that level of care unnecessary. An elderly claimant need not risk a deterioration of [his or] her fragile health to validate the continuing requirement for skilled care"); *Fox v. Bowen*, 656 F. Supp. 1236, 1248 (D. Conn. 1986) ("It is clearly contrary to [Social Security] regulations for an [ALJ] to deny benefits on the basis of informal presumptions, or 'rules of thumb,' that are applied across the board without regard to the medical condition or therapeutic requirements of the individual patient").

Second, the Secretary juxtaposed "inappropriate examples" of the Improvement Standard with a statement that the inappropriate terms *can* serve as shorthand justifications for denying claims when she apparently intended to indicate that they *cannot* be used for this purpose.

And third, rather than explain that an Improvement Standard is impermissible and the maintenance coverage standard applies, the Secretary offered "denial language" that can be used to avoid "inaccurate, shorthand terms[.]" (Doc 94-15 at 3.) Her explanation that "[t]he basis for denial should be that the beneficiary did not need skilled care" is accurate, but she does not explain how this determination should be made consistent with the maintenance coverage standard. *Id*.

Section IX.9 of the Settlement Agreement requires the Secretary to use the Educational Campaign "to communicate the SNF, home health, and OPT maintenance coverage standards . . . as set forth in Sections IX.6 through IX.8" of the Settlement Agreement. (Doc. 82-1 at 14, § IX.9.) At a minimum, Plaintiffs bargained for the accurate provision of information regarding the maintenance coverage standard and their rights under the Settlement Agreement would be meaningless without it. The Secretary makes no claim to the contrary. At least insofar as the Summary is concerned, the

Secretary breached the Settlement Agreement by failing to convey accurate information regarding the maintenance coverage standard.

For the foregoing reasons, the court GRANTS Plaintiffs' motion to enforce with regard to the Secretary's Educational Campaign and directs the Secretary to propose corrective action for Plaintiffs' consideration within forty-five days of this Order. In the event the parties cannot agree to that corrective action, they may petition the court for a resolution of their dispute.

CONCLUSION

For the foregoing reasons, Plaintiffs' motion for resolution of noncompliance with Settlement Agreement is GRANTED IN PART and DENIED IN PART. (Doc. 94.) SO ORDERED.

Dated at Burlington, in the District of Vermont, this 17 day of August, 2016.

Christina Reiss, Chief Judge United States District Court