Final 10/16/2012 See pages 10-12, Paragraphs 6 & 7

IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF VERMONT

)

GLENDA JIMMO, et al., on behalf of)
themselves and all others similarly situated,)
)
Plaintiffs,)
)
V.)
KATHLEEN SEBELIUS, Secretary of)
Health and Human Services,	
ficulti und fiumun Services,	Ś
Defendant.	Ś

Civil Action No. 5:11-CV-17-CR

'''''''''SETTLEMENT AGREEMENT

I. INTRODUCTION

WHEREAS the parties desire to resolve amicably all the claims raised in this suit without admission of liability;

WHEREAS the parties have agreed upon mutually satisfactory terms for the complete resolution of this Federal Rule of Civil Procedure 23(b)(2) class action litigation;

NOW THEREFORE, the Plaintiffs and Defendant hereby consent to the entry of this Settlement Agreement with the following terms.

II. DEFINITIONS

"Approval Date" means the date upon which the Court approves this 1. Settlement Agreement, after having determined that it is adequate, fair, reasonable, equitable, and just to the Class as a whole, after: (i) notice to the Class, (ii) an

opportunity for class members to submit timely objections to the Settlement Agreement, and (iii) a hearing on the fairness of the settlement.

2. "Class Counsel" or "Plaintiffs' Counsel" means the Center for Medicare Advocacy, Inc., Vermont Legal Aid, and Wilson Sonsini Goodrich & Rosati. "Plaintiffs' Lead Counsel" means the attorney Plaintiffs have authorized to be the main contact with Defendant's counsel.

3. The "Class" or "Class Members" means all Medicare beneficiaries as defined in Section XI.

4. "CMS" refers to the Centers for Medicare & Medicaid Services.

"Court" means the United States District Court for the District of Vermont.

6. "Defendant" or "the Secretary" means the Secretary of Health and Human Services, in his or her official capacity.

7. "Final, non-appealable denial" or "final and non-appealable" denial means a denial for which the applicable deadline, as described in federal regulations, for an appeal of a decision has expired.

8. "Named Plaintiffs" refers to the individuals and organizations who are named in the First Amended Complaint and have not been dismissed from this action by the Court as of the Approval Date.

9. "Improvement Standard" refers to a standard that Plaintiffs have alleged, but that Defendant denies, exists under which Medicare coverage of skilled services is denied on the basis that a Medicare beneficiary is not improving, without regard to an

individualized assessment of the beneficiary's medical condition and the reasonableness and necessity of the treatment, care or services in question.

10. "Parties" refers to Plaintiffs and to Defendant.

11. "Plaintiffs" refers to the Named Plaintiffs, acting on their own behalf and on behalf of all Class Members.

12. "State Medicaid agencies" refers to the agencies or their contractors within the fifty States and the District of Columbia that are responsible for administering medical assistance benefits under Title XIX of the Social Security Act.

13. "End of the Educational Campaign" means the date upon which the Educational Campaign described in Section IX.9 has been conducted and completed as agreed, as evidenced by Defendant's notification to Plaintiffs' Lead Counsel and certification in good faith that all terms of the Educational Campaign have been conducted and completed.

14. "HH" refers to "home health services" as addressed by § 1861(m) of theSocial Security Act/ 42 U.S.C. § 1395x(m);

15. "SNF" refers to "skilled nursing facility" as addressed by § 1819(a) of the Social Security Act/ 42 U.S.C. § 1395i-3(a);

16. "OPT" refers to outpatient therapy services as follows: outpatient physical therapy services as addressed by § 1861(p) of the Social Security Act/ 42 U.S.C. § 1395x(p), outpatient occupational therapy services as addressed by § 1861(g) of the Social Security Act/ 42 U.S.C. § 1395x(g), and outpatient speech-language pathology services as addressed by § 1861(ll)(2) of the Social Security Act/ 42 U.S.C. § 1395x(ll)(2),

17. "IRF" refers to "inpatient rehabilitation facility" as addressed by 42 C.F.R.Part 412, Subpart P.

18. "CORF" refers to "comprehensive rehabilitation facility" as addressed by § 1861(cc) of the Social Security Act/ 42 U.S.C. § 1395x(cc)

III. ENTIRE AGREEMENT

The terms of this Settlement Agreement and any attachments thereto are the exclusive and full agreement of the Parties with respect to all claims for declaratory and injunctive relief and attorney's fees and costs as set forth in this Settlement Agreement and in the First Amended Complaint. No representations or inducements or promises to compromise this action or enter into this Settlement Agreement have been made, other than those recited or referenced in this Settlement Agreement.

IV. APPROVAL

 This Settlement Agreement is expressly conditioned upon its approval by the Court.

2. The terms of this Settlement Agreement are fair, reasonable, and adequate. The entry of this Settlement Agreement is in the best interest of the Parties and the public.

V. FINAL JUDGMENT

If, after the fairness hearing, the Court approves this Settlement Agreement as fair, reasonable, and adequate, the Court shall direct the entry of Final Judgment (the "Final Judgment") dismissing this action with prejudice, pursuant to the terms of this Settlement Agreement and Fed. R. Civ. P. 41, except that the Court shall retain jurisdiction for the limited purposes described in Section VI of this Settlement

Agreement. The Final Judgment shall incorporate and be subject to the terms of the Settlement Agreement.

VI. CONTINUING JURISDICTION

 The Court has held, contrary to arguments made by Defendant, that it has subject matter jurisdiction over this matter. See Opinion and Order dated October 25, 2011 (Docket Entry No. 52).

2. If for any reason this Settlement Agreement (a) is not finalized by the parties, (b) is not approved by the Court following notice to class members and the fairness hearing, or (c) is in any way rendered null and void (in whole or in part), Defendant preserves all of her rights to argue (in this Court or on appeal) that the Court lacks subject matter jurisdiction over this matter.

3. Subject to the limitations and reservations set forth in the preceding paragraph, the Court will retain jurisdiction over this matter only for the limited purposes described in this paragraph for the following duration: (a) the Court will retain jurisdiction for a period not to exceed twenty-four (24) months following the End of the Educational Campaign if the Administrator of CMS issues a CMS Ruling communicating the clarified maintenance coverage standards for skilled nursing facility (SNF), home health (HH) and outpatient therapy (OPT) as set forth in Sections IX.6 and IX.7 of this Settlement Agreement within three (3) months after the effective date of the Manual Provisions; <u>or</u> (b) the Court will retain jurisdiction for a period not to exceed thirty-six (36) months following the End of the Educational Campaign if the Administrator of CMS does not issue such a CMS Ruling within three (3) months after the effective date of the Manual Provisions. Such limited jurisdiction shall be for the sole purposes of (a)

enforcing 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, (b) modifying the Settlement Agreement if jointly requested by the Parties pursuant to Section VII, (c) entering any other order authorized by the Settlement Agreement, and (d) deciding any fee petition filed by Plaintiffs, solely in the event that the parties are unable to agree on an amount of reasonable attorney's fees, as further described in Section X.

4. Notwithstanding the time frames for the Court's continuing jurisdiction discussed in the previous Section VI.3, the Court shall maintain jurisdiction to rule on a motion for enforcement of this Settlement Agreement, or for attorney's fees, filed prior to the end of the applicable time frame set out in Section VI.3. The Court will also have jurisdiction to rule on a motion for enforcement of this Settlement Agreement that was filed after the end of the applicable time frame in Section VI.3. if the Dispute Resolution process in Section VIII of this Settlement Agreement is initiated prior to the end of the time frame and if the Party files the motion for enforcement within 30 days of the other Party's written statement of disagreement with the relief requested by the moving Party.

VII. MODIFICATION

At any time while the Court retains jurisdiction over this matter as described in Section VI, Plaintiffs and Defendant may jointly agree to modify this Settlement Agreement. Any joint request for modification must be in writing, signed by both Class Counsel and Defendant's counsel, and is subject to approval by the Court.

VIII. DISPUTE RESOLUTION PROCEDURES

Either Party shall have the right to initiate steps to resolve any alleged noncompliance with any provision of the Settlement Agreement, subject to limitations and standards set forth in the Settlement Agreement.

1. If one party (the "Initiating Party") has good reason to believe that an issue of noncompliance exists, it will first give timely written notice to the other party (the "Responding Party"), including: (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. To be timely, such notice must be provided promptly. Notice 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 Court to exercise jurisdiction as described in Section VI.4 above.

2. Within thirty (30) calendar days after receiving such timely notice or within a reasonable time for an expedited resolution, the Responding Party shall respond in writing to the statement of facts and arguments set forth in the notice and shall provide its written position, including the facts and arguments upon which it relies in support of its position.

3. The Parties shall undertake good-faith negotiations, including meeting and conferring by telephone or in person and exchanging relevant documents and/or other information, to attempt to resolve the alleged noncompliance. The written notice set

forth in Section VIII.1 may be amended solely to include issue(s) related to the original notice that may arise during the meet-and-confer process described in this paragraph.

4. If the Initiating Party believes in good faith that efforts to resolve the matter have failed or if sixty (60) calendar days have elapsed from the Receiving Party's receipt of timely notice, the Initiating Party, after providing written notice to the Responding Party, may file a motion with the Court, with a supporting brief, requesting resolution of the alleged noncompliance, provided however that the relief sought by such motion shall be limited to the issue(s) of alleged noncompliance described in the written notice, as to which the Parties have met and conferred as described in Section VIII.3.

5. The Responding Party shall be provided with appropriate notice of any such motion and an opportunity to be heard on the motion, as provided under the Civil Local Rules of the District of Vermont and the Federal Rules of Civil Procedure.

6. The Initiating Party cannot seek contempt sanctions as a remedy for alleged noncompliance with the Settlement Agreement. If, however, the Initiating Party successfully argues to the Court that there has been a breach of the Agreement and obtains an order from the Court compelling the Responding Party to remedy the breach, and if the Responding Party subsequently violates that order, then the Initiating Party is free to seek contempt sanctions for that violation.

IX. INJUNCTIVE PROVISIONS

Manual Revisions

1. The agency will revise the relevant portions of Chapters 7, 8, and 15 of the Medicare Benefit Policy Manual (MBPM) 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 (SNF, HH, OPT "maintenance coverage standard"). The agency will also revise the relevant portions of Chapter 1, Section 110 of the MBPM to clarify the coverage standards for services performed in an inpatient rehabilitation facility (IRF).

2. The manual revisions to be made pursuant to this Settlement Agreement will clarify the SNF, HH, and OPT maintenance coverage standards and IRF coverage standard only as set forth below in Sections IX.6 through IX.8. Existing Medicare eligibility requirements for coverage remain in effect. Nothing in this Settlement Agreement modifies, contracts, or expands the existing eligibility requirements for receiving Medicare coverage, including such requirements found in:

a. Posthospital SNF Care, as set forth in 42 C.F.R. Part 409, SubpartsC and D, and related subregulatory guidance;

b. Home Health Services, as set forth in 42 C.F.R. Part 409, SubpartE, 42 C.F.R. Part 410, Subpart C, and related subregulatory guidance;

c. Outpatient Therapy Services, as set forth in 42 C.F.R. Part 410,Subpart B, and related subregulatory guidance; and

d. Inpatient Rehabilitation Facility services, as set forth in 42 C.F.R.Part 412, Subpart P, and related subregulatory guidance.

3. CMS will revise or eliminate any manual provisions in Chapters 7, 8, and 15 and Chapter 1, Section 110 of the MBPM that CMS determines are in conflict with the standards set forth below in Sections IX.6 through IX.8.

4. CMS will afford Plaintiffs' Counsel 21 days to review and provide a single set of written comments on the manual provisions revised or eliminated as part of settlement before the manual provisions are finalized and issued. CMS 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. If plaintiffs request, CMS will also afford Plaintiffs' Counsel a second opportunity for review and comment on these manual revisions before the manual provisions are finalized and issued; Plaintiffs' Counsel will have 14 days to review any subsequent changes made and either provide a second set of written comments or communicate its comments at a meeting between counsel. CMS 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. CMS shall retain final authority as to the ultimate content of the manual provisions.

5. In providing any set of recommendations described in paragraph 4 above, Plaintiffs agree to collect all recommendations into one consolidated document to be provided by Plaintiffs' Lead Counsel.

Maintenance Coverage Standard for Therapy Services under the SNF, HH, and OPT Benefits

6. Manual revisions will clarify that SNF, HH, and OPT coverage of therapy to perform a maintenance program does not turn on the presence or absence of a

beneficiary's potential for improvement from the therapy, but rather on the beneficiary's need for skilled care.

a. The manual revisions will clarify that, under the SNF, HH, and OPT maintenance coverage standards, skilled therapy services are covered when an individualized assessment of the patient's clinical condition demonstrates that the specialized judgment, knowledge, and skills of a qualified therapist ("skilled care") are necessary for the performance of a safe and effective maintenance program. Such a maintenance program to maintain the patient's current condition or to prevent or slow further deterioration is covered so long as the beneficiary requires skilled care for the safe and effective performance of the program. When, however, the individualized assessment does not demonstrate such a necessity for skilled care, including when the performance of a maintenance program does not require the skills of a therapist because it could safely and effectively be accomplished by the patient or with the assistance of nontherapists, including unskilled caregivers, such maintenance services will not be covered under the SNF, HH, or OPT benefits.

b. The manual revisions will further clarify that, under the standard set forth in the previous paragraph (Section IX.6.a.), skilled care is necessary for the performance of a safe and effective maintenance program only when (a) the particular patient's special medical complications require the skills of a qualified therapist to perform a therapy service that would otherwise be considered non-skilled; or (b) the

needed therapy procedures are of such complexity that the skills of a qualified therapist are required to perform the procedure.

c. The manual revisions will further clarify that, to the extent provided by regulation, the establishment or design of a maintenance program by a qualified therapist, the instruction of the beneficiary or appropriate caregiver by a qualified therapist regarding a maintenance program, and the necessary periodic reevaluations by a qualified therapist of the beneficiary and maintenance program are covered to the degree that the specialized knowledge and judgment of a qualified therapist are required.

d. The maintenance coverage standard for therapy as outlined in this section does not apply to therapy services provided in an inpatient rehabilitation facility (IRF) or a comprehensive outpatient rehabilitation facility (CORF).

<u>Maintenance Coverage Standard for Nursing Services under the SNF and HH</u> <u>Benefits</u>

7. Manual revisions will clarify that SNF and HH coverage of nursing care 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.

a. The manual revisions will clarify that, under the SNF and HH benefits, skilled nursing services are covered when an individualized assessment of the patient's clinical condition demonstrates that the specialized judgment, knowledge, and skills of a registered nurse or, when provided by regulation, a licensed practical (vocational) nurse ("skilled care") are necessary. 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. When, however, the individualized assessment does not demonstrate such a necessity for skilled care, including when the services needed do not require skilled nursing care because they could safely and effectively be performed by the patient or unskilled caregivers, such services will not be covered under the SNF or HH benefits.

b. The manual revisions will further clarify that, under the standard set forth in the previous paragraph (Section IX.7.a.), skilled nursing care is necessary only when (a) the particular patient's special medical complications require the skills of a registered nurse or, when provided by regulation, a licensed practical nurse to perform a type of service that would otherwise be considered non-skilled; or (b) the needed services are of such complexity that the skills of a registered nurse or, when provided by regulation, a licensed practical nurse are required to furnish the services. To be considered a skilled service, the service must be so inherently complex that it can be safely and effectively performed only by, or under the supervision of, professional or technical personnel as provided by regulation, including 42 C.F.R. 409.32.

c. The maintenance coverage standard for nursing services as outlined in this section does not apply to nursing services provided in an inpatient rehabilitation facility (IRF) or a comprehensive outpatient rehabilitation facility (CORF).

IRF Coverage Standard

8. Manual revisions will clarify that an IRF claim could never be denied for the following reasons: (1) because a patient could not be expected to achieve complete independence in the domain of self-care or (2) because a patient could not be expected to return to his or her prior level of functioning.

Educational Campaign

9. CMS will engage in a nationwide educational campaign, as set forth in the following Sections IX.10 through IX.14, which will use written materials and interactive forums with providers and contractors, to communicate the SNF, home health, and OPT maintenance coverage standards and the IRF coverage standards as set forth in Sections IX.6 through IX.8.

10. The educational campaign will be directed to include the following contractors, adjudicators, and providers and suppliers (collectively "recipients") through the following written educational materials ("written educational materials"):

a. Medicare Administrative Contractors (MACs, Part A/B contractors): Program Transmittal and MLN Matters article

b. Medicare Advantage (MA) Organizations (Part C contractors):
Health Plan Management System (HPMS) memorandum and MLN
Matters article

c. Part A/B Qualified Independent Contractors (QICs): MLN Matters article

d. Part C QIC/Independent Review Entity (IRE): MLN Matters article

e. Quality Improvement Organizations (QIOs, formerly PROs):Transmittal of Policy Systems (TOPS) memorandum and MLN Matters article

f. Recovery Audit Contractors (RACs): Program Transmittal and MLN Matters article

g. Administrative Law Judges (ALJs): MLN Matters article will be distributed to the Chief Administrative Law Judge for dissemination to the ALJs.

h. Medicare Appeals Council: MLN Matters article will be distributed to the Chair of the Departmental Appeals Board for dissemination to the Administrative Appeals Judges.

 Providers and suppliers: MLN Matters article to be distributed by the MACs, MA contractors, and CMS via listservs to subscribed providers.

j. Subscribers to CMS listservs: MLN Matters article

k. 1-800 MEDICARE Scripts: CMS will revise relevant 1-800
 MEDICARE customer service scripts as necessary to ensure consistency with the revised manual provisions

11. CMS will include an accompanying message with the distribution of the MLN Matters article stating that the article was prepared and is being distributed as a result of this Settlement Agreement.

12. CMS will afford Plaintiffs' Counsel 21 days to review and provide a single set of written comments on the written educational materials created as part of settlement before the materials are finalized and issued. CMS 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. If Plaintiffs request, CMS will also afford Plaintiffs' Counsel a second opportunity for review and comment on these written educational materials before they are finalized and disseminated: Plaintiffs' Counsel will have 14 days to review any subsequent changes made and either provide a second set of written comments or communicate its comments at a meeting between counsel. CMS 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. CMS shall retain final authority as to the ultimate content of the written educational materials. CMS,

through counsel, agrees to tell Plaintiffs' Counsel (through Plaintiffs' Lead Counsel) when the written educational materials have been distributed.

13. In providing any set of recommendations described in paragraph 12 above, Plaintiffs agree to collect all recommendations into one consolidated document to be provided by Plaintiffs' Lead Counsel.

14. Other educational initiatives:

a. National Call for providers & suppliers: CMS will conduct a
National Call for providers and suppliers for the sole purpose of
communicating the policy clarifications reflected by the manual revisions
agreed to as part of this Settlement Agreement as detailed in Sections IX.6
through IX.8. An audio and written transcript of the call will be made
available on the CMS website, www.CMS.gov, for those providers and
suppliers unable to attend the call.

b. National Call for contractors & adjudicators: CMS will conduct a National Call for contractors, ALJs, medical reviewers, and agency staff to communicate the policy clarifications reflected by the manual revisions agreed to as part of this Settlement Agreement as detailed in Sections IX.6 through IX.8. Following this National Call, CMS will provide all contractors and adjudicators invited to the call a summary of the call, consisting of a copy of the PowerPoint slides presented and the summary prepared by CMS of the questions posed and answers provided during this National Call.

c. For both National Calls, CMS will prepare a deck of PowerPoint slides to assist in communicating the policy clarifications reflected by the manual revisions. Before these slides are finalized, CMS will afford Plaintiffs' Counsel at least 7 days to review and provide a single set of written comments on the slides. CMS will take any recommendations from Plaintiffs' Counsel under advisement and will make a good faith effort to utilize in the final presentation 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. CMS shall retain final authority as to the ultimate content of these PowerPoint slides. In providing any set of recommendations described in this paragraph, Plaintiffs agree to collect all recommendations into one consolidated document to be provided by Plaintiffs' Lead Counsel.

d. Open Door Forum (ODF):

Following the issuance of the manual revisions made pursuant to this Settlement Agreement, CMS will include an announcement of the manual revisions and a reference to the above-described National Call for providers and suppliers as agenda items for a Home Health, Hospice, and Durable Medical Equipment ODF, a Hospital ODF, a Physicians, Nurses and Allied Health Professionals ODF, and a Skilled Nursing Facilities/Long-Term Care ODF. Following the issuance of the manual revisions, CMS

will also include an announcement of the manual revisions as an agenda item for a Medicare Beneficiary ombudsman ODF.

e. CMS will post the Program Transmittal and MLN Matters article on CMS's website, <u>www.CMS.gov</u>. CMS will inform Plaintiffs' Lead Counsel when the Program Transmittal is issued.

15. CMS will make a good faith effort to notify Plaintiffs' Lead Counsel, in advance of the National Calls and Open Door Forums described above in Section IX.14 to be held to carry out the educational campaign provided in the settlement agreement. Plaintiffs and Plaintiffs' Counsel will be permitted to attend the Open Door Forums and the National Call for providers and suppliers described above in Section IX.14. Following the National Call for contractors and adjudicators described above in Section IX.14.b, CMS, through counsel, will provide to Plaintiffs' Counsel (1) a certification that this National Call occurred; (2) a certification that guidance was given consistent with the PowerPoint slides described in Section IX.14.c and the manual revisions revised as part of this Settlement Agreement as set forth in Sections IX.6 through IX.8; (3) a certification that any questions from contractors or adjudicators were answered consistent with those manual revisions; and (4) a summary prepared by CMS of the questions posed and answers provided during this National Call.

16. CMS agrees to finalize and issue the revised manual provisions and to carry out the educational campaign provided by the settlement agreement within one year of the Approval Date.

Accountability Measures

Claims Review

17. CMS will engage in the following measures:

a. Sampling of QIC Decisions: CMS will develop protocols for reviewing a random sample of SNF, HH, and OPT coverage decisions by the QICs (for claims under Parts A, B, and C) under the SNF, HH, and OPT maintenance coverage standards set forth above in Sections IX.6 through IX.7 to determine overall trends and any problems in the application of these maintenance coverage standards. CMS will make a reasonable effort to draw the random sample of QIC decisions to reflect claims initially decided by a representative cross-section of contractors and MA Organizations. Plaintiffs' Counsel may provide suggestions to CMS as to how to identify appropriate claims for sampling, e.g., through target diagnosis codes.

b. CMS will provide updates to Plaintiffs' Counsel regarding the results of this random sampling during the bi-annual meetings referenced below in Section IX.17.f, beginning with the first meeting following completion of the educational campaign (which will be the second of the five bi-annual meetings). CMS's obligation to conduct sampling of QIC decisions as described above in Section IX.17.a pursuant to this Settlement Agreement terminates with the results reported at the fifth and final of the bi-annual meetings.

c. For any QIC decision from the random sample in which CMS finds reason to believe an error was made in applying the correct SNF, HH, and OPT maintenance coverage standards as set forth in Sections

IX.6 and IX.7, CMS will contact the QIC to determine whether an error was made. For those decisions in which an error by the QIC is confirmed, CMS will direct, or request if the agency does not have authority to direct, the QIC to correct its error.

d. If the random sampling indicates that a particular Medicare
contractor or MA organization is not applying the correct SNF, HH, and
OPT maintenance coverage standards as set forth in Sections IX.6 and
IX.7, CMS will address this issue directly with that entity. The manner in
which CMS addresses the issue will be within its discretion.

e. Review of Individual Claims Determinations: To address any individual beneficiary claims determinations that Plaintiffs believe were not decided in accordance with the SNF, HH, and OPT maintenance coverage standards as set forth above in Sections IX.6 and IX.7, CMS will agree to review and address individual claims determinations as follows:

> During the bi-annual meetings referenced below in Section IX.17.f, Plaintiffs will present CMS (through Plaintiffs' Lead Counsel) individual claims determinations it believes were not decided in accordance with the SNF, HH, and OPT maintenance coverage standards as set forth in Sections IX.6 and IX.7. The total number of such individual claims determinations Plaintiffs' Counsel presents over the course of all bi-annual meetings is not to exceed 100.

- 2. CMS will direct, or request if the agency does not have authority to direct, the pertinent Medicare contractors or MA Organizations to review and evaluate these claims and related documentation. If the review of such claims indicates that a particular Medicare contractor or MA organization is not applying the correct SNF, HH, and OPT maintenance coverage standard as set forth in Sections IX.6 and IX.7, CMS will address this issue directly with that entity. The manner in which CMS addresses the issue will be within its discretion. Workload permitting, CMS will provide updates to Plaintiffs' Lead Counsel regarding the action taken on these cases during the subsequent bi-annual meeting referenced below in Section IX.17.f, provided that CMS receives proper authorization from the beneficiary.
- f. Bi-Annual Meetings: CMS will meet with Plaintiffs' Counsel on a biannual basis to discuss the results of the sampling of claims data and the agency's review of the individual claims determinations as discussed above in Sections IX.17.a-b and IX.17.e. The meetings can also be used to bring any issues related to the settlement to the agency's attention. The first of these meetings will take place following the issuance of the revised manual provisions and prior to the completion of the educational

campaign, and meetings will continue on a bi-annual basis thereafter for a total of five (5) meetings.

18. 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.

X. ATTORNEY'S FEES

Defendant agrees to pay reasonable and appropriate attorney's fees, costs, and expenses related to work performed by Plaintiffs' Counsel in the litigation and settlement of this matter up until the Approval Date, subject to appropriate documentation and exercise of business judgment by Plaintiffs and Plaintiffs' Counsel, pursuant to the Equal Access to Justice Act. For work performed by Plaintiffs' Counsel after the Approval Date, Defendant agrees to pay reasonable and appropriate attorney's fees, costs, and expenses only for the post-Approval Date work specified in this Settlement Agreement, to be capped at \$300,000, subject to appropriate documentation and exercise of business judgment by Plaintiffs and their attorneys and pursuant to the Equal Access to Justice Act. However, if Plaintiffs initiate proceedings to enforce this Settlement Agreement, as described above, and if the Court finds that Defendant has not complied with the Settlement Agreement, Plaintiffs reserve the right to seek the payment of additional fees, costs, and expenses in connection with that enforcement proceeding that will not be subject to the above cap. Plaintiffs' Lead Counsel may submit request(s) for post-Approval fees to Defendant's Counsel for periods no less than 12 months in length, except for the last period if one or more earlier periods has been for more than 12 months.

In the event that the parties are unable to agree upon the amount of fees, Plaintiffs may retain the right to file a fee petition with the Court. Notwithstanding their agreement to limit any post-Approval attorney's fees, costs, and expenses to the above fee cap, Plaintiffs and Plaintiffs' Counsel object to the principle of a fee cap and reserve their right to object to such a cap in future cases.

XI. CLASS CERTIFICATION AND RELIEF

Class Definition

 Defendant will stipulate to the certification of a class pursuant to Federal Rule of Civil Procedure 23(b)(2) consisting of all Medicare beneficiaries who:

- a. received skilled nursing or therapy services in a skilled nursing facility, home health setting, or outpatient setting; and
- b. received a denial of Medicare coverage (in part or in full) for those services described in the previous paragraph based on a lack of improvement potential in violation of the SNF, HH, or OPT maintenance coverage standards as defined above in section Sections IX.6 and IX.7 and that denial became final and non-appealable on or after January 18, 2011; and

c. seek Medicare coverage on his or her own behalf; the definition of class members specifically excludes providers or suppliers of Medicare services or a Medicaid State Agency.

Re-Review Relief for Certain Members of the Class

2. Certain members of the class are eligible for re-review of the claim denials described above in Section XI.1.b, if the following requirements are met:

a. The services described above in Section XI.1.a that are the subject
of the denial described above in Section XI.1.b must not have been
covered or paid for by any third-party payer or insurer or Medicare, except
in the case of an individual Medicare beneficiary whose services were
paid for by Medicaid and who paid for the service or is personally or
financially liable or subject to recovery for the services; and

b. There must not have been a basis for the denial of the claim for Medicare coverage that was separate and independent from the alleged failure to apply the SNF, HH, or OPT maintenance coverage standards as defined above in Sections IX.6 and IX.7. A separate and independent basis for denial would include the failure to satisfy any procedural requirement, any Medicare eligibility requirement, or any threshold requirement for coverage, but a conclusory determination that services were not "reasonable and necessary," were not "medically necessary," or that coverage is denied using other conclusory, non-specific language, that may be based on a failure to apply the SNF, HH, or OPT maintenance coverage standards as defined in Sections IX.6 and IX.7 above would not be such a separate and independent basis for denial.

3. Claim denials described in Section XI.1.b that become final and nonappealable after the End of the Educational Campaign are not eligible for re-review under this Section (XI).

4. Claims of class members other than of the Named Plaintiffs that are currently the subject of any lawsuit pending in an Article III United States Court or have been the subject of a final, non-appealable judgment by such courts are not eligible for rereview under this Section (XI).

5. Only class members on their own behalf may receive re-review of claims under this section. No provider or supplier of Medicare services or Medicaid State Agency is permitted to receive re-review under this section on behalf of or by assignment from a class member.

6. Class members who are eligible for re-review of claim denials will be partitioned into two groups.

a. Group 1 consists of all class members who received a final, nonappealable denial of Medicare coverage (in part or in full) where that denial became final and non-appealable after January 18, 2011 and up to and including the Approval Date.

b. Group 2 consists of all class members who received a final, nonappealable denial of Medicare coverage (in part or in full) from the day after the Approval Date through and including the End of the Educational Campaign.

7. Group 1 class members seeking re-review relief as set forth in this Section (XI) will be required to identify themselves and their final, non-appealable denials to CMS no later than six (6) months after the End of the Educational Campaign. Group 2 class members seeking re-review relief as set forth in this Section (XI) will be

required to identify themselves and their final, non-appealable denials to CMS no later than twelve (12) months after the End of the Educational Campaign.

8. For each Group 1 or 2 class member who identifies himself or herself to CMS within the specified timeframe for re-review as set forth in the previous paragraph, the agency will direct, or request if the agency does not have the authority to direct, the contractor or adjudicator who last denied the class member's claim for Medicare coverage to re-review the claim under the clarified maintenance coverage standards set forth above in Sections IX.6 and IX.7, subject to the exceptions described above in Sections XI.4 and XI.5.

9. When results of the re-review process confirm that the claim was denied in error and that the care should have been covered by Medicare, the agency will reimburse for that care, or, if the agency does not have the authority to reimburse, request reimbursement for the class member for that care, subject to applicable Medicare reimbursement limits.

10. Within 10 days of Approval of this Settlement Agreement, Defendant will inform Plaintiffs' Lead Counsel of the process, including to whom class members should identify themselves (pursuant to Section XI.7 through XI.8), by which class members should identify themselves in order to obtain re-review.

11. Within 30 days after the End of the Educational Campaign, Plaintiffs' Lead Counsel shall provide Defendant with the final claim denial that Ms. Jimmo received that is at issue in this lawsuit. Defendant shall promptly process Ms. Jimmo's claim under the re-review process as set forth in Section XI.2 through XI.10. Defendant

shall make a good faith effort to issue a final decision on Ms. Jimmo's claim, if appropriate, as soon as practicable.

XII. COMPLIANCE WITH LEGAL AUTHORITY

The parties recognize that Defendant is required to comply with applicable statutes and regulations, including any future revisions to the statutes and regulations that govern Medicare coverage, and that nothing in this Settlement Agreement shall prohibit Defendant from modifying its policies and procedures to comply with any relevant statutory or regulatory changes, even if such modifications are made during the period of the Court's continuing jurisdiction under this Settlement Agreement, or from otherwise changing Defendant's regulations in a manner consistent with the Administrative Procedure Act. If Plaintiffs' Counsel believes that any such modifications to Defendant's policies and procedures, such as the Medicare Benefits Policy Manual, are not authorized by any statutory or regulatory changes, and that any such modifications would constitute a breach of any of the provisions of this Settlement Agreement, they reserve the right to initiate the Dispute Resolution process in Section VIII.

XIII. RELEASE

1. In consideration for the promises of Defendant as set forth in this Settlement Agreement, the Named Plaintiffs and all Class Members, and their heirs, administrators, successors, or assigns (together, the "Releasors"), hereby release and forever discharge Defendant and the United States Department of Health and Human Services (HHS), along with Defendant's and HHS's administrators, successors, officers, employees, and agents (together, the "Releasees") from any and all claims and causes of action that have been asserted or could have been asserted in this action by reason of, or

with respect to, Plaintiffs' allegations that Defendant has illegally applied, or has failed to properly prevent the application of, an Improvement Standard under which Medicare coverage of skilled services is denied on the basis that a Medicare beneficiary is not improving, without regard to an individualized assessment of the beneficiary's medical condition and the reasonableness and necessity of the treatment, care or services in question.

2. The above release shall not affect the right of any Class Member to seek any and all individual relief that is otherwise available in satisfaction of an individual claim against Defendant for Medicare benefits that is not based upon the allegations set forth in Section XIII.1 above.

3. The above release also shall not affect Plaintiffs' or any Class Member's right, if any, to bring a separate lawsuit challenging any new policy or procedure that is adopted by Defendant after the end of the Court's jurisdiction over this Settlement Agreement, as described in Section VI. Plaintiffs and Class Members will have no right to claim that such a change in policies or procedures violates the Settlement Agreement, but do not waive any right to claim that the new policy or procedure violates the Social Security Act, Defendant's regulations, or any other provision of law.

XIV. NO ADMISSION OF LIABILITY

Neither this Settlement Agreement nor any order approving this Settlement Agreement is or shall be construed as an admission by Defendant of the truth of any of the allegations set forth in the First Amended Complaint or the validity of the claims

asserted in the First Amended Complaint, or of Defendant's liability for any of those

claims.

The undersigned representatives of the parties certify that they are fully authorized to consent to the Court's entry of the terms and conditions of this Settlement Agreement.

Dated: October 16, 2012

<u>/s/ Judith Stein (by permission)</u> JUDITH STEIN Executive Director Center for Medicare Advocacy, Inc. P.O. Box 350 Willimantic, CT 06226 jstein@medicareadvocacy.org (860) 456-7790 Fax: (860) 456-2614

Dated: October 16, 2012

/s/ Gill Deford (by permission)

GILL DEFORD Director of Litigation Center for Medicare Advocacy, Inc. P.O. Box 350 Willimantic, CT 06226 gdeford@medicareadvocacy.org (860) 456-7790 Fax: (860) 456-2614

Dated: October 16, 2012

<u>/s/ Michael Benvenuto (by permission)</u> MICHAEL BENVENUTO Director, Medicare Advocacy Project Vermont Legal Aid 264 North Winooski Avenue Burlington VT, 05402 <u>mbenvenuto@vtlegalaid.org</u> (802) 863-5620

DAVID J. BERGER MATTHEW R. REED Wilson Sonsini Goodrich & Rosati 650 Page Mill Road Palo Alto, CA 94304 <u>DBerger@wsgr.com</u> (650) 493-9300 Fax: (650) 493-6811

Counsel for Plaintiffs

Dated: October 16, 2012

STUART F. DELERY Acting Assistant Attorney General TRISTRAM J. COFFIN United States Attorney

SHEILA M. LIEBER Deputy Director, Federal Programs Branch

<u>/s/ Steven Y. Bressler</u> STEVEN Y. BRESSLER (D.C. Bar #482492) M. ANDREW ZEE (CA Bar #272510) Attorneys Federal Programs Branch U.S. Department of Justice, Civil Division 20 Massachusetts Avenue NW Washington, DC 20530 Telephone: (202) 305-0167 Fax: (202) 616-8470 Email: <u>Steven.Bressler@usdoj.gov</u>

Counsel for Defendant