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DHHS AGREES TO PROPOSED SETTLEMENT: THE IMPROVEMENT STANDARD

On October 16, 2012, the Department of Health and Human Services ("DHHS") agreed to a proposed settlement of a lawsuit that was filed in January 2011 by the Center for Medicare Advocacy ("CMA") and the Vermont Legal Aid ("VLA"). The lawsuit, *Jimmo v. Sebelius*, No. 5:11-cv-00017 (D.C.Vt. Jan. 18, 2011), which was filed on behalf of a nationwide class of Medicare beneficiaries,[1] involved the alleged application by the Centers for Medicare & Medicaid Services ("CMS") of the "Improvement Standard," which the plaintiffs alleged resulted in the denial of coverage of certain skilled nursing and therapy services provided to Medicare beneficiaries who had medical conditions that were not expected to improve. The proposed settlement, which, if approved by the U.S. District Court for the District of Vermont, could potentially affect thousands of beneficiaries, as more specifically discussed below.

The *Jimmo* Case & the Improvement Standard

As noted above, the *Jimmo* case was brought on behalf of a class of Medicare beneficiaries who had been provided with skilled nursing and/or therapy in hospital outpatient departments, skilled nursing facilities, or in the home health setting. According to the Complaint,[2] these beneficiaries had such services denied, terminated, or reduced, including "by employees of Medicare contractors and intermediaries who [ignored] the correct coverage standards," and applied a "rule of thumb" referred to as the Improvement Standard. The Improvement Standard, the plaintiffs alleged, is "a covert rule of thumb" that is not supported by the Medicare statute or regulations, and operates as an additional condition of eligibility which effectively denies beneficiaries coverage of certain skilled services. It does this, according to the Complaint, by, among other things, failing to make assessments regarding a beneficiary's "unique condition and individual needs," and by relying not on the Medicare statute, regulations and manuals, but by relying on "more restrictive internal guidelines, policies, and local coverage determinations ("LCDs"). These more restrictive guidelines, policies, and LCDs, according to the Complaint, require that a beneficiary's condition must be expected to "improve significantly in a reasonable and generally predictable period of time." The plaintiffs alleged that the application of this Improvement Standard is, in effect, an additional condition of eligibility, "which is usually implemented at the lower levels of Medicare's administrative review process," and is contrary to the Medicare statute, regulations, and manuals. In addition, the plaintiffs alleged that the Secretary of DHHS ("Secretary") "condoned and implemented" the Improvement Standard which, the plaintiffs argued, amounted to a "clandestine policy."

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[1] The Complaint for Declaratory, Injunctive, and Mandamus Relief was filed by CMA and VLA originally on behalf of five individually named beneficiaries in the states of Connecticut, Maine, Rhode Island, and Vermont, and five national organizations, including the National Committee to Preserve Social Security and Medicare, National Multiple Sclerosis Society, Parkinson's Action Network, Paralyzed Veterans of America, and American Academy of Physical Medicine and Rehabilitation. Pursuant to the amended complaint (referenced hereinbelow), an additional beneficiary from the state of Pennsylvania, and two national organizations, Alzheimer's Disease and Related Disorders Association, Inc. d/b/a Alzheimer's Association, and United Cerebral Palsy, were added as plaintiffs.

[2] As noted, the Complaint for Declaratory, Injunctive, and Mandamus Relief was filed on October 18, 2011. Plaintiff's First Amended Complaint for Declaratory, Injunctive and Mandamus Relief was filed on March 3, 2011. The Complaint and First Amended Complaint will be referred to collectively herein as the "Complaint."

To support their argument, the plaintiffs noted in their Complaint that the federal regulations for coverage in skilled nursing facilities ("SNFs") states that "the restoration potential of a patient is not the deciding factor in determining whether skilled services are needed. Even if full recovery or medical improvement is not possible, a patient may need skilled services to prevent further deterioration or preserve current capabilities."[3] Further, the plaintiffs noted that the Medicare Benefit Policy Manual ("MBPM"), Chapter 7 – Home Health Services, states that determinations of whether skilled services are reasonable and necessary must be based on an assessment of each individual's care need for such services. In addition, the MBPM provides that " . . . denial of services based on numerical utilization screens, diagnostic screens, diagnosis, or specific treatment norms is not appropriate."[4] The plaintiffs alleged, however, that, despite provisions such as these, "lower level decision-makers . . . rarely follow these regulatory and MBPM prohibitions against the Improvement Standard."

The plaintiffs alleged that the application of the Improvement Standard violates the Medicare statute and regulations, as well as the notice-and-comment provisions of the Administrative Procedure Act, the publication requirement of the Freedom of Information Act, and the Due Process Clause of the Fifth Amendment. Accordingly, the plaintiffs requested that the District Court, among other things, declare that the Secretary's application of the Improvement Standard violates such laws, and requested that the Court grant a permanent injunction prohibiting the application of the Improvement Standard. The plaintiffs also requested that the Court certify the lawsuit as a class action.

DHHS' Motion to Dismiss

On or about April 11, 2011, the Secretary of DHHS filed a "Motion to Dismiss for Lack of Subject Matter Jurisdiction or, in the Alternative, Motion for Failure to State a Claim Upon Which Relief May be Granted." In its motions, the Secretary argued that the Court lacked jurisdiction to review the matter for a number of reasons. For example, the Secretary argued that certain plaintiffs failed to exhaust their administrative remedies, while other plaintiffs lacked standing to bring suit. In addition, the Secretary argued that the plaintiffs' Complaint failed to contain sufficient factual allegations to support a plausible claim for relief. In particular, the Secretary contended that while all of the claims in the Complaint relied on the Secretary's alleged use of the Improvement Standard, it could not be inferred from the alleged facts that the Improvement Standard even exists.

In an "Opinion and Order Denying in Part and Granting in Part Defendant's Motion to Dismiss for Lack of Subject Matter Jurisdiction and Denying Defendant's Motion to Dismiss for Failure to State a Claim," the District Court largely denied the Secretary's motions.[5] The District Court, among other things, rejected the Secretary's arguments regarding exhaustion of administrative remedies and standing and determined that the Court had jurisdiction over the matter. The Court also held that the plaintiffs had, in fact, stated a claim upon which relief may be granted and accordingly denied the Secretary's Motion to Dismiss for failure to state a claim. Interestingly, the Court also stated that it "cannot conclude as a matter of law that plaintiffs' Improvement Standard theory is factually implausible when it is supported by at least *some* evidence in

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[3] *See,* 42 C.F.R. §409.32(c).

[4] *See*, Internet Only Manual (IOM) 100-02, Medicare Benefit Policy Manual, Ch. 7, §20.3, "Use of Utilization Screens and 'Rules of Thumb'." *See also,* Medicare Benefit Policy Manual, Ch. 7, §40.2.

[5] The Court dismissed one beneficiary plaintiff for failing to satisfy the "presentment" requirement of 42 U.S.C. §405(g), and one organizational plaintiff for lack of standing

each of the individual plaintiffs' cases and where other plaintiffs have successfully demonstrated the use of illegal presumptions and rules of thumb much like plaintiffs allege here."

Proposed Settlement Agreement

As noted above, on October 16, 2012, the Secretary of DHHS and the plaintiffs agreed to a proposed settlement ("Settlement"). Although in the Settlement, the Secretary denied the existence of the Improvement Standard, and explicitly did not admit any of the allegations set forth in the Complaint, the validity of the claims asserted in the Complaint, or its liability for such claims, it agreed to the following:

- CMS will revise the relevant portions of Chapters 7, 8, and 15 of the MBPM to clarify the coverage standards for the skilled nursing facility ("SNF"), home health ("HH"), and outpatient therapy ("OPT") benefits. More specifically, MBPM revisions will:
    - Clarify that (1) 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, and that (2) 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; and
    - Clarify that an IRF claim could never be denied either because a patient could not be expected to achieve complete independence in the domain of self-care or because a patient could not be expected to return to his or her prior level of functioning.
- CMS will engage in a nationwide educational campaign, using written materials, interactive forums, and national calls to communicate the SNF, HH, and OPT maintenance coverage standards and the IRF coverage standards. The educational campaign will be directed to include, among others, contractors, adjudicators, and providers and suppliers.
- CMS will develop protocols for reviewing a random sample of SNF, HH, and OPT coverage decisions by the Qualified Independent Contractors ("QICs") (for claims under Parts A, B, and C) under the SNF, HH, and OPT maintenance coverage standards. These random samples will be used to determine overall trends and any problems in the application of the maintenance coverage standards. CMS will address any issues that arise.
- A class will be certified consisting of all Medicare beneficiaries who (a) received skilled nursing or therapy services in a SNF, HH, or OPT, (b) received a denial of Medicare coverage (in part or in full) for those services based on a lack of improvement potential in violation of the SNF, HH, or OPT maintenance coverage standards (as set forth above) 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.

If the Settlement is approved by the Court, which could take several months, it is expected to help Medicare beneficiaries who have conditions such as Parkinson's Disease, Multiple Sclerosis, and Alzheimer's Disease, which conditions are not expected to improve, obtain coverage for certain skilled nursing, and therapy services. According to a *New York Times*

article,[6] it is unclear how much the settlement might cost the government. Further, the article states that Dr. Lynn Gerber, Director of the Center for Study of Chronic Illness and Disability at George Mason University in Virginia, called the Settlement "a landmark decision for Medicare recipients with chronic illness and especially those with disability."

Please note that this article is meant to provide a brief overview of certain key documents in this matter. Should you have any questions concerning the subject matter of this article, please feel free to contact Lynn M. Barrett, Esq. at lbarrett@joneswalker.com.

—Lynn M. Barrett

[6] *See*, Pear, R. (Oct. 22, 2012) *Settlement Eases Rules for Some Medicare Patients*. *The New York Times*. Retrieved from: http://www.nytimes.com/2012/10/23/us/politics/settlement-eases-rules-for-some-medicare-patients.html

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