American Journal of Law & Medicine, 40 (2014): 7-25

Jimmo and the Improvement Standard: Implementing Medicare Coverage Through Regulations, Policy Manuals and Other Guidance

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In Jimmo v. Sebelius*, the plaintiffs alleged that the Centers for Medicare and Medicaid Services (CMS) regularly and improperly denied Medicare reimbursement for outpatient therapy treatment when the beneficiary did not show a likelihood of improvement. These denials, based on policy manuals and other guidance, appear to contradict the government's own regulations, which specifically prohibit coverage denials based solely on the so-called "Improvement Standard." In* Jimmo*, the United States District Court for the District of Vermont found that CMS' use of the Improvement Standard may have violated the rulemaking provisions of the Administrative Procedure Act (APA) and denied CMS' motion for summary judgment. Subsequently, the parties settled out of court.*

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In the settlement, CMS agreed to revise its policy manuals to clarify that the Improvement Standard was not an acceptable basis on which to deny Medicare coverage. CMS declined to defend its policies even though courts often grant deference to agency interpretations. The settlement implies that the agency feared that it would not have received such deference. It also implies that future Supreme Court decisions may give less deference to agency interpretations.

I. INTRODUCTION

Subject to some exceptions such as hospice care, Medicare covers and pays only for services that are medically necessary, defined as "reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member."[1] However, determining what is "reasonable and necessary" is not always easy. As a result, the Centers for Medicare and Medicaid Services (CMS), the administrative agency within the U.S. Department of Health and Human Services (HHS) that runs the Medicare program, often issues national coverage decisions (NCDs) on specific medical procedures.[2] Because CMS cannot evaluate every possible medical situation, it delegates the ability to make local coverage decisions (LCDs) to Medicare Administrative Contractors (MACs) to ensure that covered services are medically necessary.[3] CMS has also issued policy guidance in the form of Medicare Policy Manuals to guide MACs in the general processing of medical claims to ensure medical necessity.[4]

It is through this delegation to third-party MACs that the plaintiffs in *Jimmo v. Sebelius*[5] asserted that CMS promoted an implicit policy of requiring improvement, which was inconsistent with the promulgated regulations.[6] The plaintiff class alleged that the LCDs inappropriately limited the scope of "medical necessity" without providing the notice and comment period required under both the Medicare statute[7]

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[1] 42 U.S.C. § 1395y(a)(1)(A) (2006); *see, e.g.,* Hays v. Sebelius, 589 F.3d 1279 (D.C. Cir. 2009) (discussing medical necessity and the Secretary's ability to pay for certain drugs); Mount Sinai Hosp. of Greater Miami, Inc., v. Weinberger, 425 F. Supp. 5 (S.D. Fla. 1976) (holding that the Secretary of Health, Education and Welfare may not pay for Medicare services that are medically unnecessary).

[2] 42 U.S.C. § 1395y(a); *see also* Eleanor D. Kinney, *National Coverage Policy Under the Medicare Program: Problems and Proposals for Change*, 32 ST. LOUIS U. L.J. 869, 971 (1988) (arguing that CMS should develop a better administrative process including publication to better "promote the entitlement interest of Medicare beneficiaries . . . over the achievement of other goals," such as efficiency). For a high-level discussion of national and local coverage decisions in the outpatient therapy context, see MEDICARE PAYMENT ADVISORY COMM'N, REPORT TO THE CONGRESS: MEDICARE AND THE HEALTH CARE DELIVERY SYSTEM 237 (2013), *available at* http://www.medpac.gov/documents/Jun13_EntireReport.pdf.

[3] *See* 42 U.S.C. § 1395kk-1 (containing the statutory authority for CMS to contract with MACs); *see also* Erringer v. Thompson, 371 F.3d 625 (9th Cir. 2004) (upholding an LCD as interpretative guidance not subject to notice and comment rulemaking); Almy v. Sebelius, 749 F. Supp. 2d 315 (D. Md. 2010) (holding that the MAC's LCD process was a legitimate interpretation of Medicare coverage), *aff'd* 679 F.3d 297 (2012), *cert. denied*, 133 S. Ct. 841 (2013). LCDs account for a large portion of medical necessity determinations. In October 2011, over half of Part B procedure codes were subject to an LCD in one or more States. *See* OFFICE OF INSPECTOR GEN., OEI-01-11-00500, LOCAL COVERAGE DETERMINATIONS CREATE INCONSISTENCY IN MEDICARE COVERAGE (Jan. 2014), http://oig.hhs.gov/oei/reports/oei-01-11-00500.pdf.

[4] *See, e.g.*, *Medicare Benefit Policy Manual*, CTRS. FOR MEDICARE & MEDICAID SERVS., http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Internet-Only-Manuals-IOMs-Items/CMS012673.html?DLPage=1&DLSort=0&DLSortDir=ascending (last visited Jan. 30, 2013).

[5] No. 5:11-cv-17, 2011 WL 5104355 (D. Vt. Oct. 25, 2011).

[6] *Id.* at *1-2.

[7] *Id.*; *see also* 42 U.S.C. § 1395hh(a)(2). Except for NCDs, this provision prohibits CMS from issuing a rule that "establishes or changes a substantive legal standard governing the scope of benefits,

and the Administrative Procedure Act (APA).[8] By permitting MACs to consider costs in making coverage decisions, CMS was effectively able to control costs in direct contravention of its statutory delegation of authority.[9]

Part II of this Article reviews the regulatory status of Medicare's coverage of skilled services, including outpatient therapy services such as physical therapy, occupational therapy, and speech-language pathology services. It looks at CMS's use of informal policy guidance through the MACs to more narrowly determine medical necessity in these coverage decisions. Part III discusses the administrative law principles that guide courts in their construction of agency-promulgated regulations and informal policy guidance. Part IV lays out the facts of *Jimmo*, including the application of the Improvement Standard. In light of the regulations promulgated by CMS's statutory authority, this section discusses the level of deference the Policy Manuals and MAC's LCDs should receive. It then turns to the settlement agreement in *Jimmo* to explain how the agency violated these principles in issuing subsequent guidance to third parties. Part V explores whether the injunctive relief that plaintiffs received will expand Medicare coverage in practice and discusses some of the budgetary and political ramifications that the settlement agreement will have for Medicare and Medicaid.

The Article concludes that while the *Jimmo* settlement represents a sizeable victory for beneficiaries and providers, it is also another hurdle for a program whose costs have historically been difficult to control. By permitting MACs to consider costs in making coverage decisions, CMS is effectively able to control costs in direct contravention of its statutory delegation. The settlement in *Jimmo* and the subsequent clarifications to the Policy Manuals close this regulatory loophole and reinforce the requirement that Medicare use an individualized methodology to cover all reasonable and necessary care.

II. MEDICARE'S COVERAGE FOR OUTPATIENT THERAPY SERVICES AND THE IMPROVEMENT STANDARD

Medicare covers therapy services under Part B[10] in the skilled nursing facility (SNF), home health, and physician services settings, with separate regulations,

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the payment of services, or the eligibility of individuals . . . [to] receive benefits under this subchapter . . . unless it is promulgated by the Secretary" under notice and comment rulemaking.

[8] 5 U.S.C. § 553 (2012); *see also infra* Part III.

[9] *See, e.g.*, Jacqueline Fox, *Medicare Should, But Cannot, Consider Cost: Legal Impediments to a Sound Policy*, 53 BUFF. L. REV. 577 (2005). In the 1980s, the introduction of end-stage renal disease coverage led to exploding costs to Medicare. In response, the agency issued a policy guidance requiring beneficiaries seeking heart transplants to meet certain criteria. One of those criteria was an age requirement: no beneficiary over sixty-five would be eligible for a heart transplant. The agency deemed the benefit of a new heart to someone over sixty-five would not outweigh the cost. This change was administered through policy guidance, rather than the rulemaking process. This acted as a covert way for the agency to consider costs in its coverage decision while not explicitly saying it was doing so. *Id.*

[10] The Medicare program reimburses healthcare claims under Part A (primarily for inpatient care, such as hospital and SNF stays), and Part B (for professional care, such as services provided by physicians, therapists, and skilled nurses, which are generally outpatient services). This distinction is important because separate reimbursement schemes exist for each part. Notably, Part A is financed through a payroll tax on American workers which goes into a trust fund. Part B is financed by about twenty-five percent of Medicare beneficiaries' premiums, and seventy-five percent by general tax revenues. In 2012, Medicare had 50.7 million beneficiaries and total annual expenditures of $574 billion dollars. *See* THE BDS. OF TRS. OF THE FED. HOSP. INS. & FED. SUPPLEMENTARY MED. INS. TR. FUNDS, 2013 ANNUAL REPORT 6 (2013), http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/ReportsTrustFunds/Downloads/TR2013.pdf.

Policy Manuals, and LCDs governing each setting.[11] One function of Policy Manuals is to further interpret promulgated regulations to aid MACs in making LCDs. This Section reviews each coverage setting and concludes that while the regulations consistently specify an individualized approach, the Policy Manuals and LCDs contain categorical language related to recovery potential that is contrary to the language in the regulations.[12] Themes across settings in the Medicare coverage guidance discussed in this Part include: (1) the therapist must provide skilled services; (2) the patient's diagnosis should not be given significant weight when deciding if therapy is considered a skilled service; (3) skilled services are generally not appropriate for maintaining a level of functioning; and (4) depending on the patient's condition, if there is little chance of improvement, then Medicare will not cover the therapy. It is the ambiguity and inconsistency surrounding this last theme—the Improvement Standard—that was the topic of concern in *Jimmo*.

A. SKILLED NURSING FACILITIES

According to the regulations, the key to having therapy covered in a SNF is that the patient specifically needs skilled services.[13] This means that the therapy must be "so inherently complex that it can be safely and effectively performed only by . . . professional or technical personnel."[14] The SNF regulations clarify that "[t]he 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."[15] This regulatory language makes clear that a rule of thumb must not be used to deny therapy services. Indeed, the regulations specifically state that the restoration potential of a patient should not be outcome determinative.[16]

In contrast, policy guidance appears to lean more toward using a rule of thumb by requiring five specific criteria: (1) the therapy must be directly and specifically related to a written treatment plan; (2) the complexity and sophistication of the therapy must require the skills of the physical therapist; (3) the patient's restoration potential must create an expectation "*that the condition of the patient will improve*

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[11] *See, e.g.*, *Medicare Benefit Policy Manual: Chapter 7—Home Health Services*, CTRS. FOR MEDICARE & MEDICAID SERVS. (last updated Oct. 18, 2013) [hereinafter *Medicare Benefit Policy Manual: Chapter 7*], http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c07.pdf.

[12] This inconsistency in the policy guidance could prevent a court from giving deference to the agency's interpretation in light of the regulations. *See infra* notes 84-88.

[13] 42 C.F.R. § 409.31 (2013). SNFs generally provide services incident to a hospital stay and bill under Part A. *See id.* § 409.20; *Medicare Benefit Policy Manual: Chapter 8—Coverage of Extended Care (SNF) Services*, CTRS. FOR MEDICARE & MEDICAID SERVS., § 10.2 (last updated Oct. 26, 2012) [hereinafter *Medicare Benefit Policy Manual: Chapter 8*], http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c08.pdf. Outpatient services are provided under Part B, but sometimes a physician will refer a patient to an SNF when the skilled services needed cannot be provided in-office or in the patient's home. *See, e.g.*, *Transferring to a Nursing Facility for Kaiser Members*, SAN DIEGO CONTINUING CARE SERVS. DEP'T (last updated Apr. 2009), http://xnet.kp.org/sandiego/ccs/PDFs/Transferring%20to%20a%20Nursing%20Facility.pdf (noting that, under a Kaiser plan, one factor of SNF skilled care eligibility is that care "cannot be provided reasonably safely at a lower level of care, such as through Home Health Services or in an Outpatient Clinic").

[14] 42 C.F.R. § 409.32(a). For an example demonstrating that the need for a therapist's skills determines whether a service is skilled, rather than the patient's diagnosis, see *Medicare Benefit Policy Manual: Chapter 8*, *supra* note 13.

[15] 42 C.F.R. § 409.32(c).

[16] *See id.* § 484.4.

materially in a reasonable and generally predictable period of time" with skilled physical therapy services, or be necessary for a maintenance plan; (4) the skilled physical therapy services must be generally accepted medical practice; and (5) the services must be "reasonable and necessary."[17] This expectation of material improvement in the third criteria is new and does not appear as a coverage requirement in CMS's regulations.

At least one MAC has an LCD that is used in the SNF context that has guidelines for therapy coverage that require improvement as a general rule. Specifically, LCD L26884 provides that coverage of outpatient therapy has two basic requirements:

> (1) There must be an expectation that the patient's condition will improve significantly in a reasonable (and generally predictable) period of time; and
> (2) If an individual's expected rehabilitation potential would be insignificant in relation to the extent and duration of therapy services required to achieve such potential, therapy would not be covered because is not considered rehabilitative or reasonable and necessary.[18]

With respect to maintenance therapy programs, LCD L26884 continues that "[t]he specialized skill, knowledge and judgment of a therapist [only] may be required" in limited circumstances.[19] These limited circumstances include to "design or establish the maintenance program, assure patient safety, train the patient, family members, caregiver, and/or unskilled personnel and make infrequent but periodic reevaluations of the program."[20] Furthermore, "[t]he services of a qualified professional are not necessary to carry out a maintenance program, and are not covered under ordinary circumstances."[21] The LCD anticipates that the patient will perform the maintenance program independently or with unskilled personnel. Services are only to be covered in limited situations in which the patient's safety is at risk (e.g., a hip fracture).

In conclusion, by comparing the SNF therapy regulations with the LCD, it appears that the regulations contemplate more of an individualized decision for each patient based on the facts and circumstances while the LCD seemingly starts with a categorical exclusion of coverage and would permit coverage in more limited circumstances.

B. HOME HEALTH SERVICES

Policy guidance that conflicts with the regulations also appears in the home health setting. CMS's home health regulations generally guide MACs on how to administer the coverage parameters for skilled services by stating that MACs should base the coverage "decision on whether care is reasonable and necessary" and "based on information provided . . . concerning the unique medical condition of the

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[17] *See Medicare Benefit Policy Manual: Chapter 8*, *supra* note 13, § 30.2.2 (emphasis added).

[18] CTRS. FOR MEDICARE & MEDICAID SERVS., L26884, LOCAL COVERAGE DETERMINATION (LCD): PHYSICAL THERAPY—HOME HEALTH (2011), *available at* http://www.cms.gov/medicare-coverage-database/search/advanced-search.aspx (enter L26884 into the document ID search bar; then leave date blank and click search; then select document from results).

[19] *Id.*

[20] *Id.* at 5.

[21] *Id.* at 5.

individual beneficiary."[22] Thus, the regulations contemplate an individualized decision on coverage. The regulations state further that a coverage denial may not be "made solely on the basis of the [MAC] reviewer's general inferences about patients with similar diagnoses or on data related to utilization generally but is based upon objective clinical evidence regarding the beneficiary's individual need for care."[23]

If a patient does not make progress toward his therapy goals, then the therapist and physician should decide whether to continue therapy. If the patient's providers decide care should continue, the patient's medical record must document "with a clinically supportable statement why there is an expectation that the goals are attainable in a reasonable and generally predictable period of time."[24] Under the regulations, coverage for outpatient therapy service would be discontinued on "reasonable and necessary" grounds if the patient's "expected restorative potential would be insignificant in relation to the extent and duration of therapy services required to achieve such potential."[25] The regulations do not say that the patient must improve in order to continue coverage; rather, the regulations direct MACs to make coverage determinations on an individual basis.[26]

As in the SNF setting, CMS provides the MACs with policy guidance to further expand on how to make coverage determinations for home health therapy services in their LCDs and individual cases. At the outset, CMS clarifies in Policy Manual provisions that MACs may not deny services based on "rules of thumb" or on utilization or diagnostic screens.[27] To be "reasonable and necessary" for Medicare coverage, the therapy services must be "consistent with the nature and severity of the illness or injury, the patient's particular medical needs, including the requirement that the amount, frequency, and duration of services must be reasonable" and considered "specific, safe, and effective treatment for the patient's condition."[28] The policy guidance sets forth additional standards that must be met to cover therapy services (e.g., a plan of care) and provides three conditions, one of which must be met for Medicare to cover home health skilled therapy services.[29]

In contrast to the regulations and Policy Manual which require an individualized decision, at least one MAC has used the Improvement Standard language in its guidance to issue an LCD that limits physical therapy in the home health setting in *all* situations when "no further significant practical improvement can be expected."[30] This LCD states that "[p]hysical therapy is not covered when the documentation indicates that a patient has attained the therapy goals or has reached the point where no further significant practical improvement can be expected."

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[22] 42 C.F.R. § 409.44(a) (2013).

[23] *Id.*

[24] *Id.* § 409.44(c)(2)(F)(2).

[25] *Id.* § 409.44(c)(2)(iii)(A)(2).

[26] *Id.* § 409.44(a) ("A coverage denial . . . is based upon objective clinical evidence regarding the beneficiary's individual need for care.").

[27] *Medicare Benefit Policy Manual: Chapter 7*, *supra* note 11 § 20.3.

[28] *Id.* § 40.2.1.a-b.

[29] *Id.* § 40.2.1.d. These three conditions include that a therapist's skills must be needed to restore patient function, a therapist is needed to set a maintenance program, and limited situations exist where skilled services are needed to perform maintenance. *Id.*

[30] *See* CTRS. FOR MEDICARE & MEDICAID SERVS., L32016, LOCAL COVERAGE DETERMINATION (LCD): PHYSICAL THERAPY—HOME HEALTH (2011), *available at* http://www.cms.gov/medicare-coverage-database/search/advanced-search.aspx (enter L32016 into the document ID search bar; then leave date blank and click search; then select document from results).

C. PART B COVERAGE OF OUTPATIENT THERAPY SERVICES

Medicare Part B's Policy Manuals for outpatient therapy services also appear to apply narrower coverage criteria than those in the promulgated regulations. The regulations state that treatment plans "should strive to provide treatment in the most efficient and effective manner, balancing the best achievable outcome with the appropriate resources."[31] Long-term goals need to be "measurable" and relate to "identified functional impairments."[32] MACs are not to use frequency or duration of therapy "alone to determine medical necessity," but should use them along with "other factors such as condition, progress, and treatment type to provide the most effective and efficient means to achieve the patient's goals."[33]

In contrast, the Policy Manual employs a more categorical rule by reminding the MACs that "[t]here must be an expectation that the patient's condition will improve significantly in a reasonable (and generally predictable) period of time, *or* the service must be necessary for the establishment of a safe and effective maintenance program."[34] In some cases, "service may be intermittently necessary to determine the need for assistive equipment and/or establish a program to maximize function."[35]

The regulations, thus, do not require improvement, but the Policy Manual seems to impose such a requirement unless the therapy is part of a maintenance plan. One MAC, Cahaba Government Benefit Administrators LLC, has taken this Improvement Standard a step further in the outpatient therapy context, requiring "*significant* improvement or progress" in order to continue paying for outpatient therapy services under Part B.[36] Another MAC, Novitas Solutions, Inc., states in one of its LCDs that coverage should be limited if:

> evaluation of the patient demonstrates that the patient does not have the potential to achieve significant improvement in, restoration of, and/or compensation for loss of function in a reasonable and generally predictable period of time, or would not benefit from the establishment of a maintenance program, services would not be covered because they would not be considered reasonable and necessary.[37]

These Policy Manuals and LCDs are more similar to categorical non-coverage rules than individualized coverage determinations that the regulations intend.

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[31] *Medicare Benefit Policy Manual: Chapter 15—Covered Medical and Other Health Services,* CTRS. FOR MEDICARE & MEDICAID SERVS., § 220.1.2.B (last updated Jan. 14, 2014) [hereinafter *Medicare Benefit Policy Manual: Chapter 15*], http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c15.pdf.

[32] *Id.*

[33] *Id.*

[34] *Id.* § 220.2.B.

[35] *Id.*

[36] *See* CTRS. FOR MEDICARE & MEDICAID SERVS., L30009, LOCAL COVERAGE DETERMINATION (LCD): MEDICINE: PHYSICAL THERAPY—OUTPATIENT (last revised Sept. 19, 2013) (emphasis added), *available at* http://www.cms.gov/medicare-coverage-database/search/advanced-search.aspx (enter L30009 into the document ID search bar; then leave date blank and click search; then select document from results) ("Physical therapy is not covered when the documentation indicates the patient has not reached the therapy goals and is not making *significant* improvement or progress, and/or is unable to participate and/or benefit from skilled intervention or refused to participate . . . . Physical therapy is not covered when the documentation indicates that a patient has attained the therapy goals or has reached the point where no further *significant* practical improvement can be expected.").

[37] *See* CTRS. FOR MEDICARE & MEDICAID SERVS., L27513, LOCAL COVERAGE DETERMINATION (LCD): PHYSICAL MEDICINE & REHABILITATION SERVICES, PHYSICAL THERAPY AND OCCUPATIONAL THERAPY (last revised June 13, 2013), *available at* http://www.cms.gov/medicare-coverage-database/search/advanced-search.aspx (enter L27513 into the document ID search bar; then leave date blank and click search; then select document from results).

III. IMPLICATIONS FOR MEDICARE COVERAGE: WHICH RULES APPLY?

Even with the ambiguities and inconsistencies between the regulations, Policy Manuals and LCDs, and the application of the Improvement Standard, at least two administrative law doctrines appear to weigh in CMS's favor. Under *Bowles v. Seminole Rock & Sand Co.,* and *Chevron U.S.A., Inc. v. The Natural Resources Defense Council, Inc.*, a court generally gives substantial deference to an agency's interpretation of a statute or of its own regulations. This presents a significant hurdle for a plaintiff challenging agency action.[38] The Vermont District Court's denial of the Secretary's motion to dismiss implies that the agency's actions might not receive such significant deference or might be struck down under the APA or the Due Process Clause.[39]

A. Non-Legislative Rules and *Chevron* Deference

First, it is well recognized that CMS's interpretation of what is "reasonable and necessary" through notice-and-comment rulemaking or adjudicative rulemaking (often termed a legislative rule) is entitled to judicial deference pursuant to *Chevron*.[40] When Congress has implicitly delegated authority to the agency to resolve ambiguities in a statute, a court must accept any reasonable interpretation the agency makes and may not substitute its own interpretation.[41]

The test of validity is two-fold. First, the court must ask if Congress has explicitly spoken on the issue.[42] If the statute is unambiguous, the court and the agency must give effect to the statutory language.[43] If Congress has not specifically spoken on an issue, then there is a gap in the statutory provisions which the agency has the authority to fill.[44] The "reasonable and necessary" provision for Medicare coverage,[45] for instance, does not elaborate on the requirements of that standard. Thus, Congress did not speak to what treatments satisfy "reasonable and necessary" care in its legislation. When Congress has clearly left a gap in the statutory language, it implicitly delegates authority to the relevant agency to clarify those provisions through regulations.[46] If an agency's regulations have undergone the notice-and-comment process, or are otherwise determined not to violate due process, the court must accept them unless they are unreasonable.[47]

Because CMS is charged with administering the Medicare provisions of the Social Security Act, courts "substantially defer to" CMS's "construction of any ambiguous language in the Act, if the Secretary's construction 'is based on a permissible construction of the statute.'"[48] Because medical knowledge is often

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[38] *See* Chevron U.S.A., Inc. v. Natural Res. Def. Council, Inc., 467 U.S. 837, 844 (1984); Bowles v. Seminole Rock & Sand Co., 325 U.S. 410, 414 (1945).

[39] *See* Jimmo v. Sebelius, No. 5:11–CV–17, 2011 WL 5104355, at *22 (D. Vt. Oct. 25, 2011).

[40] *Chevron*, 467 U.S. at 843-44. For a discussion of legislative and non-legislative rules, see 1 CHARLES H. KOCH, JR., ADMINISTRATIVE LAW & PRACTICE 261-67 (3d ed. 2010).

[41] *Chevron*, 467 U.S. at 842.

[42] *Id.*

[43] *Id.* at 842-43.

[44] *Id.* at 843.

[45] *See supra* note 1 and accompanying text.

[46] *Chevron*, 467 U.S. at 843-44.

[47] *See id.* at 844 (concluding that the regulations control "unless they are arbitrary, capricious, or manifestly contrary to the statute"); *see also* KOCH, *supra* note 40, at 263-64 (discussing the requirement of notice and comment for legislative rules and the presumption that rulemaking does "not directly affect individual rights and duties").

[48] MacKenzie Med. Supply, Inc. v. Leavitt, 506 F.3d 341, 346 (4th Cir. 2007) (quoting *Chevron*, 467 U.S. at 843); *see also* Regions Hosp. v. Shalala, 522 U.S. 448, 457 (1998).

required in determining what medical services are "reasonable and necessary," courts have given CMS great flexibility in deciding whether to use an NCD, an LCD, or a case-by-case determination of medical necessity to do rulemaking.[49]

However, *Chevron* deference usually applies to agency interpretations of statutes when Congress has delegated authority, explicitly or implicitly, to the agency to speak with the force of law.[50] A clear example is when a statute instructs an agency to promulgate regulations to implement provisions of a statute. The Court in *U.S. v. Mead Corp.* narrowed *Chevron*'s deference to only those interpretations that carry the weight of law.[51] *Mead*'s "legislative versus non-legislative" distinction determines whether full *Chevron* deference will apply. Non-legislative interpretations, such as policy statements and issuances that are only meant to guide or explain the agency's stance, do not receive *Chevron* deference, but are afforded a lesser degree of deference.[52] It is not settled what level of deference applies, but many courts, including the *Mead* Court, have granted *Skidmore* deference as a lesser degree of *Chevron*.[53]

A legislative rule creates additional rights and imposes additional obligations. The agency is given the power by Congress to resolve any ambiguities, so long as they are reasonable. Thus, the regulations promulgated by CMS create the rights and obligations that define "reasonable and necessary" medical treatment as described by the statute. The requirement that improvement not be considered categorically in determining reasonableness and necessity, as dictated by CMS's regulations, receives *Chevron* deference.

This doctrine is somewhat muddled and has not been consistently applied in the Courts of Appeals.[54] Since it is unclear which agency actions receive *Chevron* deference,[55] it is also unclear how much deference the Policy Manual and related LCDs would receive if they were viewed as interpretations of the "reasonable and necessary" provision of the Act. Under *Mead*, a court can grant the lesser *Skidmore* deference if the rule falls into the non-legislative category.[56] Knowing which level of deference will be given informs the agency who will interpret its own rules: the agency or the court.[57]

The Improvement Standard is not explicitly contained in the regulations CMS promulgated through notice and comment rulemaking for outpatient therapy

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[49] Almy v. Sebelius, 749 F. Supp. 2d 315, 324-25 (D. Md. 2010); *see also id.* at 322 (quoting *MacKenzie*, 506 F.3d at 348) ("The Medicare statute provides that judicial review of a final decision of the Secretary 'is to be based solely on the administrative record, and the Secretary's findings of fact, if supported by substantial evidence, *shall be conclusive*.'" (emphasis added)).

[50] United States v. Mead Corp., 533 U.S. 218, 226-27 (2001).

[51] *Id*.

[52] *Id.* at 234-35.

[53] *Id.*; Skidmore v. Swift & Co., 323 U.S. 133, 140 (1944) (holding that rulings of an agency were not legislative in nature, but did "constitute a body of experience and informed judgment to which courts and litigants may properly resort for guidance"). The deference granted depended on "the thoroughness evident in its consideration, the validity of its reasoning, its consistency with earlier and later pronouncements, and all those factors which give it power to persuade, if lacking power to control." *Id.* at 140.

[54] *See* Lisa Schultz Bressman, *How* Mead *Has Muddled Judicial Review of Agency Action*, 58 VAND. L. REV. 1443, 1445-46 (2005).

[55] *See id.* at 1445; Thomas J. Fraser, *Interpretative Rules: Can the Amount of Deference Accorded Them Offer Insight into the Procedural Inquiry?,* 90 B.U. L. REV. 1303 *passim* (2010) (discussing the Court's attempts to better define the scope of *Chevron*).

[56] Fraser, *supra* note 55, at 1325.

[57] Bressman, *supra* note 54, at 1445.

services.[58] Indeed, CMS cites a number of regulatory instances where the Improvement Standard is forbidden.[59] However, language embodied in the Policy Manuals and in the LCDs indicates a categorical improvement requirement, which served as the basis for the denials relied upon by the MACs, the administrative law judges (ALJs), and the Appeals Board in *Jimmo*. Policy Manuals and LCDs do not undergo the notice and comment process required by the APA, but deny rights to beneficiaries previously provided to them through procedurally valid regulations. The District Court of Vermont, however, was convinced that while these sub-regulatory materials exist, plaintiffs cited "scant" facts of the Improvement Standard's existence.[60]

B. Deference Under *Seminole Rock*

Policy statements and guidance documents are usually considered agency interpretations of agency regulations. When reviewing these documents, the deference applied is derived from *Seminole Rock*[61] and *Auer v. Robbins*[62] rather than *Chevron*. *Seminole Rock* and *Auer* require courts to give an agency's view of its own regulations "controlling weight unless it is plainly erroneous or inconsistent with the regulation."[63] The Supreme Court has emphasized the importance of careful adherence to the *Seminole Rock* standard in the Medicare context, which deals with "a complex and highly technical regulatory program, in which the identification and classification of relevant criteria necessarily require significant expertise and entail the exercise of judgment grounded in policy concerns."[64]

The heightened deference could possibly be defeated if the Improvement Standard contained in the Policy Manuals and LCDs is "plainly erroneous or inconsistent" with the binding regulations.[65] While the Court has not spoken specifically on this standard, *Seminole Rock* deference will not be extended.[66] For instance, in *Exelon Generation Co. v. Local 15*, the Seventh Circuit declined to provide deference to the Nuclear Regulatory Commission's interpretative rule that allowed third-party arbitral review where prior regulations had explicitly forbidden it.[67] *Seminole Rock* deference was not appropriate for three independently sufficient reasons, notably that the agency's prior stance was antithetical to the new policy, and the policy change had to undergo notice-and-comment procedures.[68]

In another case, the Third Circuit reviewed EPA regulations on the dumping of dioxin into a port and found that the agency's interpretation of those regulations did not deserve *Seminole Rock* deference.[69] While the regulations required testing for certain contaminants, the Green Book allowed the agency to select which tests it

[58] *See supra* Part II.
[59] Jimmo v. Sebelius, No. 5:11–CV–17, 2011 WL 5104355, at *20 (D. Vt. Oct. 25, 2011).
[60] *Id.*
[61] Bowles v. Seminole Rock & Sand Co., 325 U.S. 410, 414 (1945).
[62] Auer v. Robbins, 519 U.S. 452, 461 (1997).
[63] *Seminole Rock*, 325 U.S. at 414.
[64] Thomas Jefferson Univ. v. Shalala, 512 U.S. 504, 512 (1994) (quoting Pauley v. BethEnergy Mines, Inc., 501 U.S. 680, 697 (1991)) (internal quotation marks omitted).
[65] *Seminole Rock*, 325 U.S. at 414.
[66] *See e.g.*, Exelon Generation Co. v. Local 15, 676 F.3d 566 (7th Cir. 2012), *reh'g en banc denied*, 682 F.3d 620 (7th Cir. 2012); Clean Ocean Action v. York, 57 F.3d 328 (3d Cir. 1995).
[67] *Exelon Generation Co.*, 676 F.3d at 576.
[68] *Id.* at 576-77.
[69] Clean Ocean Action, 57 F.3d at 332-33.

would conduct.[70] This resulted in the dumping of a contaminant, which should have been identified in the testing set forth in EPA's regulations.[71] The court held that "[t]he language of the EPA's regulations is unambiguous" and that the agency's re-interpretation of that regulation through the Green Book "is inconsistent with the plain meaning of that language."[72] The Third Circuit declined to extend deference to the EPA.[73]

While CMS is generally entitled to deference, as *Thomas Jefferson University v. Shalala* clearly states, several courts have disagreed with the Secretary's interpretations of the agency's regulations. In March 2013, the D.C. Circuit declined to extend *Seminole Rock* deference to CMS's interpretation of its regulations regarding Medicare reimbursement for teaching and intern costs.[74] Meanwhile, the Fifth Circuit has begun to apply a narrower reading of *Seminole Rock* and *Auer*, holding that only interpretations of published regulations receive deference.[75] Under that standard, an LCD would be an interpretation of the Policy Manual, which is itself an interpretation of the regulations.[76]

The Vermont District Court's denial of the Secretary's motion to dismiss suggests that the court may not have deferred to CMS's interpretations of its regulations as embodied in Policy Manuals and the LCDs. While courts rarely find that an interpretation is plainly erroneous, the fact that CMS's regulations seemingly prohibit using a categorical Improvement Standard as the basis for claims denial was likely sufficient to meet the summary judgment standard. As described in Part II, the Policy Manuals and LCDs seemingly contradict the requirements in the regulation, at least in part. Furthermore, according to the other courts that have ruled on the issue, there is no uncertainty that requiring improvement without regard to individual patient needs violates the Medicare regulations.[77] Those courts did not consider a challenge to the Policy Manuals and LCDs themselves, however, but merely reviewed the Secretary's coverage decision. The plaintiffs in *Jimmo* challenged the language of the Policy Manuals and LCDs under the APA and the Medicare statute itself.[78] The Vermont District Court's refusal to dismiss the case and the Secretary's willingness to settle indicate that at least some evidence existed that the agency's interpretations may not have been accepted under *Seminole Rock*.

Despite what ruling might have been handed down in *Jimmo*, the future of the *Seminole Rock* doctrine may already be in jeopardy.[79] In a recent Supreme Court case concurring opinion, Chief Justice Roberts expressed great disappointment with the application of *Seminole Rock* to the regulations at issue.[80] He openly suggested

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[70] *Id*. at 330, 333.

[71] *Id.* at 330.

[72] *Id.* at 333.

[73] *Id.* at 332-33.

[74] Kaiser Found. Hosps. v. Sebelius, 708 F.3d 226, 230 (D.C. Cir. 2013).

[75] Elgin Nursing & Rehab. Ctr. v. U.S. Dep't of Health & Human Servs., 718 F.3d. 488, 493 (5th Cir. 2013); Castellanos-Contreras v. Decatur Hotels, L.L.C., 622 F.3d 393, 407-08 (5th Cir. 2010) (Dennis, J., dissenting).

[76] *See Elgin Nursing & Rehab. Ctr.*, 718 F.3d at 493 ("All of our decisions applying *Seminole Rock* and *Auer*, however, have addressed only an agency's direct interpretation of its published regulations."). According to this standard, an LCD, as an interpretation of an interpretation, would not be entitled deference.

[77] Papciak v. Sebelius, 742 F. Supp. 2d 765, 767 (W.D. Pa. 2010); Anderson v. Sebelius, No. 5:09–CV–16, 2010 WL 4273238, at *7 (D. Vt. Oct. 25, 2010).

[78] Jimmo v. Sebelius, No. 5:11–CV–17, 2011 WL 5104355, at *2 (D. Vt. Oct. 25, 2011).

[79] *See* Aneil Kovvali, Seminole Rock *and the Separation of Powers*, 36 HARV. J.L. & PUB. POL'Y 849, 849 (2013) (noting that "Seminole Rock deference has . . . faced significant criticism").

[80] Decker v. Nw. Envtl. Def. Ctr., 133 S. Ct. 1326, 1338 (2012) (Roberts, C.J., concurring).

that it may be time to change the doctrine. In dissent, Justice Scalia, the author of the *Auer* opinion, launched a full-throated attack on the concept, finding that the Court's cases do not provide a persuasive justification for affording such deference.[81] Similarly, two years earlier, Justice Scalia questioned the broad discretion of *Auer* in a dissenting opinion.[82] The Fifth Circuit's narrow reading of *Seminole Rock* and *Auer* drastically reduces the level of deference that agencies have typically enjoyed in their interpretations of their own regulations.[83]

IV. THE *JIMMO* CASE

This section reviews the facts of the coverage denial decisions in *Jimmo* before turning to the settlement agreement. While it is unclear whether a court of law would defer to CMS on the merits of the Improvement Standard case that the plaintiffs brought, it is clear that the District Court in Vermont ruled against summary judgment because it thought that there was at least some evidence that possibly neither *Chevron* nor *Seminole Rock* deference applied.

A. THE APPLICATION OF THE IMPROVEMENT STANDARD

The Improvement Standard can be seen in the appeals history of the lead plaintiff in *Jimmo*. Glenda Jimmo, a Medicare beneficiary in Vermont, is "legally blind [with] a below-the-knee amputation" due to diabetes and a related circulatory disorder.[84] After certifying that Ms. Jimmo was homebound and creating a plan of care, her physician ordered skilled nursing services on an intermittent basis as well as home health aide services.[85] The MAC in charge of the area where Ms. Jimmo lives denied nearly a year of her claims for payment, both initially and on redetermination.[86] At redetermination, her CMS contractor said that "[t]he likelihood of change in the patient's condition requiring skilled nursing services was not supported in the documentation."[87]

Ms. Jimmo appealed this coverage determination to an ALJ, who denied coverage and noted that the "[o]bservation and assessment of the Beneficiary was not necessary as the Beneficiary was stable . . . . The Beneficiary's condition did not significantly [change] during the period at issue and the plan of care did not undergo changes."[88] This implies that there was no expectation of improvement for Ms. Jimmo. Alleging that the Improvement Standard was applied in contravention of the CMS regulations, Ms. Jimmo appealed to the MAC. When the MAC did not act quickly enough, she appealed to the District Court. The MAC later upheld the ALJ, saying "the wound care was not complex, the beneficiary was stable and seen

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[81] *Id.* at 1340.

[82] Talk Am., Inc. v. Mich. Bell Tel. Co., 131 S. Ct. 2254, 2265-66 (2011) (Scalia, J., dissenting).

[83] Elgin Nursing & Rehab. Ctr. v. U.S. Dep't of Health & Human Servs., 718 F.3d 488, 493-94 (5th Cir. 2013); Castellanos-Contreras v. Decatur Hotels, L.L.C., 622 F.3d 393, 407-08 (5th Cir. 2010) (Dennis, J., dissenting).

[84] *Id.* at para. 48. The plaintiffs also included four other beneficiaries as well as a number of national organizations including the National Committee to Preserve Social Security and Medicare, the Multiple Sclerosis Society, the Parkinson's Action Network, and United Cerebral Palsy. *See, e.g.*, *id.* at paras. 55, 64, 69.

[85] *Id*. at para. 49.

[86] *Id*. at para. 50.

[87] *Id.* at para. 51 (quoting the Quality Improvement Contractor's decision).

[88] *Id.* at para. 52 (quoting the ALJ's decision).

frequently in her physician's office for lesions and debridement, and neither her condition nor the plan of care changed significantly during the period at issue."[89]

Another plaintiff in the *Jimmo* case, "KR," was also denied coverage based on the Improvement Standard. KR was a Medicare beneficiary by virtue of her quadriplegia, cerebral palsy, and partial paralysis.[90] Her physician ordered skilled physical therapy in order to evaluate her, perform therapeutic exercise, teach movement and gait training, and outline a home exercise program.[91] Coverage of these services was denied because "therapy services may be covered [only] when there is a reasonable expectation that the beneficiary will show measurable improvement in performing normal daily activities."[92] At the appeals level, KR alleged that the ALJ relied on the Improvement Standard in stating that "[t]he services must be provided with the expectation that the condition of the patient will improve materially in a reasonable and generally predictable period of time."[93] The ALJ further stated that "one cannot determine whether there is a reasonable expectation of material improvement . . . . [T]he submitted documentation does not support that [KR] had experienced an acute episode or exacerbation of chronic condition resulting in a complex functional deficit to warrant skilled intervention."[94]

The crux of the plaintiffs' argument in both of these fact scenarios was that the Improvement Standard was a "rule of thumb" or non-individualized decision that served as a categorical rule. The plaintiffs alleged that these categorical decisions masqueraded as one of a number of phrases, including that the beneficiary needs "maintenance services only," has "plateaued," or is "chronic," "medically stable," or not improving.[95]

B. THE SETTLEMENT AGREEMENT AND REVISED POLICY MANUAL PROVISIONS

After CMS failed to obtain summary judgment and dismissal of the case in the District Court, possibly due to a potential violation of the APA,[96] in October 2012, the parties entered into a class action settlement agreement that became effective immediately.[97] The purpose of the settlement agreement was to "ensure that claims are correctly adjudicated in accordance with existing Medicare policy, so that Medicare beneficiaries receive the full coverage to which they are entitled."[98] The settlement required two major actions by CMS: (1) revision of its Policy Manuals to clarify that the Improvement Standard should not be used as a categorical rule; and

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[89] *Id.* at para. 54 (quoting the MAC's decision).
[90] *Id.* at para. 55.
[91] *Id.* at para. 58.
[92] *Id.* at para. 60 (quoting the Quality Improvement Contractor's decision).
[93] *Id.* at para. 62 (quoting the ALJ's decision).
[94] *Id.*
[95] *Id*. at para. 2.
[96] *See* Jimmo v. Sebelius, No. 5:11–CV–17, 2011 WL 5104355, at *22 (D. Vt. Oct. 25, 2011) (finding that some evidence of the Improvement Standard exists in the Plaintiff's Amended Complaint of "illegal presumptions and rules of thumb"). For further discussion of the administrative law provisions possibly underpinning the court's denial of summary judgment, see *supra* Part III.
[97] Settlement Agreement, Jimmo v. Sebelius, No. 5:11–CV–17, 2011 WL 5104355 (D. Vt. Oct. 25, 2011), *available at* http://www.medicareadvocacy.org/wp-content/uploads/2012/12/Jimmo-Settlement-Agreement-00011764.pdf. For example, therapy caps still apply for outpatient therapy services. *See infra* note 122.
[98] Jimmo v. Sebelius *Settlement Agreement Fact Sheet*, CTRS. FOR MEDICARE & MEDICAID SERVS. 1, http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/SNFPPS/Downloads/Jimmo-FactSheet.pdf (last visited Jan. 16, 2013).

(2) conducting a campaign to educate both beneficiaries and providers of the clarifications and correct adjudication of claims.[99]

The manual provisions subject to revision include those chapters in the Policy Manual for therapy services in the context of SNF, home health, and Part B outpatient therapy.[100] While the settlement agreement states that nothing in the agreement "modifies, contracts, or expands the existing eligibility requirements for receiving Medicare coverage,"[101] the revisions are meant to clarify that coverage of therapy services "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."[102] To be 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."[103]

On December 6, 2013, CMS issued a program transmittal (revised as number R176BP) which contains the clarifications required by the settlement agreement.[104] The transmittal has two overarching points: (1) that no Improvement Standard is to be applied; and (2) documentation must be kept to facilitate accurate coverage determinations. On the first point, the revisions clarify that a beneficiary's lack of restoration potential alone cannot serve as the basis for denying coverage, without regard to an individualized assessment of the beneficiary's medical condition and the reasonableness and necessity of the treatment. Conversely, coverage would not be available in a situation where the beneficiary's maintenance care needs can be addressed safely and effectively through the use of non-skilled personnel or personally by the beneficiary.

Enhanced documentation guidance is also presented in the transmittal generally and in particular clinical scenarios. While the presence of appropriate documentation is not, in and of itself, an element of the definition of a skilled service, such documentation serves as the means by which a provider would be able to establish, and a MAC would be able to confirm, that skilled care is, in fact, needed in a given case. MACs are directed to consider the entirety of the clinical evidence in a patient's medical file in order to determine medical necessity (no magic words or phrases are required in documentation although the transmittal does point to some shorthand that is not appropriate).

For the educational campaign, CMS agreed to issue outreach articles on the topic to a variety of stakeholders including MACs, ALJs, providers and suppliers.[105] In order to measure the effectiveness of the educational campaign, CMS will sample a number of decisions at the contractor administrative level in order to gauge whether the contractor is still applying the Improvement Standard.[106] CMS will also

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[99] *Id.* at 2.

[100] For a discussion of these manual provisions, see *supra* Part II.

[101] Settlement Agreement, *supra* note 97, at 9.

[102] *Id.* at 10-11.

[103] *Id.* at 13 (discussing skilled nursing services at 42 C.F.R. § 409.32 (2013)); *see also supra* note 14 and accompanying text.

[104] CTRS. FOR MEDICARE & MEDICAID SERVS., PUB. 100-02 MEDICARE BENEFIT POLICY TRANSMITTAL R176BP (Dec. 13, 2013) [hereinafter TRANSMITTAL R176BP], *available at* http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R176BP.pdf. A transmittal is a communication to the MACs to change the Policy Manual.

[105] Settlement Agreement, *supra* note 97, at 15.

[106] *Id.* at 20.

retroactively address certain individual cases where the Improvement Standard has been applied.[107]

On December 13, 2013, CMS began its educational campaign with the release of a MLN Matters educational summary of the updates to the Policy Manual.[108] This summary notes that skilled therapy services can involve both restorative care and maintenance therapy if certain standards are met. Specifically for maintenance therapy, the article states:

> Even if no improvement is expected, under the SNF, HH, and OPT coverage standards, skilled therapy services are covered when an individualized assessment of the patient's condition demonstrates that skilled care is necessary for the performance of a safe and effective maintenance program to maintain the patient's current condition or prevent slow further deterioration. Skilled maintenance therapy may be covered when the particular patient's special medical complications or the complexity of the therapy procedures require skilled care.[109]

The article continues that coverage of therapy services depends on "an individualized assessment of the beneficiary's medical condition and the reasonableness of the necessity of treatment, care, or services in question."[110] This article and the transmittal show that CMS has taken an individualized care approach to therapy coverage in its clarifications. CMS cautions, however, that sufficient documentation must be in the patient's medical record to justify coverage of maintenance therapy.

CMS continued its educational outreach with a National Provider Call on December 19, 2013. This call reviewed the changes in the revised Policy Manual, highlighting that in the maintenance context, coverage of therapy services "does not turn on the presence or absence of a beneficiary's potential for improvement, but rather on the beneficiary's need for skilled care."[111] During the call, CMS staff said that the MLN Matters article and the National Provider Call were the first steps in the agency's educational campaign and that, although the LCDs have not been changed yet, CMS expects the MACs to change their LCDs as they become more educated about the changes in the Policy Manual.[112] CMS plans additional education sessions in the future.

V. THE COST OF REPEALING THE IMPROVEMENT STANDARD

The *Jimmo* settlement has broad practical implications for healthcare policy, particularly in terms of costs. The Center for Medicare Advocacy (CMA) has estimated that "anywhere from tens of thousands to hundreds of thousands of

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[107] *Id.* at 20-27. This retroactive secondary review process is only for beneficiaries, not providers or state Medicaid agencies.

[108] *See Manual Updates to Clarify Skilled Nursing Facility (SNF), Inpatient Rehabilitation Facility (IRF), Home Health (HH), and Outpatient (OPT) Coverage Pursuant to* Jimmo v. Sebelius, CTRS. FOR MEDICARE & MEDICAID SERVS. (last revised Jan. 15, 2014), http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/MM8458.pdf.

[109] *Id.* at 2 (quoting TRANSMITTAL R176BP, *supra* note 104).

[110] *Id.* (quoting TRANSMITTAL R176BP, *supra* note 104).

[111] *See* Presentation, Medicare Learning Network (MLN), *Jimmo v. Sebelius* Settlement Agreement 10 (Dec. 19, 2013), *available at* http://www.cms.gov/Outreach-and-Education/Outreach/NPC/Downloads/121913-Jimmo-Slideshow.pdf.

[112] *See* Transcript, MLN Connects National Provider Call, Ctrs. for Medicare & Medicaid Servs., Program Manual Updates to Clarify SNF, IRF, HH, and OPT Coverage Pursuant to *Jimmo v. Sebelius* 8-9 (Dec. 19, 2013), *available at* http://www.cms.gov/Outreach-and-Education/Outreach/NPC/Downloads/JIMMO-12-19-13-Edited-Transcript.pdf.

beneficiaries" will benefit from the newly clarified coverage criteria.[113] This means that Medicare will make payments for those beneficiaries' services which it previously would not have made, resulting in significant cost increases for the program.

Increased utilization of therapy services as a result of the settlement is indeed of concern to Medicare financing. Robert Reischauer, a Medicare public trustee and former head of the Congressional Budget Office (CBO), said that the settlement would "[u]nquestionably . . . increase costs. How much, I can't say."[114] *The New York Times* similarly reported that other budget experts expressed views similar to Reischauer.[115] Some costs could potentially be offset by avoiding hospital admissions during a medical emergency.[116] The general consensus, however, seems to be that the Improvement Standard has had a chilling effect, dissuading therapists from providing skilled therapy services up front. Thus, more beneficiaries will receive care after the settlement is implemented, costing more to the Medicare program.[117]

Medicaid, the federal-state health care program for low-income individuals, is also financially impacted by the settlement. Many of the beneficiaries who will be helped by the clarified coverage criteria are dually eligible for both Medicare and Medicaid, with Medicaid traditionally paying the cost of therapy services that are not covered by Medicare. With the clarified coverage criteria, it is likely that Medicare will pick up more of the cost of therapy for dual eligibles; Medicaid would thus save money. Indeed, at least one Commissioner of the Medicaid and CHIP Payment and Access Commission (MACPAC) has stated that the change in the manual provisions and processing of claims could cause a cost shift from Medicaid to Medicare budgets. However, exactly how the interaction between the two programs will ultimately unfold is unclear. This uncertainty caused the Tennessee Medicaid Director to withdraw from the dual eligibles demonstration program, which is overseen by the CMS Medicare-Medicaid Coordination Office.

The cost of unlimited therapy services has long been a concern of federal healthcare programs.[118] To counter the rising cost of outpatient therapy services, Congress placed a hard cap on the amount of combined outpatient therapy services

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[113] Michelle M. Stein, *End of Medicare Improvement Standard Could Benefit Medicaid Budgets*, INSIDE HEALTH POL'Y (Nov. 21, 2012), http://insidehealthpolicy.com/Inside-Health-General/Public-Content/end-of-medicare-improvement-standard-could-benefit-medicaid-budgets/menu-id-869.html.

[114] Robert Pear, *Settlement Eases Rules for Some Medicare Patients*, N.Y. TIMES (Oct. 22, 2012), http://www.nytimes.com/2012/10/23/us/politics/settlement-eases-rules-for-some-medicare-patients.html?_r=0; *see also* Brett Norman, *Broader Therapies Could Further Strain Medicare*, POLITICO (Feb. 13, 2013), http://www.politico.com/story/2013/02/broader-therapies-could-further-strain-medicare-87529.html (noting that while CMS says there will be no budgetary impact because coverage has not changed, patient advocates say such a position is "naive").

[115] Pear, *supra* note 114.

[116] *See* Norman, *supra* note 114.

[117] *Id.*

[118] After finding a rising trend in outpatient therapy services payments in the early 2000s, the Medicare Payment Advisory Commission (MedPAC) estimated that Medicare spent about $5.7 billion on outpatient therapy services in 2011, with 37% in the SNF setting and 30% in the private practice of physical therapy. *See* MEDICARE PAYMENT ADVISORY COMM'N, REPORT TO THE CONGRESS: MEDICARE AND THE HEALTH CARE DELIVERY SYSTEM 241 (2013), http://www.medpac.gov/documents/Jun13_EntireReport.pdf; *Outpatient Therapy Services Payment System*, MEDICARE PAYMENT ADVISORY COMM'N (2012), http://www.medpac.gov/documents/MedPAC_Payment_Basics_12_OPT.pdf; *Outpatient Therapy Services*, MEDICARE PAYMENT ADVISORY COMM'N (2005), http://www.medpac.gov/documents/Dec05_Medicare_Basics_OPT.pdf.

Medicare would pay in § 4541 of the Balanced Budget Act of 1997.[119] At the time, the CBO estimated that this hard cap would save Medicare Part B $5.2 billion over ten years.[120] However, Congress later recognized the hardship this hard cap placed on beneficiaries' access to services (e.g., on those having to choose between learning to walk and learning to speak after a stroke) and the burden on providers to calculate the caps.[121] Hard caps do not provide flexibility to customize care decisions, which is a hallmark of medical necessity. In 2006, as part of the Deficit Reduction Act, Congress passed a temporary exceptions process, whereby beneficiaries could receive additional therapy services paid for by Medicare above the cap if the services were medically necessary.[122] CBO scored this process as costing about $500 million for 2006.[123] The exceptions process was originally intended to be temporary, but Congress has continued to extend the exception over the years. For example, Congress, in § 603 of the American Taxpayer Relief Act of 2012,[124] extended the exception for a year at a cost of about $1 billion for 2013-2014.[125] Most recently, Congress extended the exceptions process for three months from December 31, 2013 to March 31, 2014 in the Bipartisan Budget Act of 2013[126] at a cost of about $100 million.[127] This rising cost of the exceptions process indicates that the increased utilization of therapy services as a result of the *Jimmo* settlement could be millions, if not billions, of dollars.

In a 2012 MedPAC session on improving payment for Medicare outpatient therapy services, MedPAC Commissioner Herb Kuhn, echoed this sentiment, describing the *Jimmo* settlement as "an extremely impactful decision" that has perhaps "now established the de facto long-term care benefit under Medicare."[128] In

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[119] Balanced Budget Act of 1997, Pub. L. No. 105-33, 111 Stat. 454.

[120] *Budgetary Implications of the Balanced Budget Act of 1997*, CONG. BUDGET OFFICE 24 (Dec. 1997), http://www.cbo.gov/sites/default/files/cbofiles/ftpdocs/3xx/doc302/bba-97.pdf.

[121] *See* MEDICARE PAYMENT ADVISORY COMM'N (2013), *supra* note 118.

[122] Deficit Reduction Act of 2005, Pub. L. No. 109-171, § 5107, 120 Stat. 42. The hard cap for therapy services was later divided into one cap for Physical Therapy/Speech-Language Pathology and one cap for Occupational Therapy, both indexed to inflation. Each cap is set at $1,920 in allowed charges for 2014.

[123] *S. 1932 Deficit Reduction Act of 2005*, CONG. BUDGET OFFICE 28 (Jan. 27, 2006), http://www.cbo.gov/sites/default/files/cbofiles/ftpdocs/70xx/doc7028/s1932conf.pdf.

[124] American Taxpayer Relief Act of 2012, Pub. L. No. 112-240, 126 Stat. 2347 (2013). The Affordable Care Act extended the exceptions to therapy caps through December 31, 2010; the Medicare and Medicaid Extenders Act (MMEA) of 2010 extended the therapy caps exceptions through December 31, 2011; and the Middle Class Tax Relief And Job Creation Act (MCTRJCA) of 2012 extended the therapy caps exceptions through December 31, 2012.

[125] *Detail on Estimated Budgetary Effects of Title VI (Medicare and Other Health Extensions) of H.R. 8, the American Taxpayer Relief Act of 2012*, CONG. BUDGET OFFICE 1 (Jan. 9, 2013), http://www.cbo.gov/sites/default/files/cbofiles/attachments/SenateHR8-TitleVI_0.pdf.

[126] Continuing Appropriations Resolution, Pub. L. No. 113-67, 127 Stat. 1165 (2013). The Bipartisan Budget Act of 2013 contains the Pathway for SGR Reform Act of 2013, which extends the therapy caps exceptions process in section 103.

[127] *Estimate for Amendment to H.J. Res. 59, Pathway for SGR Reform Act of 2013,* CONG. BUDGET OFFICE 1 (Dec. 11, 2013), http://www.cbo.gov/sites/default/files/cbofiles/attachments/Extenders_RevisedAmd_to_HJRes59.pdf. MedPAC estimates "that about 20 percent of beneficiaries receiving outpatient therapy would have their therapy truncated at the cap" without this legislation. *See Temporary Payment Policies in Medicare: Hearing Before the Subcomm. on Health, Comm. on Energy and Commerce,* 113th Cong. 9 (2014) (testimony of Glenn M. Hackbarth, Chairman of MedPAC), http://docs.house.gov/meetings/IF/IF14/20140109/101627/HHRG-113-IF14-Wstate-HackbarthG-20140109.pdf.

[128] *See* Transcript of Public Meeting, Medicare Payment Advisory Comm'n 133 (Nov. 1, 2012), *available at* http://www.medpac.gov/transcripts/Nov2012Transcript.pdf.

March 2013, MedPAC recommended that Congress develop national guidelines for therapy services, taking the decision-making out of the hands of CMS and the MACs.[129] The Commission was concerned that requiring only a physician certification of necessity for therapy would lead to an increased abuse of therapy services.[130]

The Senate Finance Committee has begun to explore replacing the therapy cap with a new medical review program for outpatient therapy that would make use of the medical documentation for each individual patient's case. This proposal is in the Chairman's mark to the Sustainable Growth Rate (SGR) Repeal and Medicare Beneficiary Access Improvement Act of 2013, which is one of the three bills likely to be discussed by Congressional leaders in the spring of 2014 in an effort to resolve the SGR dilemma.[131] The proposal seeks to first identify situations where there is a pattern of higher billing compared to other providers (sometimes called "outliers"), where a particular therapist has a high claims denial percentage, or where a therapist has questionable billing practices.[132] The proposed legislation would direct CMS to use prior authorization medical review for these and other situations for services furnished to a particular beneficiary above a certain monetary threshold. Prior authorization would end if the therapist has a low denial rate under prior authorization. This approach is an attempt to balance fraud enforcement and excessive payments against the legitimate therapy needs of Medicare beneficiaries.[133] This is also in line with the *Jimmo* settlement because it allows for more individualized care decisions and better aligns with the underlying premise of medical necessity. Furthermore, with the political support of groups like the American Physical Therapy Association and the Therapy Caps Coalition,[134] this proposal may have the political momentum it needs to resolve the issue of the appropriate amount of Medicare-covered therapy.

VI. CONCLUSION

The *Jimmo* settlement represents a sizeable victory for beneficiaries and providers, but is also another hurdle for a program whose costs have historically

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[129] MEDICARE PAYMENT ADVISORY COMM'N (2013), *supra* note 118, at 245.

[130] *Id.*

[131] *See Description of the Chairman's Mark: The SGR Repeal and Medicare Beneficiary Access Improvement Act of 2013*, U.S. SENATE COMM. ON FINANCE 39-42 (Dec. 10, 2013), http://www.finance.senate.gov/legislation/details/?id=a275e061-5056-a032-5209-f4613a18da1b.

[132] *Id.* The legislation would look to other situations as well including newly enrolled therapy providers, treatment of a specific type of medical conditions, or excessive services furnished by a single therapy provider or group.

[133] MedPAC agrees with this approach to balancing program integrity against individualization of therapy decisions. Hard caps "impede access to necessary and useful care for Medicare beneficiaries. For the right clinical indications, outpatient therapy services provide significant benefits." Hackbarth, *supra* note 127, at 9. Conversely, an automatic exceptions process does not control the volume of therapy services provided. This is evidenced by MedPAC's finding of wide geographic variation in outpatient therapy services. *Id.* at 10. Another problem is that "Medicare lacks basic information to evaluate the medical necessity of therapy services, such as patients' functional status and the outcomes of therapy services." *Id.* MedPAC makes three recommendations to Congress on reforming outpatient therapy services: (1) improve physician oversight and program integrity; (2) ensure access to care while managing Medicare's costs; and (3) strengthen management of the therapy benefit in the long-term. *Id.*

[134] *See* Michelle M. Stein, *Finance SGR Package Replaces Therapy Caps with Prior Authorization*, INSIDE HEALTH POL'Y (Dec. 12, 2013), http://insidehealthpolicy.com/201312102455425/Health-Daily-News/Daily-News/finance-sgr-package-replaces-therapy-caps-with-prior-authorization/menu-id-212.html?s=dn.

been difficult to control.[135] Medicare's regulations purport to require individualization of care, where restorative potential does not decide medical necessity. This patient-centric theme is politically favorable, but the jungle of the program's rules and procedures grants significant deference to non-governmental contractors who are permitted to establish their own rules (LCDs). By allowing MACs to implement an Improvement Standard, CMS was able to rely on administrative simplicity to limit outpatient therapy costs while distancing itself from unpopular coverage decisions. The settlement in *Jimmo* closes this regulatory loophole and refocuses Medicare on its stated task, which is to provide individualized coverage determinations. However, the settlement puts additional financial strain on the Medicare program. Congress has recognized the need for a new approach to therapy caps in light of Medicare's strained finances. A prior authorization medical review process may be the solution.

[135] The latest Medicare Trustee's Report estimates that the Medicare Part A trust fund will be depleted in 2026. BDS. OF TRS. OF THE FED. HOSP. INS. & FED. SUPPLEMENTARY MED. INS. TR. FUNDS, 2013 ANNUAL REPORT 6 (2013), *available at* http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/ReportsTrustFunds/Downloads/TR2013.pdf.