



National Council on Disability

An independent federal agency making recommendations to the President and Congress to enhance the quality of life for all Americans with disabilities and their families.

May 17, 2016

Administrator Andrew Slavitt
Centers for Medicare and Medicaid Services (CMS)
U.S. Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244

Dear Administrator Slavitt:

I write on behalf of the National Council on Disability (NCD) -- an independent, nonpartisan federal agency charged with providing advice to Congress, the President, and other federal agencies on matters affecting the lives of people with disabilities -- to urge you to withdraw CMS's March 11 proposed rule regarding changes to Medicare's Part B drug payment model due to its likelihood of disproportionately negatively affecting people with chronic health conditions; and to utilize NCD as a convener to more fulsomely engage patient stakeholders who stand to be most impacted by the effects of the rule.

CMS's stated purpose of this proposed rule is to "improve outcomes and reduce expenditures for Part B drugs." While we appreciate the challenge of proposing policies that reduce prescription drug expenditures while at the same time doing no harm to patient self-direction, to the doctor-patient relationship, and/or to patient outcomes; we believe that the proposed rule does not succeed in doing no harm. CMS noted that the proposed rule was aligned with the Administration's strategy of encouraging "better care" and "healthier people," however overwhelmingly, it is patient groups and their specialty care providers who have voiced concern that this rule would have the opposite effect of such pursuits, which shows at a minimum that the process CMS undertook to involve stakeholders in the development of the NPRM may not have been adequate to address concerns.

For several years now, NCD has traveled the country to host stakeholder forums regarding states' transitions to Medicaid managed care to promote greater dialogue and contact between key CMS regional office staff and the disability community regarding managed care waiver applications and dual eligible demonstration proposals. Each forum involved seven stakeholder groups comprising consumers/self-advocates, families, other advocates, providers, informal family caregivers, state government agency workers, managed care organizations (MCO), researchers, and various professionals in academia. On the basis of this extensive stakeholder engagement, NCD was able to confidently advance recommendations to CMS regarding transitions in the service delivery system.

Indeed, NCD has extensive experience with stakeholder engagement as a means to inform and confirm its own policy recommendations. In fact, in 2012, in our *Guiding Principles: Successfully Enrolling People with Disabilities in Medicaid Managed Care Plans* publication, NCD identified key stakeholder involvement as a guiding principle and stated the

importance of “fully engag[ing] [stakeholders] in **designing, implementing, and monitoring** the outcomes and effectiveness”¹ of the proposed systems change (emphasis added). Of the importance of this step, we wrote:

Active, open and continuous dialogue with all affected parties offers the best prospects for creating and maintaining a service delivery system that meets the needs of people with disabilities. All participants must be confident that the transition to a managed care system will yield better outcomes for people with disabilities. The involvement of disability stakeholders should not end with approval of a state's managed care plan. Instead, stakeholders should participate in monitoring the implementation of the plan and provide feedback on system performance and needed plan modifications on an ongoing basis.²

We reference NCD's work in this different healthcare topic area because of its relation in *process* to what seems lacking in CMS's approach to this NPRM – namely, a thoughtful and robust process of stakeholder engagement in the *development* of the proposal itself, the five-year plan to *implement* the proposal, and in the *monitoring* of its outcomes and effectiveness in achieving its aims. We believe that CMS has received the amount of negative reaction to its NPRM in large part due to the absence of meaningful stakeholder engagement, and as the federal voice for the more than 50 million Americans with disabilities, including chronic health conditions, we are willing to assist CMS in its stakeholder engagement should they choose to withdraw their rule and desire to begin anew with stakeholders assisting in informing the proposed rule's development.

In addition to CMS's inadequate stakeholder engagement, NCD is also concerned that the outcomes CMS wishes to improve through this rule may not be as all-encompassing in their focus as they should be; that this proposed rule could act as a deterrent to the use of new medications that could radically improve the quality of one's life; and that some of the proposed value-based pricing models may utilize assessments of value that are diametrically out of synch with core tenets of disability civil rights.

A bedrock philosophy of disability civil rights is “independent living,” as embraced and reflected in many federal disability civil rights laws. The U.S. Commission on Civil Rights has observed that a key element of independent living is self-determination for people with disabilities: “Independent living programs insist on client self-choice *rather than* incorporation of the client into a set of goals established by program managers, service professionals, or funding mechanisms”³ (emphasis added). This “client self-choice” is consistent with the theme of “patient-centeredness” that permeates the Affordable Care Act, with which so many disability organizations related during the development and passage of the law.

In NCD's *Guiding Principles* document previously mentioned, another core principle regarding quality management stated, “Monitoring strategies must be developed to ensure

¹ National Council on Disability, *Guiding Principles: Successfully Enrolling People with Disabilities in Managed Care Plans* (2012), <http://www.ncd.gov/publications/2012/Feb272012>.

² Ibid.

³ *Accommodating the Spectrum*, *supra* n. 17, at 83-84, quoting Timothy M. Cole, “What's New About Independent Living?,” 60 *Archives Physical Med. & Rehabilitation* 458-62 (1979).

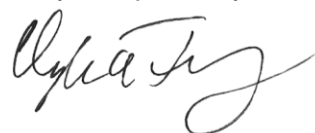
that: (a) assessments... are person-centered;(c) services are tailored to achieve outcomes desired by the individual, meet the individual's needs, and are modified as his or her needs change..."⁴

Clinical effectiveness should not singularly determine the way in which the government values and therefore prices a medication. For example, two drugs may be very similar in clinical effectiveness but vary considerably in the manner in which a particular individual experiences side effects – some side effects being quite extreme or even debilitating. Therefore, treating them as clinically equal and thus favoring the less expensive of the two in pricing policies may well result in that individual experiencing worsened outcomes, whereas because of the formulation of the assessment, the Government may view the cost savings for clinically similar drugs as an “improved outcome.” The definition of what an “improved outcome” entails, then, is quite different among stakeholders, and CMS’s pursued policies must reflect the importance of both. People with chronic health conditions, many of whose current medications are at the heart of this proposed rule, have been on an array of medication prior to the expensive ones on which they currently rely and thus have valuable firsthand knowledge of relative “value” as well as their own practical definitions of what constitutes “improved outcomes” when living with a chronic disease. CMS should seek to glean this variety of stakeholder experiences to inform their policy development. While it is true that many new medications carry a great expense with their use, some radically improve the quality of one’s life in ways that may enable fuller participation in society, including employment. The improvement in the quality of one’s life must also be considered when seeking to define “improve outcomes,” lest the absence of its consideration act as a deterrent to new medications’ coverage and use.

For the aforementioned reasons, NCD urges CMS to withdraw its proposed rulemaking and pursue meaningful stakeholder engagement to inform revisions or wholesale changes to the proposed rule. As exemplified in states’ experiences with Medicaid managed care rollout, foregoing this critical step will result in a proposed national policy that the disability community will view with determined opposition.

NCD stands ready to assist CMS with its stakeholder engagement. Please do not hesitate to contact us to discuss this offer further. Please contact NCD staff member Anne Sommers, Director of Legislative Affairs and Outreach, at asommers@ncd.gov to follow-up on this correspondence.

Very Respectfully,



Clyde Terry
Chairperson

Cc:// House Energy and Commerce Committee
Susan Janeczko, Jasmine McKenzie

⁴ National Council on Disability, *Guiding Principles: Successfully Enrolling People with Disabilities in Managed Care Plans* (2012), <http://www.ncd.gov/publications/2012/Feb272012>.