MEDICARE RIGHTS CENTER
Getting Medicare right

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April 16, 2020

VIA ELECTRONIC SUBMISSION

Xavier Becerra
Administrator
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD, 21244

Re: RIN 0938-AT88 Medicare Program; Medicare Coverage of Innovative Technology (MCIT) and Definition of "Reasonable and Necessary"; Delay of Effective Date; Public Comment Period (CMS-3372-IFC)

Dear Administrator Becerra:

The Medicare Rights Center (Medicare Rights) appreciates this additional opportunity to comment on the Medicare Program; Medicare Coverage of Innovative Technology (MCIT) and Definition of "Reasonable and Necessary"; Delay of Effective Date; Public Comment Period (CMS-3372-IFC) interim final rule. Medicare Rights is a national, nonprofit organization that works to ensure access to affordable health care for older adults and people with disabilities through counseling and advocacy, educational programs, and public policy initiatives. Each year, Medicare Rights provides services and resources to nearly three million people with Medicare, family caregivers, and professionals.

We reaffirm our support for ensuring greater access to appropriate innovative technologies and necessary care for people with Medicare.

"Reasonable and necessary" definition

CMS seeks comments on whether the public had adequate opportunity to provide input on the proposed formalization of a definition of "reasonable and necessary." We have significant concerns that

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the bundling of the MCIT provisions and the "reasonable and necessary" definition proposals may have confused commentors and led to less stakeholder engagement than would otherwise have occurred. Because of this, we urge CMS to restart the rulemaking process for the "reasonable and necessary" definition, severing it from the MCIT provisions if necessary.

CMS also seeks comments on whether the agency adequately responded to objections to the proposed rule. We do not believe our objections to the proposed rule were adequately or substantively addressed. The existence of a long-standing definition does not mean the definition is adequate or without ambiguity. As any definition moves from guidance to regulation, it must be assessed to ensure that it is truly consistent with the law and the needs of beneficiaries.

The proposed language includes several ambiguous or misleading phrases that threaten Medicare beneficiaries' access to care. We point primarily to the definition "Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition or to improve the function of a malformed body member." It is vital to update this language to include not just functional improvement but the maintenance of function or slowing the deterioration of function. This would bring the definition in line with the *Jimmo v. Sebelius* settlement which affirms that Medicare covers care to maintain or prevent deterioration of a patient's functional status, not solely to improve functional abilities. In our experience, providers' continued and widespread misunderstanding of Medicare coverage rules has led to many Medicare beneficiaries being denied necessary care. Codifying this definition without change will simply perpetuate, and perhaps exacerbate, this misunderstanding.

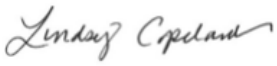
We also urge refinement of the language that the item or service "meets, but does not exceed, the patient's medical need" and is "at least as beneficial as an existing" alternative. The former, for example, may cause problems for individuals who are gradually losing function and whose needs will necessarily change over relatively short time frames. Technologies that may aid beneficiaries as they pass through various levels of need may appear on the surface to "exceed the patient's medical need," but may be the most appropriate to ensure the beneficiary has consistent access to necessary care as they age. We urge a thoughtful exploration of this issue, including what can be classified as meeting a beneficiary's need, how variable beneficiary needs may be, what timelines are appropriate, and how to define "at least as beneficial" to ensure that there is a true balancing of all important considerations.

We reiterate cautious support of a consideration of the commercial market if and only if it is used to expand coverage, rather than to restrict or deny it. Commercial insurers may not expect to keep their enrollees for a lifetime, and may choose coverage based on short-term, profit-oriented goals that must not become part of Medicare policy. We must also ensure that the bases for Medicare coverage are transparent, with opportunities for public notice and comment where possible. to ensure reasonableness, equity, and a lack of discrimination.

In addition, we also caution against including language about "clinically relevant distinctions" between commercially insured individuals and Medicare beneficiaries unless it is clear what evidence, metrics, and factors would be considered in determining what these differences might be. While most people with Medicare are over age 65, many are Medicare eligible due to disability or end-stage renal disease. Subpopulations within Medicare have varying needs and cannot be placed into any single category. We must ensure that all decisions about coverage consider all beneficiaries and do not leave subpopulations behind.

Thank you again for this opportunity to provide additional comment. For further information, please contact Lindsey Copeland, Federal Policy Director at LCopeland@medicarerights.org or 202-637-0961 and Julie Carter, Senior Federal Policy Associate at JCarter@medicarerights.org or 202-637-0962.

Sincerely,



Lindsey Copeland
Medicare Rights Center