**Intersect Healthcare, Inc.**
8600 LaSalle Rd. Suite 625
Towson, MD 21286
(410) 252-4343

April 16, 2021

Seema Verma, MPH
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
ATTN: CMS-3372-IFC
P.O. Box 8013
Baltimore, MD 21244-1850

**Re: Medicare Coverage of Innovative Technology (MCIT) and Definition of "Reasonable and Necessary"**

Dear Administrator Verma:

Intersect Healthcare, Inc. (IHI) is pleased to submit its comment on the Centers for Medicare and Medicaid Services (CMS) proposed rule, Medicare Coverage of Innovative Technology (MCIT) and Definition of "Reasonable and Necessary."[1]

As detailed below, IHI has comments and concerns about the proposed rule's modifications to the codified definition of "reasonable and necessary" and new coverage determination MCIT program.

IHI is a provider of denial and appeal management consulting and denial management technology for healthcare providers. Through their affiliate Denial Research Group, IHI also offers clinical appeal consulting to help providers protect their revenue, including medical necessity and coding audits, and QIO/FI/RAC/MIP Medicare & Medicaid appeals aimed at obtaining the proper DRG assignment and reimbursement.

In this proposed rule, CMS proposes changes including a codified definition of "reasonable and necessary" whose third element—(3) appropriate—would be expanded to include additional requirements. CMS clarifies that the meaning of "appropriate" will be based on commercial health insurers' coverage policies rather than the standards in the practice of medicine. As for the MCIT program, CMS proposes its coordination with manufacturers undergoing the FDA regulatory processes to introduce "breakthrough devices" into the stream of healthcare commerce. CMS explicitly states that the timing of coverage is at the manufacturer's discretion, which can weaken CMS oversight of coverage determinations involving "breakthrough devices."

[1] *See* 86 Federal Register 14542 (March 17, 2021), https://www.govinfo.gov/content/pkg/FR-2021-03-17/pdf/2021-05490.pdf

**Definition of "Reasonable and Necessary"**

IHI strongly supports efforts to increase access to healthcare to ensure patients can receive the appropriate medical care, which stems from the standards in the practice of medicine. Under the current definition, an item or service is deemed ''reasonable and necessary'' if it is (1) safe and effective; (2) not experimental or investigational; and (3) appropriate, including the duration and frequency that is considered appropriate for the item or service, in terms of whether it is:

- 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;
- Furnished in a setting appropriate to the patient's medical needs and condition;
- Ordered and furnished by qualified personnel;
- One that meets, but does not exceed, the patient's medical need; and
- At least as beneficial as an existing and available medically appropriate alternative.

Based on the agency's revisions and response to objections to the proposed rule, IHI encourages the agency and commenters to clarify whether the proposed changes to a codified definition of "reasonable and necessary" is patient-focused. Generally, medical necessity refers to whether a treatment is clinically appropriate for a condition[2] whereas coverage refers exclusively to whether the insurer provides payment for treatment.[3] The purpose of the proposed rule's modified and codified "reasonable and necessary" definition remains unclear.

**Medicare Coverage of Innovative Technology (MCIT)**

As a leader of innovative technology, IHI strongly supports efforts to use technology to better serve health systems.

The agency's proposed rule that introduces the MCIT pathway appears to receive favorable recognition from non-providers (i.e., manufacturers, insurance companies). Conversely, providers, those who actively treat patients in various settings, are concerned with the operational and clinical issues presented by the MCIT.

Based on the agency's revisions and response to objections to the proposed rule, IHI encourages the agency and commenters to recall that the legislative intent of Medicare clearly states "the physician is to be the key figure in determining utilization of health services."[4]

Assuming there is clarity on the purpose of the proposed rule regarding patient care, IHI emphasizes the importance of patient-focused healthcare to preserve the value of care.

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[2] *See* 45 C.F.R. § 144.103.

[3] *Id.*

[4] *See* 1965 U.S.C.C.A.N. 1943, 1986; *see also Hultzman v. Weinberger*, 495 F.2d 1276, 1279 (3d Cir. 1974); *see also Reading v. Richardson*, 339 F.Supp.295, 300-01 (E.D. Mo. 1972); *see also Kuebler v. Secretary*, 579 F. Supp. 1436, 1440 (E.D.N.Y. 1984); *see also Breeden v. Weinberger*, 377 F. Supp. 734, 737 (M.D. La. 1974).

IHI does not support effecting a modified and codified definition of "reasonable and necessary" as well as the FDA's Breakthrough Program through the MCIT unless the agency considers clinical evidence supported by the practice of medicine.

IHI appreciates the opportunity to comment on this proposed rule. If you have any questions or require additional information, please contact Chrysalis Borja, cborja@intersecthealthcare.com or 410-252-4343 ext. 144.

Sincerely,

Brian McGraw

Brian McGraw
President

Raymond Kendall Smith, Jr., MD, SFHM
Chief Physician Advisor

Denise Wilson, MS, RN, RRT
Senior Vice President of Appeal Services