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Advancing Health in America

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November 2, 2020

Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W., Room 445-G
Washington, DC 20201

RE: Proposed Rule: CMS–3372–P, Medicare Program; Medicare Coverage of Innovative Technology (MCIT) and Definition of "Reasonable and Necessary;" (Vol. 85, No. 170), September 1, 2020

Dear Ms. Verma:

On behalf of our nearly 5,000 member hospitals, health systems and other health care organizations, our clinician partners – including more than 270,000 affiliated physicians, 2 million nurses and other caregivers – and the 43,000 health care leaders who belong to our professional membership groups, the American Hospital Association (AHA) appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) proposed revision to the definition of "reasonable and necessary" for purposes of Medicare coverage determinations.

Medicare will only cover items and services under Medicare Parts A and B of the program that, among other requirements, are determined to be "reasonable and necessary." The agency relies on a definition of "reasonable and necessary" in the Program Integrity Manual (PIM), which states that an item or service may be considered reasonable and necessary if it meets the following three criteria:

1. It is safe and effective;
2. It is not experimental or investigational; and
3. It is appropriate, including the duration and frequency in terms of whether the service or item is:

- Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the beneficiary's condition or to improve the function of a malformed body member;
- Furnished in a setting appropriate to the beneficiary's medical needs and condition;
- Ordered and furnished by qualified personnel; and
- One that meets, but does not exceed, the beneficiary's medical need.

The agency proposes to codify in regulations this definition with some modifications. Specifically, the agency proposes to allow for an alternative approach to meeting the third criterion by considering whether the item or service is covered in the commercial market. In other words, if an item or service could not meet the current third criterion, it could still be covered if the item or service is covered by certain commercial health plans. By adding this alternative approach to meeting criterion three, the agency suggests that it seeks to expand coverage, such as in instances in which commercial plans have more quickly moved to cover newer therapies. However, the agency later suggests that it could replace the third criterion completely with an assessment of whether commercial plans cover the item or service. Note that while not explicit, we interpret the rule to include both fully insured health plans and self-insured coverage. However, we ask that the agency provide greater specificity on how it defines commercial coverage prior to proceeding in the policy development process.

Below, we provide input on both the codification of a definition of "reasonable and necessary" in the Code of Federal Regulations, as well as on the proposed modifications and alternatives to the definition itself.

CODIFICATION OF A DEFINITION OF "REASONABLE AND NECESSARY" IN FEDERAL REGULATIONS

The agency proposes to codify the definition of "reasonable and necessary" at 42 CFR 405.201. This section of the regulations relates to "Medical Services Coverage Decisions That Relate to Health Care Technology." However, based on the broad language in the rule that references "items and services" without any limitation to breakthrough technologies, we remain uncertain about whether the proposed definition would apply only to health care technology or to all Medicare Part A and B items and services. We request the agency provide further clarity prior to moving forward with this proposal.

In either event, **AHA strongly opposes the elevation of definitional guideposts from a manual provision to enforceable standards in the Code of Federal Regulations**, especially without a comprehensive assessment of the impact of that change and a clearer articulation of the process by which the new standard will be imposed**.** Codification of sub-regulatory guidance poses a real risk of altering the context and manner in which the definition and its new criteria can be applied and enforced. For example, codification presents a risk of constraining the discretion the

agency's Administrative Law Judges have long exercised to resolve coverage disputes that turn on differences in medical opinion and judgment. So too, once codified, ambiguities in the manual provision could enable inconsistent enforcement by other actors, including Recovery Audit Contractors on audit, the Office of the Inspector General in civil monetary penalty proceedings, criminal prosecutors (see *U.S. v. Paulus*) and Department of Justice attorneys and relators in *qui tam* cases brought under the civil False Claims Act (see *U.S. ex rel. Polukoff v. St. Mark's Hosp., United States v. Care Alternatives*, and *Winter ex rel. U.S. v. Gardens Reg'l Hosp. & Med. Ctr. Inc.*).

As the CMS preamble acknowledges, the proposed rule's definitional criteria raise a number of unaddressed procedural and evidentiary issues. **We believe all such issues should be addressed and resolved through notice and comment rulemaking before the criteria are elevated in form and substance to enforceable code of federal regulation standards.** Again by way of example, nothing in the proposed rule addresses whether the agency expects codification of the definitional criteria to change the way providers and suppliers assess coverage for existing therapies or whether the criteria are to be implemented on a beneficiary-specific, patient-focused basis or on the basis of a class or category of therapy more generally. Moreover, the proposed rule fails to make clear that providers and suppliers will be subject to no additional documentation or certification requirements as a result of the codification of the manual language.

AHA strongly urges CMS to state clearly that that the proposed definition will have no impact on and will not change existing documentation or certification standards. So too, CMS should make clear that codification of the definition will not require re-assessment of existing coverage determinations under its new terms – in answer to the agency's request for comment (85 Fed. Reg. 543320), to the extent the new definition could be viewed to narrow the "reasonable and necessary" standard, AHA believes existing determinations that favor coverage of an item or service should be "grandfathered." AHA requests that CMS formally seek input from stakeholders on these and other important issues of practical implementation before codifying a definition of "reasonable and necessary."

PROPOSED MODIFICATIONS AND ALTERNATIVES TO THE DEFINITION OF "REASONABLE AND NECESSARY"

The AHA strongly supports efforts to expand access to care. While the Medicare program is often a leader in coverage of new therapies, there may be instances where the commercial market covers a new item or service before Medicare. Therefore, we agree that it is reasonable to consider commercial market coverage to the extent that an item or service could otherwise not meet the third criterion. **However, we do not support replacing the third factor entirely and relying solely on what is occurring in the commercial market. Such an approach would undoubtedly result in a contraction of coverage, inhibit CMS' ability to oversee the program, create unpredictability in coverage, result in further delays in bringing new therapies to**

beneficiaries, and not align with transparency objectives in public programs. We urge the agency to consider the following concerns:

- **Public Payers Often Lead in Coverage.** The Medicare and Medicaid programs are often leaders when it comes to coverage of new therapies. For example, Medicare and state Medicaid programs were among the first payers to cover new chimeric antigen receptor (CAR) T-cell therapies. Years later, many commercial payers continue to only approve coverage of such therapies on a case-by-case basis. It is unclear whether such an approach by commercial payers would be deemed "coverage" for purposes of this proposal. Therefore, we question whether looking to commercial coverage would contract, rather than expand, coverage to newer therapies.

- **Relying on Commercial Insurers Would Reduce Transparency in Coverage Decisions, including for the Federal Government.** Commercial insurers presumably use a number of different factors to make coverage determinations. What those factors are, however, are not fully known to anyone outside of their organizations, including CMS. What is known, however, is that the commercial market plans that CMS would look to for purposes of coverage determinations serve populations that are very different from fee-for-service Medicare beneficiaries. CMS focuses on the needs of the aged and certain disabled patient populations while commercial insurers primarily insure working-aged adults and families. Commercial insurers have no interest in expanding coverage of an item or service to meet the needs of a population their health insurance product does not cover; doing so could increase the cost of private coverage, negatively impacting their enrollees. CMS would, therefore, be ceding its authority — at least in part — to commercial insurers over which it has no influence and whose objectives will not always align with the agency's influence. And while the agency would have little influence over coverage decisions, it would remain responsible for ensuring that Medicare beneficiaries have access to the Part A and B services to which they are entitled. Therefore, this approach would seemingly put the agency at considerable risk.

  Lack of transparency would not be limited, however, to the government. Many stakeholders with expertise in caring for Medicare beneficiaries, including hospitals and health systems, provide input on Medicare coverage determinations through a public comment process. Deferring to commercial insurer coverage would reduce this opportunity to obtain expert guidance directly from those caring for this population and would rely solely on insurers whose products are intended for a very different population.

  Finally, commercial payers can change the factors they use to make coverage decisions at any time. For example, a commercial insurer may consider a number of factors when making coverage decisions at the beginning of a coverage year. However, their priorities may change over time and result in mid-year coverage changes. While insurers are technically not supposed to make substantial changes

over the course of a coverage year, they often do. For example, a number of health insurers have decided mid-coverage year to alter the providers from which their enrollees can access certain services. For example, Cigna, following Anthem's lead, recently announced that it would no longer cover certain imaging procedures from certain types of in-network providers. This change in coverage came mid-year without the opportunity for enrollees or contract providers to provide feedback.

- **There is wide variation in commercial coverage policies.** CMS acknowledges that it would have to determine what constituted "coverage" by a commercial plan. The challenge would be significant as wide variation exists across plans. Benefits can vary across plans offered by the same insurer, and there are many state laws that mandate certain benefits. In addition, as noted above, an insurer may only cover a new therapy on a case-by-case basis, and it is unclear whether this would constitute "coverage" for purposes of these regulations. An additional complication is that there is no central, publicly available database to access commercial coverage policies which limits any public comment on potential commercial coverage policy options.

While we are not opposed to considering coverage in the commercial market for purposes of Medicare coverage determinations, we strongly disagree with making it a deciding factor. Given the number of open questions related to this rule, we encourage the agency to reconsider the proposal and only move forward when it is able to provide additional specificity, particularly as it relates to what items and services this definition would apply to, which commercial plans specifically would be considered, what oversight mechanisms the agency would use to ensure coverage determinations align with federal policy and meet beneficiary needs, and how the agency would define "coverage," including in instances where a plan makes coverage determinations on a case-by-case basis.

Thank you again for the opportunity to provide input. Please contact me if you have questions, or feel free to have a member of your team contact Molly Smith, vice president of coverage policy, at (202) 626-4639 or mollysmith@aha.org.

Sincerely,

/s/

Thomas P. Nickels
Executive Vice President