Alliance FOR AGING RESEARCH
Catalyzing Innovation for Healthy Aging

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The Honorable Diana DeGette
US Representative
2111 Rayburn House Office Building
Washington, DC 20515

The Honorable Fred Upton
US Representative
2183 Rayburn House Office Building
Washington, DC 20515

Dear Representatives DeGette and Upton,

The Alliance for Aging Research, www.agingresearch.org, is the leading nonprofit organization dedicated to accelerating the pace of scientific discoveries and their application to vastly improve the universal experience of aging and health. The Alliance was honored to provide input on, and support for, the medical research and clinical development provisions in the *21st Century Cures Act* in 2016. We are thankful for your continued leadership in this space and your next exciting step with *Cures 2.0* to modernize coverage and access. Our feedback on the priority reforms identified is below.

Digital Health Technologies

Digital health technology has the potential to enable older adults to live independently and "age in place." However, there are significant gaps between the potential benefits digital health technology can have for older Americans and the barriers that are thwarting the widespread adoption of these cutting-edge technologies by Medicare beneficiaries. A significant barrier blocking the widespread utilization of digital health and software products for older adults is a lack of harmonization between the Food and Drug Administration (FDA) and the Centers for Medicare and Medicaid Services (CMS). Currently, if a digital health product is approved through the FDA's breakthrough pathway process, it can take up to three years for CMS to make a coverage decision for that technology.

An additional barrier impeding the uptake of this technology is the lack of appropriate benefit categories for many new digital health products. The current use of general codes for these products makes it difficult to bill for services. New permanent codes are needed to make it easier to bill for new technology.

For example, continuing glucose monitoring (CGM) systems for diabetes come with receivers that display glucose data. The receivers are considered durable medical equipment, which allow the systems to be covered by CMS. In 2018, the American Association of Diabetes Educators wrote CMS to tell them about FDA-approved medical applications for smart phones that allow older adults to passively share their glucose results with designated family caregivers and healthcare providers. Unfortunately, patients who were using a CGM medical app, either in place of the receiver or in

conjunction with it, were being denied coverage for their supplies by Medicare. After several additional organizations brought public pressure to CMS, Medicare finally decided to cover it.

It is critical that *Cures 2.0* harmonizes CMS coverage, coding, and payment processes for FDA-approved digital health products to avoid more coverage gaps like these.

Medicare Coding, Coverage & Payment

Each year, professional societies are playing a larger role in shaping Medicare coverage decisions by requesting National Coverage Analyses (NCAs), or NCA reviews, which are informing the content included in subsequent National Coverage Determinations (NCDs). Professional society requests are often sent in anticipation of an FDA approval of a new device, or an additional indication of an already-approved device. Such requests typically outline what the professional society believes the preferred NCD should look like, including detailed operator and institutional requirements.

Often, the resulting NCD will include "Coverage with Evidence Development" (CED) for those procedures provided outside of FDA-approved indications. CED requires procedures to be performed in clinical studies that meet requirements set forth in the NCD and approved by CMS. Professional societies may also recommend additional "conditions of coverage" such as procedural volume requirements, as well as mandatory participation in a prospective, national, audited registry. Those same professional societies will typically also propose to develop and manage said registry and fund it through annual fees paid by participating hospitals.

We implore policymakers to question the outsized role of professional societies in choreographing CMS coverage decisions and create guardrails to prevent undue influence. Patients are often stuck in the middle of territorial claims among healthcare professionals, as well as between major medical centers and smaller, community-based/rural hospitals. These dynamics have dragged out certain coverage determination processes for years, resulting in significant treatment access issues for certain beneficiary groups such as minorities and those who live in rural communities. Equal access and quality care for all Medicare beneficiaries should be the guiding principle of coverage decisions.

Coverage with Evidence Development (CED)
First, the evidence threshold needed to end CED should be explicitly defined by CMS. Because CED falls under the NCD statutory authority, there is no specific enforcement mechanism to ensure timely research reporting compliance, which results in an ad hoc process that leaves Medicare beneficiaries in a state of uncertainty regarding their treatment. In an August 2011 article, *Improving the Quality and Efficiency of the Medicare Program Through Coverage Policy*, the authors state, "The current authority is sufficiently ambiguous to prevent CMS from fully developing and implementing coverage with evidence development consistently and systematically."[1]

In its 2014 guidance on CED, within the section "Ending CED", CMS states that the purpose of the studies is to "produce evidence that will lead to revisions in Medicare coverage policies," and cites two examples of completed CED processes—NCDs for oncologic uses of FDG PET, and ventricular

[1] https://www.urban.org/sites/default/files/publication/27516/412392-Improving-the-Quality-and-Efficiency-of-the-Medicare-Program-Through-Coverage-Policy.PDF.

assist devices.[2] *The implication here is that there would be a clear beginning and end to the CED process.* The "Ending CED" section further states that "a CED cycle is considered completed when CMS completes a reconsideration of the CED coverage decision and removes the requirement for study participation as a condition of coverage."[3] In our experience, CED can be kept in place beyond when it is reasonable and necessary.

***Cures 2.0* should mandate that CMS lay out milestones and a targeted end date for CED, and that CMS should be required to be clear about what specific evidence it needs to make an ultimate coverage decision (currently, evidence questions are often very broad). CMS should not be allowed to place quota numbers on CED, such as with PET imaging.**

Incentivizing Shorter Hospital Stays

Decisions made during a hospital admission affect outcomes and resource use well beyond the hospitalization episode. The goal should be to reward good longer-term patient outcomes and provide value to the health care system. However, the incentives often are not fully aligned—especially in situations in which hospitals are asked to pay more for better outcomes. Such problems are particularly acute in fields where technology is evolving rapidly. Hospitals face the difficult situation of having to choose between profits and patients, because payments reflect resource use instead of value generation.

In an ideal world, payment levels would be based on comparative cost and clinical outcomes, adjusted for patient risk, and would be indifferent to how we achieve those outcomes. In the real world, diagnosis-related group payments are reflective of historic patterns of resource use, and the limited adjustments to that underlying structure, which current payment reform efforts entail, will not change that distortion fundamentally.

***Cures 2.0* should mandate that CMS/CMMI develop payment models to encourage treatment choices that coincide with clinical outcomes, patient-centered outcomes, and total cost to the health care system. In a field with rapidly evolving technology, this could be accomplished by setting a bundled price for all medical costs within one year of the procedure, ideally with a pay-for-performance component. Such a payment model would make hospitals indifferent to the cost components and reward them for achieving the best value for the money.**

Clinical Trial Design for CED

We recognize the importance of CMS utilizing clinical trial data in making coverage decisions under CED; however, we support more flexibility in the clinical trial data the agency should accept. Currently, CMS can require randomized clinical trials for study participation, and preclude potential Medicare coverage of observational studies, as well as trial designs agreed upon between sponsors and the FDA, such as a single-arm pivotal trial or a non-randomized arm within a larger study program. CMS has the discretion to determine that these parts of a clinical study would be ineligible for reimbursement of the routine costs to treat Medicare subjects. This is significant because the coverage of the items and services that are generally available to Medicare beneficiaries can be financially critical to medical device companies engaging in clinical trials.

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[2] https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=360.
[3] Ibid.

CMS acknowledges these issues. In its August 14, 2019 initiation of a national coverage analysis for Transcatheter Mitral Valve Repair (TMVR) (section 20.33), CMS indicated an openness to "reviewing the NCD requirement for randomized controlled trials of non-FDA approved indications and considering if it should be changed to reduce burden and encourage innovation in this space."

For example, in the case of clinical trials for heart failure patients with secondary or functional mitral regurgitation (FMR), CMS should remove its clinical trial randomization requirement for coverage *because it is unethical*. The prognosis among patients with heart failure and FMR on guideline-directed medical therapy alone is very poor. In the COAPT trial, approximately two-thirds of patients who had guideline-directed medical therapy alone (control group) died or were hospitalized for heart failure within two years.[4] The study found that the annualized rate of all hospitalizations for heart failure within 24 months was 35.8 percent per patient-year in the device group as compared with 67.9 percent per patient-year in the control group; and death from any cause within 24 months occurred in 29.1 percent of the patients in the device group as compared with 46.1 percent in the control group. CMS should recognize that such significant differences in major health outcomes between device and control group participants should not be forced to continue in order to qualify for coverage. Additionally, we know of no published studies on TMVR trial design that cite a unique necessity for randomization.

***Cures 2.0* should mandate that trials approved by the FDA to comport with the review and approval process should de facto be accepted by CMS as qualifying for Medicare coverage for the routine care costs associated with participation in a clinical trial and any such trials that CMS pays for under this policy should be required to be accepted by the agency as evidence for coverage and reimbursement decisions.**

Harnessing Real World Evidence (RWE)

Patient registries have the potential to help inform—and play an essential role in—decision-making in science, development, and testing of new therapies and devices, and subsequent payment policy for innovations in treatment and care.

The Pew Charitable Trusts convened a series of multi-stakeholder meetings in 2014 to develop a set of recommendations on the use of registries to improve patient safety.[5] We believe that CMS should leverage the thought leadership of this effort and include the recommendation that a qualifying registry should "streamline registry data collection through efficiencies that reduce the time and cost of reporting:

1. The number of patients followed in a registry should reflect its underlying purpose.
2. Registry of data fields should be limited to the data most relevant to the purpose of the registry, and they must use standardized definitions.

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[4] Centers for Medicare & Medicaid Services. August 14, 2019. National Coverage Analysis (NCA) Tracking Sheet or Transcatheter Mitral Valve Repair (TMVR) (CAG-00438R). Available at https://www.cms.gov/medicare-coverage-database/details/nca-tracking-sheet.aspx?NCAId=297&CoverageSelection=Both&ArticleType=All&PolicyType=Final&s=All&KeyWord=TMVR&KeyWordLookUp=Title&KeyWordSearchType=And&bc=gAAAACAAQAAA&..

[5] PEW. September 3, 2014. Medical Device Registries: Recommendations for advancing safety and public health. Available at http://www.pewtrusts.org/en/research-and-analysis/reports/2014/09/medical-device-registries.

3. Registries should be coordinated with national efforts to improve quality measure reporting."[6]

Currently, CMS often includes participation in a patient registry as a condition of coverage for hospitals performing a service—in essence an additional "condition of participation" specific to receiving reimbursement for a particular service. Specialty societies apply to develop and run these registries and often charge hospitals annual fees to be members. The specialty societies own the registry data and determine what types of analyses may be conducted using the data, for which they may also impose a charge.

The information contained in these registries are used by CMS to determine coverage and payment policy, yet CMS has no direct access to the data, and no enforcement or oversight over whether their registry-related evidence questions are answered at all, let alone within a set period of time. These registries are being used specifically to inform Medicare coverage decisions yet exist completely outside public access. Transparency and accessibility are essential for the public, policymakers, and patients to have confidence in the data and the process.

***Cures 2.0* should give CMS unfettered registry data access, the ability to limit charge amounts by specialty societies for hospital registry participation, the enforcement authority to sanction registry managers if evidence-questions are not answered in a reasonable timeframe, and veto power over what types of analyses the specialty societies may conduct using the data.**

Transparency in RWE

Each year, professional societies are playing a larger role in shaping Medicare coverage decisions by requesting NCAs or NCA reviews and informing the content included in subsequent determinations. Patient organizations, Medicare beneficiaries, and the public do not have access to site-specific outcomes data collected by CED-approved registries that would otherwise help consumers make more informed decisions about where to access their procedure services. Under the Hospital Inpatient Quality Reporting Program, CMS collects quality data from hospitals paid under the Inpatient Prospective Payment System, with the goal of driving quality improvement through measurement and transparency by publicly displaying data for this purpose. It is also intended to encourage hospitals and clinicians to improve the quality and cost of inpatient care provided to all patients. The hospital-specific data collected through the program are available to consumers and providers on the Hospital Compare website at: https://www.medicare.gov/hospitalcompare/search.html. An example of this can be found at the New York Department of Health, which publishes annual data on risk-adjusted measures for cardiac procedures by hospital in New York State.[7]

***Cures 2.0* should require CMS to publicly report site-specific, risk-adjusted patient registry health outcomes that are collected by specialty societies as part of the CED process.**

Our organization has worked with more than a dozen national organizations representing patients, family caregivers, aging organizations, advocates for minority and women's health, and providers on these issues. We now call on Congress to require CMS to develop policies that provide all Medicare

[6] Ibid.

[7] New York State Department of Health. Cardiovascular Disease Data and Statistics. Available at www.health.ny.gov/statistics/diseases/cardiovascular/.

beneficiaries access to all FDA-approved appropriate treatments and put patient-centered care into practice. If appropriate, our organization can draft legislative language on the above issues and provide further details about how these issues are impeding the delivery of innovative, life-saving, and life-improving care to Medicare beneficiaries across the nation.

Thank you for taking our views into consideration and for your work on the Committee on this important effort. If you have questions for our organization, please do not hesitate to contact the Alliance's Public Policy Manager, Ryne Carney, at (202) 688-1242 or rcarney@agingresearch.org.

Sincerely,

Susan Peschin, MHS
President and CEO