Alliance FOR AGING RESEARCH
1700 K Street, NW | Suite 740 | Washington, DC 20006
info@agingresearch.org | www.agingresearch.org

July 14, 2025

The Honorable Robert F. Kennedy, Jr.
Secretary
U.S. Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, DC 20201

Re: HHS Request for Information (RFI): Ensuring Lawful Regulation and Unleashing Innovation to Make American Healthy Again (Docket ID No. AHRQ-2025-0001)

The Alliance for Aging Research ("Alliance") is the leading nonprofit organization dedicated to changing the narrative to achieve healthy aging and equitable access to care. The Alliance strives for a culture that embraces healthy aging as a greater good and values science and investments to advance dignity, independence, and equity. The Alliance appreciates the opportunity to respond to the Department's request for regulations and Guidance that could be waived, modified or streamlined to reduce administration burdens. In this letter, the Alliance will address two topics within Medicare: Coverage with Evidence Development, which applies under question 1, and a measure within the five-star rating system for secure nursing facilities, which applies under question 3.

Coverage with Evidence Development

AAR recommends that HHS eliminate three "Guidances" (which constitute 25 individual regulations), as outlined in question 1 of the RFI. These guidances refer or are related to the prior Administration's "Coverage with Evidence" (CED) policy that interfere with beneficiary access to drugs and devices. The suggested changes would restore the Agency's Advisory Opinion issued by the CMS General Counsel on January 14, 2021 which correctly concluded that there is no statutory authority to adopt or implement a CED policy. More specifically, the three Guidance documents that should be withdrawn are:

1. Coverage with Evidence Development Guidance Document, August 7, 2024, available at https://www.cms.gov/files/document/ced-guidance2024pdf.pdf (no OMB Control Number);
2. CMS National Coverage Analysis Evidence Review Guidance Document August 7, 2024, available at https://www.cms.gov/files/document/cms-evidence-review2024pdf.pdf (no OMB Control Number); and

3. Medicare Program; Transitional Coverage for Emerging Technologies; 89 Fed. Reg. 69724 (Aug. 12, 2024), applying the CED policy to Medicare coverage of breakthrough medical devices through the "transitional coverage for emerging technologies (or TCET) policy announced in the Federal Register.

Each of the three Guidance documents imposes a barrier to Medicare beneficiary access to drugs and devices by imposing vague, subjective and nonworkable "clinical trial" or "registry" barriers to Medicare coverage. More specifically, CMS has refused to cover certain FDA-approved drugs and devices that should be covered for their on-label uses because the Agency, using vague and undefined standards not authorized by way, deems that there is not sufficient medical evidence to support a "reasonable and necessary" finding without further CMS-approved studies. Both practically and legally, however, the CED process does not work, and simply serves as a barrier to beneficiary access to FDA-approved treatments. Moreover, to the extent that a select small number of beneficiaries who participate in the clinical "trials" are able to have their use of the drugs or devices covered, it is administratively burdensome for both beneficiaries and providers to do so. As a result, patient safety and the integrity of the Medicare program are compromised by the use of CED.

In a recent article summarizing the failures of the CED program in the Journal Health Affairs entitled Medicare's 'Coverage With Evidence Development': A Barrier to Patient Access and Innovation, https://schaeffer.usc.edu/research/medicares-coverage-with-evidence-development-a-barrier-to-patient-access-and-innovation/ Joe Grogan summarized the failure of the CED program as follows:

> Since 2005, 27 medical devices or procedures have been subjected to CED. However, only four had their evidence development programs retired and their national coverage retained. CMS ceded coverage of an additional two devices or procedures to the discretion of Medicare's regional administrative contractors. The remaining 21 items and services continue to be subject to CED, and none have preset time frames for "graduating" from the program and receiving a final coverage determination. Even amongst the products that graduated CED, the time elapsed between initiation and graduation ranged between four and 12 years. Multiple products that were amongst the first to receive CED continue to be required to generate clinical data today, almost 20 years later.

Mr. Grogan also documented the administrative barriers imposed by the CED program:

> The fact is CED is a never-ending coverage purgatory for innovators, with more than 30 complex steps required simply to establish a program. Once CMS announces coverage of a product under CED, an organization must step in to sponsor a study to collect the evidence. This involves determining investigators, establishing a governing protocol, getting approval from both an institutional review board and CMS, preparing a database or registry in which data can be submitted, determining funding for the study, identifying and enrolling patients,

> and general clinical practice. The details behind each of these steps are extensive, and mistakes can be costly….Furthermore, the resources required to facilitate CED can inhibit evidence development. It is not always clear who should bear the costs of participation, who should bear the costs of developing systems to collect and input data, or who should be responsible for sharing with data registries…. This creates inconsistencies in coverage rules and access based on where a Medicare beneficiary lives, as contractors can set different rules for the regions they cover.

Given this failure, Mr. Grogan concluded that: "CMS should scrap CED altogether, choosing instead to default to coverage of on-label use for FDA-approved drugs. Where CMS is unsure of the medical necessity of an item or service, it should defer coverage to its regional administrative contractors to make claim-by-claim determinations concerning medical necessity. At minimum, CMS should refrain from placing drugs which receive FDA approval under CED…" Mr. Grogan's conclusions are supported by the patient community, that published a report in February 2023 and came to the very same conclusions. https://www.agingresearch.org/wp-content/uploads/2023/02/Facade-of-Evidence-CED-2-13-2023.pdf

Requiring beneficiaries to participate in clinical trials or registries is also **against federal law**: Section 1801 of the Medicare law states, "Nothing in this title shall be construed to authorize any Federal officer or employee to exercise any supervision or control over the practice of medicine or the manner in which medical services are provided, or over the selection, tenure, or compensation of any officer or employee of any institution, agency, or person providing health services; or to exercise any supervision or control over the administration or operation of any such institution, agency, or person." Section 1801 was included in the law to offset the criticism made by opponents of the proposal that Federal legislation would give Federal officials the opportunity and the right to interfere in the diagnosis and treatment of the individual. The CED policy, however, does exactly that.

A beneficiary's decision to not participate in a CED clinical study does not necessarily reflect unwillingness, as there are often access barriers outside a patient's control. These agency-directed restrictions may include, but are not limited to, care setting or provider eligibility criteria or limits on CED clinical study enrollment. Post-market randomized control trial requirements (RCTs) may be unpalatable to beneficiaries and present ethical issues, as RCT study design in CED may require some Medicare beneficiaries to receive a placebo for a device, diagnostic, or prescription drug already found to be "safe and effective" by the FDA. Beneficiaries may be required to pay coinsurance for a placebo in order to maintain a blinded study. Some populations may experience mistrust based on historical experience or have legal concerns that create hesitancy to have personal health data collected in a clinical study. By creating barriers to patient access, denying that there are barriers, and placing the onus for shortcomings on sponsors and patients, CMS interferes with and restricts the medical autonomy of Medicare beneficiaries.

Beyond the burdensome administrative requirements on both beneficiaries and providers, the CED program is **illegal** and threatens the integrity of the Medicare program. In the first

Trump Administration, the General Counsel of the Department of Health and Human Services, Robert Charrow, issued a clear Advisory Opinion demonstrating that CMS lacked authority to implement the CED program. The Advisory Opinion, rescinded by the Biden Administration and taken off the HHS website, can be found at https://drive.google.com/file/d/1swctNCEARvrK0Nzr6ja3268gwcsyR0Ff/view, is explicit that there is no current legal authority for the CED program. The rescinded Advisory Opinion, which should be restored, stated:

> CMS has previously interpreted SSA Section 1862(a)(1)(E) as authority to make Medicare payment for items and services provided to study participants in CED clinical trials, under the theory that AHRQ "supports" this research by endorsing it. Accordingly, although AHRQ is neither conducting the research, nor actively supporting the research through funding or other means, CMS has taken the position that AHRQ's endorsement of the research is sufficient to qualify as "support" under SSA Section 1142.
>
> OGC has re-examined this issue and concluded that this prior interpretation of "support" leads to Medicare payment that is unlawful under Section 1862, because AHRQ has not been "supporting" the clinical trials and research required as part of an NCD using CED. The term "support" as used in SSA Section 1142 is not defined, **but this broad reading of the term is fundamentally inconsistent with the regulatory definition of "support" at 42 C.F.R. § 93.221.** While this definition applies to research oversight under Title IX of the Public Health Service Act ("PHS Act"), and therefore is not controlling for purposes of interpreting the term "support" under SSA Section 1142, OGC now believes that the correct interpretation of the term "support" is to read it as having a meaning consistent with the definition of this term at 42 C.F.R. § 93.221....Therefore, in order for an NCD using CED to lawfully invoke the exception at SSA Section 1862(a)(1)(E), AHRQ must "support" the study within the meaning of the definition at 42 C.F.R. § 93.221, which will involve more than merely endorsing the clinical study.

For this reason, even if the administrative burden and impairment of the Medicare program's integrity were not sufficient justification to rescind and withdraw the above three documents, the legal analysis similarly requires withdrawal at this time.

The 25 individual CEDs that must be repealed can be found here: https://www.cms.gov/medicare/coverage/evidence

1. Allogeneic Hematopoietic Stem Cell Transplant for MDS
2. Allogeneic Hematopoietic Stem Cell Transplant for Multiple Myeloma
3. Allogeneic Hematopoietic Stem Cell Transplant for Myelofibrosis
4. Allogeneic Hematopoietic Stem Cell Transplant for Sickle Cell Disease
5. Amyloid PET
6. Autologous Platelet-rich Plasma

7. CPAP For Obstructive Sleep Apnea
8. Cochlear Implantation
9. Extracorporeal Photopheresis for Bronchiolitis Obliterans Syndrome Following Lung Transplant
10. FDG PET and Other Neuroimaging Devices for Dementia
11. Home Oxygen for COPD
12. Implantable Pulmonary Artery Pressure Sensors for Heart Failure Management
13. Leadless Pacemakers
14. Monoclonal Antibodies Directed Against Amyloid for the Treatment of Alzheimer's Disease (AD)
15. NaF-18 PET for Bone Metastasis
16. Off-label use of Colorectal Cancer Drugs
17. Percutaneous Image-guided Lumbar Decompression for Lumbar Spinal Stenosis
18. Percutaneous Left Atrial Appendage Closure (LAAC)
19. Pharmacogenomic Testing for Warfarin Response
20. TENS for chronic low back pain
21. Transcatheter Aortic Valve Replacement
22. Transcatheter Edge-to-Edge Repair (TEER)
23. Transcatheter Edge-to-Edge Repair for Tricuspid Valve Regurgitation (T-TEER)
24. Transcatheter Tricuspid Valve Replacement (TTVR)
25. Vagus Nerve Stimulation (VNS) for Treatment Resistant Depression (TRD)

Lastly, CMS released a proposed guidance in January titled, "Study Protocols That Use Real-world Data" which seeks to make CED more predictable and clear for sponsors. The Alliance strongly opposes any future adoption of this guidance. As written, it establishes a highly structured real-world data study protocol framework for NCDs with CED, outlining elements such as fit-for-purpose study design, use of control arms, blinding where feasible, pre-specified endpoints, enrollment benchmarks, diversity requirements, and oversight mechanisms. While the research framework may appear methodologically sound, in practice it represents a significant and concerning expansion of CED. It effectively transforms CED into an ongoing federal research mandate disguised as coverage, undermining FDA's regulatory authority and imposing open-ended data collection requirements on manufacturers. This approach goes well beyond CMS's statutory authority under current law. Given these serious legal concerns, and all of the concerns with CED more broadly outlined above, CMS should withdraw the proposed guidance in its entirety.

Antipsychotic Measure Within the 5-Star Rating System for Secure Nursing Facilities

Our comments below primarily focus on general deregulatory recommendations under Executive Order 14192, "Unleashing Prosperity Through Deregulation". They outline an opportunity to eliminate the Long-Stay Antipsychotic Medication Quality Measure from the CMS Nursing Home Care Compare Five-Star Quality Rating System.

To better align with best clinical practices and published provider guidelines, CMS should remove the Long-Stay Antipsychotic Medication quality measure from the Nursing Home Compare Five-Star Quality Rating System and instead modernize the Minimum Data Set (MDS) to better distinguish between appropriate and inappropriate use of antipsychotics among residents of skilled nursing facilities (SNFs) and long-term care facilities.
The existing Long-Stay Antipsychotic Medication quality measure meets the following deregulatory criteria included in RFI question #3:

- ✓ *"[Is] confusing or unnecessarily complicated";*
- ✓ *"Require[s] an excessive number of reports or unreasonable record keeping, or information that is not needed or used effectively";*
- ✓ *"Carr[ies] excessive penalties";*
- ✓ *"Are conflicting";*
- ✓ *"Impede[s] access to or delivery of care or services";*
- ✓ *"Impede[s] efforts to innovate";*
- ✓ *"[Is] obsolete"; and/or*
- ✓ *"Otherwise interfere[s]e with the public or private sector's ability to address chronic health conditions or otherwise promote the health and wellbeing of Americans."*

CMS previously created an unscientific and punitive measure to curb the use of antipsychotics in nursing homes regardless of the appropriateness for the patient. The measure is an unsophisticated, blunt formula of the "percent of residents who received an antipsychotic medication" calculated by dividing the number of residents on a medication by the total number of residents in the SNF. There are only three diagnoses exempted from the measure: schizophrenia, Huntington's disease, and Tourette's syndrome. As noted in the clinical guidance published by the American Psychiatric Association (APA), similar measures promulgated by the National Quality Forum (NQF) include bipolar disorder among the conditions exempted from the measure and many stakeholders have advocated it be added as an exemption to the CMS measure; yet CMS only permits three exempted conditions. Further, as highlighted in the APA guidelines, the measure fails to distinguish between clinically appropriate and inappropriate prescribing, instead it merely captures total use of antipsychotics. The measure has led to clinically necessary treatments being withheld, causing harm to residents and burdening providers. Specifically, this approach forces facilities to prioritize regulatory compliance over patient-centered care, often leading to unintended negative outcomes like the inappropriate discontinuation of medically necessary medications. While we agree that individuals should not be improperly medicated, there are legitimate and appropriate clinical uses of antipsychotic medications that is being suppressed due to this measure.

<u>Specific Concerns with the Existing Measure</u>:

1. *Is Confusing or Unnecessarily Complicated & Requires An Excessive Number of Reports or Unreasonable Record Keeping, Or Information that is Not Needed or*

Used Effectively

The measure and related oversight protocols impose overly complex documentation requirements that may conflict with Section 1801 of the Social Security Act (42 U.S.C. § 1395).[1] These requirements dictate that nursing homes may only use antipsychotic medications when nonpharmacological interventions are contraindicated, requiring extensive documentation to justify their use. Additionally, CMS compels facilities to attempt gradual dose reduction, regardless of a patient's medical history, clinical stability, or wishes. The result is a cycle in which residents are taken off medications they have successfully used, become destabilized, and then must be restarted on medication, often multiple times and with stops in emergency rooms and psychiatric wards along the way. This practice burdens clinicians and caregivers with excessive documentation and causes treatment disruptions, rather than supporting individualized, quality, evidence-based care.

While the Revised Long-Term Care (LTC) Surveyor Guidance is directed at surveyors, the policies it instructs surveyors to enforce—such as rigid rules on PRN (as-needed) antipsychotic orders, mandatory behavioral intervention tracking, and ongoing gradual dose reduction requirements—translate directly into burdensome obligations for providers. Facilities must expend substantial resources creating and maintaining extensive documentation, not because it enhances clinical outcomes, but because it is necessary to demonstrate compliance with inflexible and untested federal standards.

Further, the Long-Stay Antipsychotic Medication quality measure also duplicates existing medication review and quality assurance programs at the state level and overlaps internally with Medicare's own oversight mechanisms, such as the Plan Program Integrity Medicare Drug Integrity Contractors (PPI MEDICs). ***Additionally, the 917-page Revised LTC Surveyor Guidance already includes nearly 20 pages related to psychotropic medication use, including documentation of behavioral interventions, justification for medication use, and gradual dose reduction mandates, which facilities must already follow during survey and certification reviews***. As a result, the use of this measure in the Five-Star Rating System introduces unnecessary and overlapping scrutiny on top of what providers are already required to demonstrate through MDS documentation and during state surveys.

2. Carries Excessive Penalties and Misleads Beneficiaries and Families

The measure's heavy weighting in the Nursing Home Care Compare Five-Star Rating system can result in significant star rating downgrades for minor documentation discrepancies, misrepresenting quality of care to families evaluating the long-term care facilities for their loved ones, and unfairly penalizing facilities serving high-need populations. The outsized weighting of the Long-Stay Antipsychotic Medication quality

[1] MDS 3.0 Quality Measures Users Manual. See Table 2-27 (PDF pg.38). *https://www.cms.gov/files/document/mds-30-qm-users-manual-v170.pdf*

measure over other nursing home quality measures can mislead beneficiaries and their families regarding a local nursing facility's overall safety. On CMS's Nursing Home Care Compare Five-Star Rating system,[2] each facility's reported "percentage of long-stay residents who received antipsychotic medication" is listed, and the national average and state average percentages are listed below it for comparison. No further information is provided to offer context on how to interpret results for this measure, except two general statements "lower percentages are better" (with a downward pointing arrow) and "antipsychotic medications can be used to treat certain mental health conditions." While this reported percentage may reflect a facility's adherence to CMS's detailed reporting requirements, it does not tell individuals and families anything about the quality of care at a facility with respect its appropriate use of medications. Again, this is because the measure only counts how many people receive an antipsychotic without any regard for medical necessity or appropriateness.

3. *Conflicts with Patient-Centered Care and Published Guidelines*

The current measure disregards and contradicts clinical practice guidelines published by the APA, as referenced earlier, which support the appropriate use of these medications in managing dementia-related agitation and psychosis, and does not reflect the clinical standards used in other areas of care.[3]

The APA Practice Guideline on the Use of Antipsychotics to Treat Agitation or Psychosis in Patients with Dementia importantly notes, "Available administrative data allow calculations of the rates of antipsychotic use in nursing homes (Partnership to Improve Dementia Care in Nursing Homes 2015) and other settings. Such data show significant regional and state-to-state variability; **however, they have a number of confounds and do not provide details about the reasons these medications are being prescribed or the severity of symptoms exhibited by the patient. Thus, these data reflect antipsychotic use but, like the currently endorsed NQF measures, do not provide information about appropriate use of antipsychotic medications in individuals with dementia** [emphasis added]."[4]

The APA guideline reflects the medical consensus that antipsychotics can be both appropriate and beneficial for certain patients when nonpharmacological interventions are ineffective or contraindicated. By contrast, CMS's existing Long-Stay Antipsychotic Medication quality measure imposes a one-size-fits-all rigid standard, effectively discouraging any pharmacologic intervention unless non-drug alternatives are exhausted. CMS's current framework not only contradicts expert clinical guidance but also conflicts

---

[2] https://www.medicare.gov/care-compare/?providerType=NursingHome

[3] American Psychiatric Association (APA), "The American Psychiatric Association Practice Guideline on the Use of Antipsychotics to Treat Agitation or Psychosis in Patients with Dementia." May 2016. https://psychiatryonline.org/doi/epdf/10.1176/appi.books.9780890426807

[4] Ibid.

with the agency's own stated intent to support care that is tailored to a resident's "specific, diagnosed, and documented condition." Yet in practice, CMS policies default to a blanket assumption that all use of antipsychotics is harmful, regardless of a particular patient's diagnosis, clinical history, wants, or response to treatment.

4. *Impedes Access to or Delivery of Care or Services and Interferes in the Practice of Medicine*

This 2012 measure conflicts with Section 1801 of the Social Security Act, which expressly prohibits federal interference in the practice of medicine:

"SEC. 1801. [42 U.S.C. 1395] Nothing in this title shall be construed to authorize any Federal officer or employee to exercise any supervision or control over the practice of medicine or the manner in which medical services are provided, or over the selection, tenure, or compensation of any officer or employee of any institution, agency, or person providing health services; or to exercise any supervision or control over the administration or operation of any such institution, agency, or person."

Further, CMS's Revised Long-Term Care (LTC) Surveyor Guidance, referenced earlier, which directs oversight of antipsychotic prescribing practices, underscores CMS' interference with the practice of medicine as it includes extensive requirements for psychotropic prescribing, including strict rules for PRN (as needed) orders, behavioral intervention assessments, and gradual dose reduction mandates.[5] ***These requirements effectively dictate clinical practice by requiring facilities to document extensive justifications for any use of antipsychotics, regardless of patient-specific clinical needs. The measure creates an inflexible and burdensome framework that limits clinician judgment and ultimately prohibits patients from receiving the care they need***. The cumulative effect is a one-size-fits-all oversight model that lacks sensitivity to individual patient needs and clinical judgment, ultimately conflicting with the principle that CMS should not dictate medical practice. Moreover, as noted earlier, the measure often causes beneficiaries who have been stable on antipsychotic medications while living in the community to be taken off of their medications once admitted for a long-stay in a SNF; the type of care and medication a beneficiary receives should be dictated by their diagnosis and specific clinical characteristics, not the site of care where they are being treated.

<u>Solution</u>

Eliminating the measure from public quality reporting while making several low-burden, meaningful changes to the MDS would support transparency, protect patient safety, and allow clinicians to provide individualized care consistent with the latest professional

[5]CMS, "Center for Clinical Standards and Quality, Revised Long-Term Care (LTC) Surveyor Guidance: Significant revisions to enhance quality and oversight of the LTC survey process, QSO-25-12-NH," January 15, 2025, https://www.cms.gov/files/document/qso-25-12-nh.pdf.

psychiatric standards. ***This measure, which is <u>not</u> governed by formal notice-and-comment rulemaking, could be removed through subregulatory channels, including issuing a Quality Safety & Oversight (QSO) memoranda or updates to the Nursing Home Care Compare Technical Users' Guide***. This flexible authority makes it a prime candidate for elimination under the Administration's deregulatory agenda. At the same time, Project PAUSE recommends that HHS and CMS work to change the MDS to:

(1) Expand the reasons for why gradual dose reduction has not been attempted to include a new category stating: "documented use of the drug and dose as clinically appropriate;" and
(2) Require that in cases where gradual dose reduction has not been attempted, both a physician and a pharmacist must independently document that gradual dose reduction is either clinically contraindicated or that the use of the drug and dose are clinically appropriate and beneficial.

These low-burden improvements to the MDS would yield more meaningful information for oversight and facility surveyors. For instance, expanding the list of acceptable reasons for not attempting gradual dose reduction to include "documented use of the drug and dose as clinically appropriate and beneficial," and requiring attestation by both a physician and a pharmacist in such cases, would add clinical nuance without adding significant reporting complexity. For patients who are stable on antipsychotic medication and have a documented on-going need for and benefit from treatment, ideally providers would not need to regularly restate why gradual dose reduction has not been attempted as they are clearly contraindicated. ***This tailored approach could significantly reduce administrative burden and maintain program integrity while allowing facilities and surveyors to focus on the quality of care provided to skilled nursing and long-term care residents.***

Conclusion
These two suggestions for reform within HHS would allow the Trump Administration to repeal nearly 30 regulations and would serve to protect patients and Medicare beneficiaries, ensuring they have access to the care they need. With questions, please contact.

Sincerely,

Sue Peschin
President & CEO

Adina Lasser
Director of Public Policy and Government Relations