September XX, 2016

Mr. Andrew Slavitt
Acting Administrator
Centers for Medicare & Medicaid Services
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, D.C. 20201

Patrick Conway, M.D., MSc
Deputy Administrator, Innovation & Quality
Chief Medical Officer
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Dear Mr. Slavitt and Dr. Conway,

The Center for Medicare and Medicaid Innovation (CMMI) is charged with testing and evaluating voluntary healthcare payment and service delivery models with the intent of increasing quality and efficiency while reducing program expenditures under Medicare, Medicaid, and the Children's Health Insurance Program (CHIP).[1] However, as evidenced by three recently proposed mandatory models, CMMI has exceeded its authority, failed to engage stakeholders, and has upset the balance of power between the legislative and executive branches.[2] What makes these proposals even more disconcerting is their potentially negative effects on patients, especially our vulnerable seniors. Policies that have the potential to create access issues for beneficiaries, further provider consolidation, and reduce provider participation in Medicare can drastically deteriorate quality of care our seniors rely on. This would be a step backwards in our unified effort to move to higher quality, more value based care for our nation's seniors. We ask that you cease all current and future planned mandatory initiatives under the CMMI.

Until recently, the tests and models developed by CMMI were implemented, as intended, on a voluntary, limited-scale basis where no state, healthcare provider, or health insurer had any obligation to participate. However, on November 24th, 2015, the Centers for Medicare and Medicaid Services (CMS) published a final rule requiring at least 800 hospitals in 67 geographical areas selected by CMS to participate in a new bundled payment model for hip and knee replacements, the Comprehensive Care Joint Replacement (CJR) Model.[3] Furthermore, on March 8th, 2016, CMS released a proposed rule that requires thousands of providers across the country to comply with a new drug payment model under Part B of Medicare.[4] The proposed Part B Drug Payment Model is a clear example of the CMMI's overstep of authority, given the mandatory participation required of thousands of providers and millions of patients with serious conditions and rare diseases on a near-nationwide scale. Most recently, on July 25th, 2016, CMS announced the Cardiac Bundled Payment Model (Cardiac Models) that forces one quarter of all metropolitan areas across the nation into bundled payments for certain severe cardiac conditions and expands the controversial CJR Model to include more hip services.[5] In contravention of the statute, these CMMI models were developed absent input from impacted stakeholders and fail to include safeguards to protect the delicate

[1] Social Security Act Sec. 1115A(a).
[2] CMS bases its authority for the Part B Proposal on Section 1115A, which can be viewed as an unconstitutional delegation of legislative power. Article I, Section 1 of the Constitution prohibits Congress from delegating its legislative powers to other bodies, including executive agencies like CMS. See Whitman v. Am. Trucking Assn's, 531 U.S. 457, 472 (2001).
[3] 80 Federal Register 73274, November 24, 2015.
[4] 81 Federal Register 13230, March 11, 2016.
[5] See proposal on July 25, 2016 at https://innovation.cms.gov/Files/x/advancing-care-coordination-nprm.pdf

balance of quality, cost, and access to care for beneficiaries. These mandatory models overhaul major payment systems, commandeer clinical decision-making, and dramatically alter the delivery of care.

By focusing solely on cost-savings without adequate regard to the detrimental effects that the CJR Model, Part B Drug Payment Model, and Cardiac Models may potentially have, CMS at best has heeded only part of its statutory duty—"reduc[ing] program expenditures"—at the expense of its other duties—"preserving or enhancing the quality of care."[6] However, a 2015 blog post by the Congressional Budget Office would suggest that CMMI's demonstrations do not in fact reduce costs, stating that they have "not yet yielded noticeable savings."[7] In addition to failing to cut costs, mandating participation in large scale demonstrations could have the opposite effect of "preserving or enhancing the quality of care."[8] We are aware that some models tested under demonstration programs fail to produce quality improvements and anticipated cost savings. This is why the statute authorized the Secretary to "*test* innovative payment and service delivery models"[9]—not *mandate* them for all providers in designated geographical areas. CMMI's mandatory models "experiment" with thousands of patient lives without prior testing on a smaller scale or even a basic indication that they will actually achieve improved quality or, at the very least, maintain present quality.

CMMI has failed to meet its statutory requirements for implementing models, including starting with a limited, "Phase I" test, engaging stakeholders in model development, and describing the "defined population" and "deficits in care"[10] the model seeks to address. As a result, Medicare providers and their patients are blindly being forced into high-risk government-dictated reforms with unknown impacts. Any true medical experiment requires patient consent. However, patients residing in an affected geographical area will have no choice about their participation.

As elected Representatives of our constituents and patients who will be directly impacted by these CMMI models or "experiments," we are limited in our rightful ability to act on behalf of our constituencies to alter, delay or upend these mandatory demonstration programs. CMS' Part B proposal, for example, would rewrite Medicare Part B payment law in 75% of the country without going through the Constitutional procedures where legislation is debated and approved in both chambers of Congress, and subsequently signed by the President. These most basic tenants of our government, intended by our Founding Fathers to preserve and maintain balance of power, have clearly been neglected. CMMI interprets their authority to "test" innovative models on a limited basis as a means to substantially alter both the delivery and reimbursement of care without any input or approval from Congress and the constituents we represent.

Accordingly, we insist CMMI stop experimenting with Americans' health, and cease all current and future planned mandatory initiatives within the CMMI. Additionally, we ask that you commit to ensuring future CMMI models fully comply with current law, including: limiting the size and scope

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[6] 42 U.S.C. § 1315a(a).

[7] *Estimating the Budgetary Effects of Legislation Involving the Center for Medicare and Medicaid Innovation,* Congressional Budget Office

[8] As Justice Scalia cautioned, "*Chevron* allows agencies to choose among competing reasonable interpretations of a statute; it does not license interpretive gerrymanders under which an agency keeps parts of statutory context it likes while throwing away parts it does not." Michigan v. EPA, 576 U.S. __ (2015), slip op. 9 (citing Chevron v. NRDC, 467 U.S. 837 (1984)).

[9] 42 U.S.C. § 1315a(a)(1) (emphasis added).

[10] Social Security Act Sec. 1115A(b)(2)(A).

of CMMI demonstrations so they represent true tests rather than wholesale changes to statute; seeking Congressional approval if expansion of test models require changes to the underlying statute; and establishing an open, transparent process that supports clear and consistent communication with physicians, patients and other relevant stakeholders in the development of new CMMI models.

We look forward to your response detailing next steps as to how the agency plans to ensure that the CMMI will cease current mandatory initiatives and refrain from pursuing any future initiatives that exceed CMMI's scope of authority.

Sincerely,

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Thomas Price, M.D.	Charles W. Boustany, Jr., M.D.	Erik Paulsen