

THE PROPOSED MODEL EXCEEDS THE LIMITS OF THE CMMI STATUTE

Background: Under Social Security Act (SSA) § 1115A, CMMI models must begin with a test phase (called Phase I), which is limited to a “defined population” with “deficits in care.” CMMI may waive certain statutory requirements “solely” for Phase I testing purposes. CMMI may expand a model in duration and scope in Phase II (including nationwide implementation), but only after: (1) the HHS Secretary finds that expansion (a) would reduce Medicare spending without reducing quality of care or improve quality without increasing spending, and (b) would not “deny or limit the coverage or provision of benefits”; and (2) the CMS Chief Actuary finds that expansion would not increase net spending.

The proposed Part B drug payment model exceeds the statutory limits on Phase I testing -- which must be the starting point for a CMMI model -- for three reasons:

-First, the model does not address a “defined population” with “deficits in care.” It would cover Medicare beneficiaries in 75% of the country taking nearly any Part B drugs (too large and diverse a population to be a “defined population” with “deficits in care.”)

-Second, the model’s sheer size -- covering virtually all Part B drugs and mandating participation by all beneficiaries and providers in three-quarters of the country -- exceeds a Phase I “test.” MedPAC highlighted this concern in a 2012 report warning that the planned scope of CMMI’s dual eligible models (which was much smaller than the Part B model) “makes the demonstrations appear to be large-scale program changes rather than true demonstrations.”¹

-Third, the model exceeds the scope necessary for testing. This model has clear risks (it jeopardizes patients’ access to medicines for serious diseases, and would operate on a near-national scale without meeting the statutory safeguards for an “expanded” model), but CMMI never mentions any effort to limit the model to a scale that reduces risks to patients to those necessary for research purposes.

As a large-scale program change rather than a Phase I “test,” the model cannot include waivers of Medicare requirements: the CMMI statute permits waivers “solely” for Phase I testing.²

THE PROPOSED MODEL RAISES CONSTITUTIONAL CONCERNS

This proposed model is not permitted by the CMMI statute. But if the CMMI statute did allow CMMI to cancel the Medicare statute in 75% of the country, it would raise serious constitutional concerns -- and statutes must be interpreted to avoid raising constitutional concerns.

-Non-delegation

-Bicameralism and presentment

THE PROPOSED MODEL VIOLATES SECTION 3601 OF THE AFFORDABLE CARE ACT

¹ MedPAC, Medicare and the Health Care Delivery System (June 2012) at 64 (emphasis added).

² SSA § 1115A(d)(1).

Under ACA § 3601, no ACA provision (which includes the CMMI statute) may result in a reduction of guaranteed Medicare benefits.

Conclusion: The proposed rule gives CMMI more power than it can lawfully exercise.