

Biogen strongly supports the Senate Chronic Care Working Group's recent policy recommendations that would require Center for Medicare and Medicaid Innovation (CMMI) undertake public notice-and-comment rulemaking when developing and implementing innovative payment and delivery-of-care models. Specifically, we support the Working Group's proposal to require CMMI to allow at least a 30-day public comment period for all innovation models in advance of their finalization. We recommend that this comment period meet existing requirements governing notice-and-comment rulemaking, including but not limited to, requiring CMMI to: notify stakeholders of the opportunity to provide comments in a predictable manner (e.g., through publishing a notice in the Federal Register); and respond to substantial points raised by the public feedback received, including providing an explanation of how the Agency resolved significant issues raised by stakeholders.¹ Such changes ensure that models developed by CMMI adequately take into account the feedback of key stakeholders which ultimately helps the Agency develop models that improve patient care.

We also support allowing CMMI to continue to have flexibility in refining implementation of these models once finalized, assuming that any intended changes to the model do not substantively or significantly alter its scope or structure.

Lastly, aside from improving CMMI's mechanism for stakeholder feedback, we would recommend that the Working Group consider requiring CMMI provide more frequent updates with regards to its existing demonstrations and future demonstrations. Currently, CMMI is required to provide an update to Congress at least once every other year beginning in 2012.² We recommend CMMI provide public updates at least annually to further increase transparency into the agency's activities and priorities and improve stakeholder engagement. More frequent public updates would enable stakeholders to better provide guidance and feedback to CMMI on demonstration projects and help CMMI identify potential hurdles in further implementation of models.

¹ Administrative Procedures Act (APA) § 553(b).

² ACA § 1115A.