

Section 12002 of the 21st Century Cures Act requires HHS to conduct a study of the effects of the 2016 Medicaid Managed Care Final Rule provisions that clarified policy on coverage of IMD services in lieu of other covered services. The State and Territory survey for which we are requesting clearance was developed and is needed to help answer the 5 mandated study questions. The data collected through the survey will be used by CMS develop a Report to Congress as required by the Act; this report is due by December 2019.

The State and Territory survey was published in the federal register October 23, 2018 for a 60-day comment period. During this time, only 1 individual provider submitted comments, this provider submitted 3 comments. Each of these comments are included below; they are out of scope and so therefore no action will be taken in response. Specifically, no requirements or documents will be revised nor will any burden estimates be revised as a result of the comment.

Comment 1: For item 1 and other provider submission requirements, are all process improvements to data submission being analyzed in regards to provider efficiency and provider clarity?

CMS Response: The comment is out of scope of the request.

Action(s) Taken: No action will be taken. Specifically, no requirements or documents will be revised nor will any burden estimates be revised as a result of the comment.

Comment 2: DHHS should be consistent in policy implementation studies and these should not be reliant on federal mandates. In example, DHHS is required to study results of impacts of policy coverage in item 2 (21st Century Cures). Yet in item 3, pre-authorization for durable medical equipment seeks continuation without mention of information being utilized for analysis. Is DHHS analyzing pre-authorization of DME impacts on cost and health outcomes, and if not, why not? The wording of many public notices indicates that studies of policy effects are implemented only in accordance to requirements handed down by Acts or new legislation. Is there a means in which policy studies can become routine?

CMS Response: The comment is out of scope of the request.

Action(s) Taken: No action will be taken. Specifically, no requirements or documents will be revised nor will any burden estimates be revised as a result of the comment.

Comment 3: Is DHHS assessing all avenues to collect Exchange information that addresses non-participants?

CMS Response: The comment is out of scope of the request.

Action(s) Taken: No action will be taken. Specifically, no requirements or documents will be revised nor will any burden estimates be revised as a result of the comment.