

CMS-10661, OMB 0938-New

Response letter for 60 day federal register comment period

CMS wants to thank all 4 commenters for their valuable input. Two of the commenters were national DME vendor advocacy organizations, along with one state and one anonymous commenter. Comments mostly concerned the policy guidance in the State Medicaid Director's Letter #18-001 (SMDL) and the fact that it came out late in 2017 with little time for states to prepare. One comment did question our burden estimates stating they were too low. CMS used burden estimates which we have used for similar demonstrations of the upper payment limit in the Medicaid program in the past, and are OMB approved. CMS further estimates that there will be no significant burden to states in terms of collection of information, as states should only need to query these data from their existing MMIS systems. Medicaid regulations and the Social Security Act require states to run an economic and efficient Medicaid program, and these data are currently needed to draw down FFP. Specific comments and CMS' responses are found below.

In general, this PRA 60 day comment period was specifically intended for comments related to the collection of information required in the SMDL to demonstrate compliance with the limit on federal financial participation for certain DME HCPCS codes as required by statute. CMS developed a State Fee Schedule Drop (Spreadsheet) (hereafter referred to as the "data tool") for states who choose to demonstrate compliance with the statute using the limit on FFP set to the amount that Medicare would pay for similar items in the aggregate. States who choose instead to set their rates at or below Medicare for the relevant DME items would NOT have to use this data tool and no collection of information would need to occur, as compliance would be set in states' Medicaid state plans.

Most of the comments were not concerning this potential collection of information burden, but rather concerning the policy nuances of the SMDL. Regardless, CMS has tried to answer all of the concerns raised in the feedback it received here and continues to work with states to resolve any issues. In addition to these responses, CMS is actively working on FAQs, SOTA calls, and other policy guidance for states to ease administrative burden.

Comment 1: Concerns over the late release of the official SMDL (12/27/17) from CMS and lack of details in the letter concerning the specifics of the implementation of the statute including specific HCPCS codes involved.

Response 1: The original statute had an effective date of January 2019, this was moved up by a year to January 2018 in the 21st Century Cures Act. CMS started the process early for regulation writing, then CMS was redirected to provide guidance through a State Medicaid Director's Letter (SMDL). This process was expedited, but the normal clearance process with revisions and input took longer than anticipated, thus the late release date. CMS also initiated an all state SOTA call for guidance on 12/7/2017 to give advance guidance to states, and we continue to provide timely policy guidance to states.

CMS Action: CMS is developing further policy guidance in the form of FAQs, SOTA calls, and working individually with states to answer any questions through conference calls and a dedicated Medicaid DME mailbox (MedicaidDME@cms.hhs.gov).

Comment 2: Concerns over the lack of a study to evaluate the impact on access of cutting Medicaid DME payment rates to Medicare levels before the demonstration goes into effect.

Response 2: In this statute, as with many others before, Congress asked for an evaluation of the impact of the implementation of this limit on FFP of relevant DME on access to Medicaid beneficiaries. CMS is working with its HHS partners to complete a prospective evaluation of the impact of this SMDL as the policies are implemented in each state.

CMS Action: CMS is working with its HHS partners to complete a prospective evaluation of the impact of this SMDL as the policies are implemented in each state.

Comment 3: Concerns that the Medicare DME competitive bid program rates were developed for Medicare population and not a very different Medicaid population.

Response 3: In the statute, the Congress decided that the Competitive Bidding Program (CBP) that Medicare implemented starting in 2008 was working sufficiently well to apply the program to the Medicaid program. It was not the intent of CMS to compare the Medicare and Medicaid populations, but rather to implement the statute mandated by Congress.

CMS Action: CMS will include this question in future FAQs.

Comment 4: Concerns that any cuts in DME may predominantly affect children and adults with significant disabilities and chronic medical conditions, with 37 of the 255 codes this vendor defines as, “Complex Rehab Technology” being affected in the SMDL. Vendor states Medicare exempts CRT in its CBP, using code KU.

Response 4: CMS recognizes all Medicare codes as it applies to the demonstration tool. States will need to provide the Medicare codes relevant to each HCPCS code and provide a crosswalk if necessary to explain any state codes that do not align with Medicare codes. CMS will recognize any modifier that Medicare uses for the relevant DME HCPCS codes, and these are incorporated already into the data tool.

CMS Action: CMS will include this question in future FAQs.

Comment 5: Concerns that reducing FFP for DME will cause hardship for people with disabilities.

Response 5: Nothing in the guidance or statute limits what states provide to people with disabilities or even what states can pay for DME. There is a limit on the amount of money that the federal government will pay for the relevant DME in the aggregate as compared with the relevant Medicare DME fee schedules. States retain the flexibility to make payments that best serve their Medicaid beneficiaries.

CMS Action: CMS will include this question in future FAQs.

Comment 6: PRA submission and “other materials” contained confusing, incomplete and misleading information.

Response 6: CMS has made every attempt to provide timely and complete information to states concerning the implementation of this statute and SMDL. CMS has worked with over 10 states individually and continues to provide ongoing assistance through the Medicaid DME mailbox (MedicaidDME@cms.hhs.gov).

CMS Action: CMS continues to develop policy guidance and work with state requests.

Comment 7: Concern that there is a lack of FAQs and other policy guidance to answer specific questions.

Response 7: CMS is working with states to resolve issues and offer guidance to specific queries. We are compiling questions and answers to be included in a future FAQs document for further policy guidance.

CMS Action: CMS continues to develop policy guidance and work with state requests.

Comment 8: Concern that states need to go to oversight boards/legislators/others before adjusting rates, and not enough time to do so.

Response 8: CMS will work with states that wish to change their rates, which is one of the options for a state to come into compliance. States should engage with CMS early and explain their process for changing rates. Following public notice requirements, states may submit state plan amendments to CMS to comply with rates up to the last day of the first quarter (March 31, 2018) to come into compliance with the statute.

CMS Action: None, since **CMS has not heard from any state about this issue to date.** CMS will work with any state that expresses their desire to comply with this statute via a state plan amendment.

Comment 9: Reporting period in PRA is stated as federal fiscal year, but SMDL states calendar year.

Response 9: The reporting period will be calendar year, not federal fiscal year. The Medicare rates that are in effect on January 1 of each year will be the ones used for this demonstration for the entire calendar year for ease of administration, even if Medicare changes the rates quarterly or retrospectively.

CMS Action: **CMS updated the PRA to reflect this change.**

Comment 10: Complaints that time to research would take over 60 hours, and that PRA estimates are an underestimate.

Response 10: The collection of information estimates for this demonstration (if needed) or changing the state plan are based on previous UPL collection of information estimates that have been approved by OMB in the past. This DME demonstration in the aggregate uses a CMS created tool to estimate compliance with the SMDL and ease administrative burden. States who

choose to demonstrate will only need to query and then copy and paste the relevant HCPCS codes with modifiers into the data tool CMS is supplying. CMS will analyze the data for states and inform states of any potential excess in the limit on FFP.

CMS Action: CMS will include this question in future FAQs.

Comment 11: Concerns that billing methodologies are different between the CBP in Medicare and states' billing for certain DME (e.g., negative pressure wound pumps, one state uses a daily rate and Medicare uses a monthly rate).

Response 10: CMS would ask the states to work out a comparable billing methodology to show compliance for this demonstration or set their rates. In this example if Medicare used a monthly rate and the state used a daily rate, the state could take their daily rate and multiply that by 30 days to get a monthly rate for comparison to the Medicare rate and for use this value in the data tool.

CMS Action: CMS will include this question in future FAQs.