Response to Public Comments

Our proposed rule (CMS-2482-P, RIN 0938-AT82) published in the Federal Register on June 19, 2020 (85 FR 37286). Public comments were received regarding State Plan Requirements, Findings, and Assurances under §447.518(d)(2) and (d)(3). A summary of the comments and our response follows. In sum, our proposed requirements and burden estimates were finalized without change.

Comment: Several commenters raised concerns about the proposed data reporting requirements for states participating in CMS-authorized SRAVBP arrangements and the burden it may place on state Medicaid agencies, such as additional administrative expenses. A few commenters noted that if more CMS-authorized SRA VBP contracts are signed between manufacturers and state Medicaid agencies, the administrative burden may become too great for current state Medicaid staff and require additional resources, such as additional staff, system changes, and physical office space. Another commenter suggested that CMS delay finalizing the proposal states to provide CMS specific data elements associated with CMS-authorized VBP SRAs to ensure that the data elements can be easily collected and would not unintentionally create additional administrative burden to state Medicaid agencies in collecting and reporting the data elements.

Response: Our final regulation does not require that states participate in CMS authorized VBP SRAs with manufacturers, or any other VBP arrangement. Rather, the regulation addresses the challenges faced by manufacturers and states regarding the impact of the VBP arrangements on MDRP price reporting obligations and the regulatory challenges that may impede manufacturers and payer progress in structuring and implementing VBP arrangements. However, we recognize that states may encounter administrative burden associated with CMS-authorized SRAVBP arrangements. This is one of the reasons that we have requested that states provide specific data elements associated with participating in VBP arrangements via CMS-authorized SRAs, so that we can determine how we can help states reduce these burdens, which may facilitate their contracting with manufacturers.