Justification for a Non-substantive Change
Quarterly Medicaid and CHIP Budget and Expenditure Reporting for the Medical Assistance Program, Administration and CHIP
CMS-10529 (OMB 0938-1265)

As explained below, we request OMB approval by December 1, 2022, to accommodate the early reporting states.

Summary

CMS requests OMB's approval of a routine non-substantive change to add two new lines to the Form CMS.64.9 and CMS-64.9T series of forms and one new line to the Form CMS.64.21U series of forms in the MBES/CBES. The new reporting lines are needed to ensure that states and territories can receive accurate funding for new legislative requirements.

The added reporting lines will not impose any additional burden on states or territories since states and territories are already knowledgeable about the process of claiming expenditures. The lines will be added to existing standard reporting forms which will require minimal action from states and territories to select the new reporting line from those forms and input the quarterly expenditure amount to be claimed.

Legal Basis

The added lines are necessary for accurate reporting, transparency, and oversight of states' and territories' Medicaid and CHIP expenditures authorized through the implementation of section 1945A of the Social Security Act (the Act) for Health Homes for Children with Medically Complex Conditions and the reporting of Drug Rebate Offset amounts as a result of our December 31, 2020 (85 FR 87000) final rule (CMS–2482–F; RIN 0938–AT82). The manufacturer reporting of multiple best prices connected to a VBP arrangement was delayed until July 1, 2022, in accordance with our November 19, 2021 (86 FR 64819) final rule (CMS-2482-F2; RIN 0938-AT82).

Under section 1945A of the Act, beginning October 1, 2022, states and territories have the option to cover health home services for Medicaid-eligible children with medically complex conditions[1]. Often, children with medically complex conditions require specialized diagnostic or treatment services that may not always be readily available from providers within their state of permanent residence (home state).

Beginning July 1, 2022, manufacturers will be able to report varying "best price" points (i.e., multiple best prices) for a covered outpatient drug to the Medicaid Drug Rebate Program

[1] A child with medically complex conditions is defined in section 1945A(i)(1) of the Act to be an individual under 21 years of age who is eligible for medical assistance under the state Medicaid plan (or under a waiver of such plan), and who has at least (1) one or more chronic conditions that cumulatively affect three or more organ systems and severely reduces cognitive or physical functioning (such as the ability to eat, drink, or breathe independently) and also requires the use of medication, durable medical equipment, therapy, surgery, or other treatments; or (2) one life-limiting illness or rare pediatric disease, as defined at 21 U.S.C. 360ff(a)(3).

(MDRP) if associated with a VBP arrangement that meets the definition of such an arrangement at 42 CFR 447.502, and that arrangement is offered to all states.

Manufacturers will be reporting these VBP arrangements to CMS, and states and territories will be notified of these VBP arrangement offerings. States and territories will be able to decide whether or not to participate in the reported VBP arrangements. These arrangements will consist of additional rebates or price concessions that states and territories may be able to earn based on the drug's clinical outcomes in Medicaid beneficiaries. This new authority was finalized by CMS in our December 31, 2020 final rule.

Nonsubstantive Change

Implementation of Section 1945A of the Act for Health Homes for Children with Medically Complex Conditions requires a new line item. **LINE 49, HEALTH HOMES FOR CHILDREN WITH MEDICALLY COMPLEX CONDITIONS,** has been added to the CMS-64.9 and CMS-64.9T MAP series of forms. The line will be available for entry beginning with the quarter ending on December 31, 2022 (October 1, 2022 thru December 31, 2022 reporting period) for states and territories that have an approved SPA for this legislation.

The line is necessary for accurate reporting, transparency, and oversight of states' and territories' Medicaid and CHIP expenditures matched at the Regular FMAP + 15% for the first two quarters that a state has an approved SPA. Quarters 3 and onward will revert to the regular FMAP rate. Total Computable will not be enterable for Indian Health Services, and Family Planning but would be allowed for Optional Breast and Cervical Cancer which is at the Enhanced FMAP rate. The FMAP matching rate is capped at 90%

Implementation of our December 31, 2020 (85 FR 87000) final rule (CMS–2482–F; RIN 0938–AT82) regarding the reporting of Drug Rebate Offset amounts as a result of the VBP legislation requires a new line item. **LINE 7A7, DRUG REBATE OFFSET – VALUE BASED PURCHASING,** has been added to the CMS-64.9 and CMS-64.9T MAP series of forms. The line will be available for entry beginning with the quarter ending on December 31, 2022 (October 1, 2022 thru December 31, 2022 reporting period) for all states and territories that have drug rebates that are related to prescribed drugs that were purchased under the VBP guidelines.

The line is necessary for accurate reporting, transparency, and oversight of states' and territories' Medicaid and MCHP drug rebates returned by states and territories. Total Computable will be enterable for Indian Health Services, Family Planning, and for Optional Breast and Cervical Cancer which is at the Enhanced FMAP rate.

Implementation of our December 31, 2020 (85 FR 87000) final rule (CMS–2482–F; RIN 0938–AT82) regarding the reporting of Drug Rebate Offset amounts as a result of the VBP legislation requires a new line item. **LINE 8A7, DRUG REBATE OFFSET – VALUE BASED PURCHASING,** has been added to the Forms CMS-64.21U MCHIP series of forms. The line will be available for entry beginning with the quarter ending on December 31, 2022 (October 1, 2022 thru December 31, 2022 reporting period) for all states and territories that have drug rebates that are related to prescribed drugs that were purchased under the VBP guidelines.

The line is necessary for accurate reporting, transparency, and oversight of states' and territories' Medicaid and MCHP drug rebates returned by states and territories. Total Computable will be the enterable field which has the Federal Share calculated at the Enhanced FMAP rate and applies to the CHIP allotment

Approval Timeframe

States and territories have the option to start reporting on the new lines effective with the quarter ending on December 31, 2022 (October 1, 2022 thru December 31, 2022 reporting period) with expenditures due to CMS by January 31, 2023.

Most states and territories start reporting in the last month of the quarter, but all states must report during the 30 days following the end of the quarter. Therefore, we are requesting OMB approval for the new lines by December 1, 2022, but no later than December 31, 2022.

Securing OMB's approval by December 1, 2022, would allow early reporting states and territories to continue with early reporting. Since Federal regulations require that states must report within 30 days of the end of the quarter, the new lines must be approved by December 31, 2022.