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All-State Medicaid & CHIP Call

January 7, 2021

State Health Official (SHO) Letter #20-004

- On December 22nd, 2020, CMCS released the State Health Official (SHO) Letter, *Planning for the Resumption of Normal State Medicaid, Children's Health Insurance Program (CHIP), and Basic Health Program (BHP) Operations Upon Conclusion of the COVID-19 Public Health Emergency (PHE).*

- Over the course of the COVID-19 PHE, state Medicaid, CHIP, and BHP programs adopted many flexibilities offered by CMS to respond effectively to their local outbreaks and comply with the requirements of section 6008 of the Families First Coronavirus Response Act (FFCRA). When the PHE concludes, states will need to end the temporary flexibilities and waivers granted to manage the pandemic and return to regular operations.

- The SHO letter provides guidance to states on planning for the eventual return to regular operations, including ending temporary authorities when the PHE concludes, making temporary changes permanent in certain circumstances, procedures for ending coverage and policies authorized under expiring FFCRA provisions, and addressing pending eligibility and enrollment actions that developed during the PHE.

State Health Official Letter Table of Contents

Section I. Background

Authority Effective and Termination Dates

Authority / Provision	Effective Date	Termination Date
Medicaid & CHIP 1135 Waivers	March 1, 2020	Expires at the end of PHE.
Appendix K of the 1915(c) HCBS Waiver Instructions and Technical Guidance	January 27, 2020 or any later date elected by state	For Appendix K submissions in response to the COVID-19 PHE, the termination date will be no later than six months after the expiration of the PHE.
Medicaid Disaster Relief SPA for the COVID-19 PHE	March 1, 2020 or any later date elected by state	Expires at the end of PHE or any earlier approved date elected by state.
CHIP Disaster Relief SPA (specific to COVID-19 PHE)	Start of state or federally declared emergency	Expires at the end of PHE or at state discretion before end of PHE.
BHP Blueprint Revisions	March 1, 2020 or any later date elected by state	Expires no later than the end of PHE, unless a later date is requested and approved by CMS.
Medicaid and CHIP Disaster Relief MAGI-Based Verification Plan Addendum	Any date elected by state	Expires on a date selected by the state.
1115 Demonstration to Respond to the COVID-19 PHE	March 1, 2020 or any later date elected by state	Expires no later than 60 days after end of PHE.

Section I. Background

Key Dates for Termination of Conditions for FFCRA FMAP Increase

FFCRA Section 6008(b) Conditions for 6.2 Percentage Point Increase for FMAP	Termination Date
Maintenance of Effort (eligibility standards, methodologies, procedures) – Section 6008(b)(1) of FFCRA	Expires the first day of the month following the calendar quarter in which the PHE ends.
Premium Restrictions – Section 6008(b)(2) of FFCRA	Expires the first day of the month following the calendar quarter in which the PHE ends.
Continuous Enrollment – Section 6008(b)(3) of FFCRA	Expires the first day of the month following the month in which the PHE ends.
Coverage of, and Cost-sharing Exemption for, COVID-19-related Testing and Treatment – Section 6008(b)(4) of FFCRA	Expires the first day of the month following the calendar quarter in which the PHE ends.

All of the conditions described in section 6008(b) of the FFCRA extend beyond the end of the COVID-19 PHE, including (in some cases) through the end of the calendar quarter in which the PHE ends (if the state claims the temporary FMAP increase under FFCRA section 6008 in that quarter). However, Disaster Relief SPAs expire on the date the PHE expires (and could expire sooner). Therefore, states may need to amend their underlying state plans to ensure that they are able to meet the FFCRA section 6008(b) conditions for the entire period during which those conditions apply.

Section II. Resuming Normal Operations Before the End of the PHE and Continuing Temporary Authorities Beyond the PHE

- <u>Resuming Normal Operations Before the End of the PHE</u>
  - CMS recommends states consider transitioning back to normal operations in a phased approach as individual flexibilities are no longer needed to address the COVID-19 PHE.

- <u>Extending Temporary Flexibilities Beyond the PHE</u>
  - States may find that some flexibilities may be useful to extend on a temporary or permanent basis.
  - Section II of the SHO outlines the steps states need to take if they wish to extend SPA authorities, BHP Blueprint revisions, verification process changes, or Appendix K flexibilities beyond the PHE.

Section III. Regulatory Requirements for Concluding Temporary Authorities

- States will not need to take action to terminate temporary authorities that were approved with specified sunset dates; however, states will need to comply with relevant regulatory provisions when they transition back to regular operations results in, for example, terminations of coverage or a reduction of benefits.

- Section III of the SHO outlines the regulatory requirements states will need to comply with, including processes to redetermine eligibility, provision of advance notice and fair hearing rights, and data reporting.

- States must also comply with these requirements when returning to regular operations after FFCRA provisions end.

Section IV. Other Requirements for Ending Specific Authorities

- In many cases, states modified processes to adopt a certain flexibility or used a temporary exception to respond to the PHE.

- Section IV of the SHO discusses the requirements for ending these authorities, including:
  - Terminating coverage in the optional Medicaid COVID-19 testing group
  - Terminating coverage for individuals determined ineligible for Medicaid during the PHE
  - Ending temporary verification plan changes, flexibilities granted via regulatory concurrence, temporary 1915(c) Appendix K flexibilities, Section 1135 waivers, Section 1115 demonstrations, and requesting formal approval of emergency IT funding requests

Sections V and VI

Section V. Operational and Managed Care Considerations:

- In addition to complying with relevant regulatory requirements when terminating temporary authorities or changes made to comply with FFCRA provisions, states will need to take into account other operational considerations when transitioning back to regular operations.
- Section V of the SHO outlines operational considerations for states, including notifying providers, updating IT systems and internal processes, ensuring accurate financial reporting, and considerations for managed care.

Section VI. Resuming Normal Eligibility and Enrollment Operations: Addressing Pending Eligibility and Enrollment Actions:

- Section VI of the SHO outlines CMS' expectations related to returning to routine eligibility and enrollment operations when the PHE ends.

Sections VII – VIII and Appendices

Section VII. Strategies to Support Returning to Routine Operations:

- Section VII highlights best practices and eligibility and enrollment strategies that states may consider adopting to meet the requirements and expectations outlined in this letter and restore regular operations efficiently.

Section VIII. Program Integrity Considerations:

- CMS will release guidance specific to COVID-19 program integrity issues.

Appendices:

- Appendix A: Provides background on the emergency authorities approved during the PHE.
- Appendix B: Provides a snapshot of the regulatory requirements states must comply with as they transition back to regular operations and the flexibilities subject to each requirement.
- Appendix C: Outlines the actions necessary to resolve pending eligibility and enrollment actions and end section 1135 waivers, as well as the timeframes within which each action is expected to be completed.
- Appendix D: Summarizes the operational considerations related to terminating temporary authorities or changes made to comply with FFCRA provisions.

Extending Section 1915(c) Appendix K Flexibilities

- Many states' approved Appendix K authorities related to the COVID-19 PHE are currently set to terminate during the first quarter of 2021.
- States should routinely assess whether flexibilities will be needed beyond their specified termination date and may seek CMS approval to extend or modify their Appendix K flexibilities if necessary.
- In recognition of the uncertainties associated with the period of time in which the COVID-19 PHE will be in effect, subsequent CMS approvals of state requests for new or extended Appendix K flexibilities will specify that the Appendix K flexibilities will terminate no later than **six months** after the expiration of the PHE.
- If needed, states may submit an updated Appendix K application to extend or modify the end date.
- Additional detail related to extending Appendix K flexibilities can be found in Section II of the SHO.

Resuming Normal Eligibility and Enrollment Operations

- After the PHE, states will need to complete any backlog of pending COVID-related eligibility and enrollment actions and resume routine operations in four key areas:
  - Applications
  - Verifications for individuals enrolled based on self-attested information, as applicable,
  - Redeterminations based on changes in circumstances, and
  - Renewals.

- During the PHE, CMS expects states to take steps to prioritize actions that ensure eligible individuals are able to enroll and remain enrolled in coverage, including:
  - Making timely determinations of eligibility for new applicants
  - Completing renewals for individuals whose eligibility can be renewed based on available information, and
  - Initiating verifications of all eligibility criteria for individuals enrolled based on self-attested information when eligibility can be verified based on available information.

- States are encouraged to process as many pending verifications, renewals and redeterminations based on changes in circumstances as possible to limit the backlog of pending actions the state will need to complete when the PHE ends.

Addressing Pending Eligibility and Enrollment Actions

- States may take up to **four months** following the end of the month in which the PHE ends to process pending applications received during the PHE and resume routine operations.

- States may take up to **six months** following the end of the month in which the PHE ends to verify eligibility for individuals enrolled based on self-attested information, to process redeterminations based changes in circumstances, and to complete pending renewals and resume routine operations.

- States will need to develop and document an operational plan to achieve the timelines outlined in the guidance. While states do not submit these plans to CMS for approval, states will submit data to CMS to demonstrate their progress.

- States are expected to use a risk-based approach to complete backlogs of pending actions in a manner that prioritizes actions for individuals who are likely to no longer be eligible and minimize the extent to which coverage is provided to individuals who no longer meet eligibility criteria. This can include prioritizing cases for individuals in groups who are likely to no longer be eligible or cases based on the length of time the action has been pending

- States may choose to adopt existing eligibility and enrollment strategies, such as Express Lane Eligibility or continuous eligibility for children, to efficiently process pending actions.

Questions

Overview of Medicaid's Drug Utilization Review (DUR)/Value Based Purchasing (VBP) Regulation

Centers for Medicare and Medicaid Services (CMS)

Center for Medicaid and CHIP Services (CMCS)

Division of Pharmacy (DP)

CMS-2482-F Timeline

December 31, 2020: Published in Federal Register

March 1, 2021: Effective date of regulation

January 1, 2022: Effective date of certain provisions - Multiple Best Price, VBP, SDUD, Line Extension reporting by states

January 1, 2023: Effective date of assurance of manufacturer cost sharing assistance for AMP and best price determination

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Final Regulation Goals

- Modify MDRP to Support Value Based Purchasing Arrangements (VBP)
- Implement Opioid-Related Provisions of SUPPORT Act and Create new DUR Standards
- Align Medicaid Drug Rebate Program (MDRP) to Statute and Changes in Marketplace

Modifications to MDRP to Support Value Based Purchasing Arrangements (VBP)

- Defines Value Based Purchasing Arrangements (VBP)
- Clarifies that VBP is considered a performance requirement under a “Bundled Sale”
- Allows for Reporting of Multiple Best Prices under a VBP arrangement (effective January 2022)
- Modifies manufacturer reporting for a VBP arrangement (12 Quarter Reporting Rule)
- Specifies Certain VBP State Plan Reporting Requirements (effective January 2022)

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Define Value Based Purchasing Arrangements (§447.502)

Value-based purchasing (VBP) arrangement means an arrangement or agreement intended to align pricing and/or payments to an observed or expected therapeutic or clinical value in a select population and includes, but is not limited to:

(1) Evidence-based measures, which substantially link the cost of a covered outpatient drug to existing evidence of effectiveness and potential value for specific uses of that product; and/or

(2) Outcomes-based measures, which substantially link payment for the covered outpatient drug to that of the drug's actual performance in patient or a population, or a reduction in other medical expenses.

Multiple Best Prices (§447.505) (Effective 1/1/2022)

- If a manufacturer offers a VBP arrangement (as defined at 447.502) to all states, the lowest price available from a manufacturer may include varying best price points for a single dosage form and strength as a result of a VBP arrangement

- This will permit manufacturers to report multiple best prices based upon a VBP arrangement

- Significant departure from traditional interpretation that only a single best price can be reported for each dosage form and strength of a drug each quarter.

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Line Extension Definition (Effective 1/1/2022)

- ACA established alternative rebate calculation (ARC) for line extension drugs to mitigate a manufacturer's reduction in rebate liability on older drugs
- Provides clarity to manufacturers regarding drugs that are line extensions for the purpose of alternative rebate calculation
- Only the original drug has to be an oral solid drug for ARC to apply
- Definition of LE includes:
  - *extended release formulations
  - *change in dosage form
  - *change in route of administration
  - *change in ingredients
  - *change in strength
  - *Excludes abuse deterrent formulations

Minimum DUR Provisions: SUPPORT Act Requirements (§456.703(e))

Codifies SUPPORT Act requirements which went into effect October 2019. States DUR standards include:

- Prospective and retrospective opioid reviews
- Maximum daily morphine milligram equivalents
- Concurrently prescribed opioids and benzodiazepines or antipsychotics
- Monitoring of antipsychotic prescribing for children
- Identification of potential fraud or abuse by enrolled individuals, prescribers and pharmacies

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Minimum DUR Provisions: Additional Opioid-Related Standards (Effective 3/1/2021)

1. Opioid therapy
    - Days supply limits for opioid naïve patients
    - Quantity limits
    - Therapeutic duplication limitations
    - Early fill limitations
2. Medication Assisted Treatment (MAT)
    - Beneficiary receives opioid(s) after being prescribed drugs used for MAT or an Opioid Use Disorder (OUD) diagnosis
3. FDA-approved antagonist/reversal agents
    - Co-prescribing or co-dispensing to high risk beneficiaries

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State Reporting Requirements (§447.511) (Effective 1/1/2022)

- State invoice data due no later than 60 days from end of rebate period, unless due date falls on weekend or Federal holiday then it is the first business day following that weekend or Federal holiday.
- Adjustments made to the data must be submitted to manufacturer and CMS.
- Data must be certified by SMD, Deputy SMD, individual who has equivalent authority, or individual delegated the authority to perform the task

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Questions