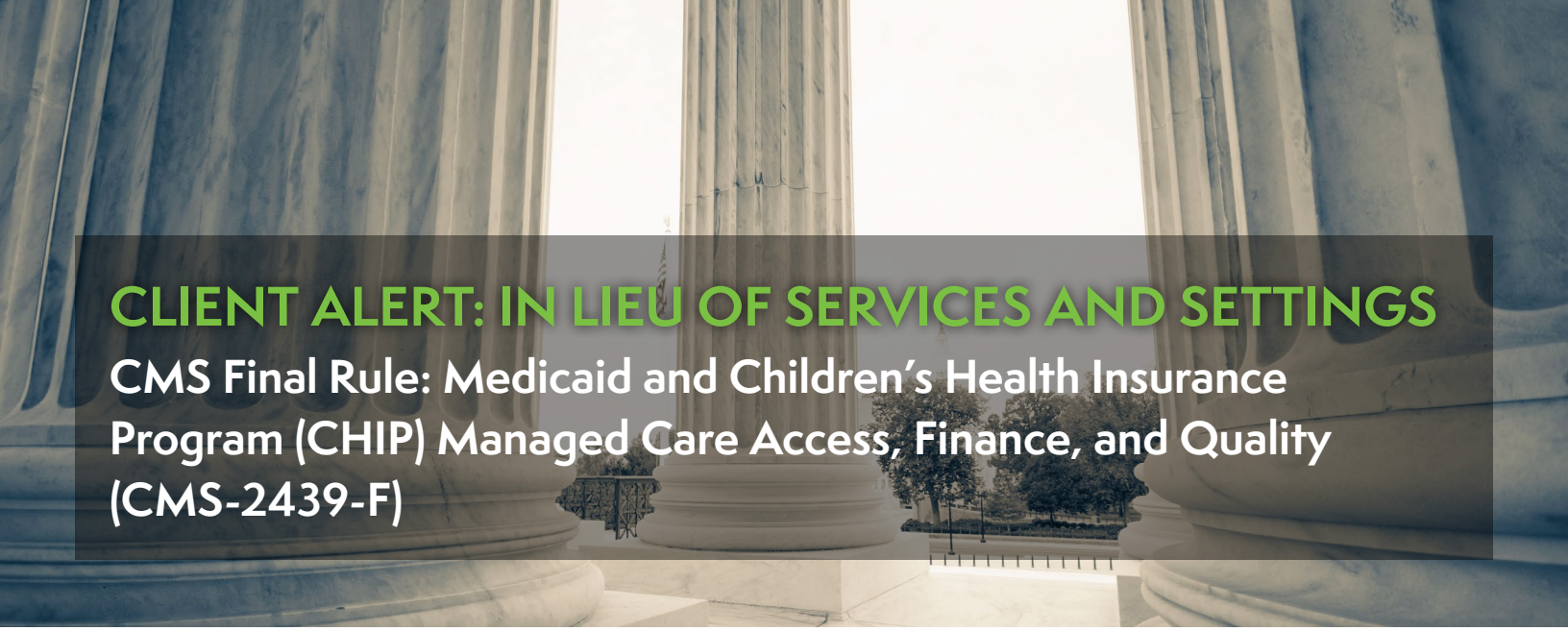

CLIENT ALERT: IN LIEU OF SERVICES AND SETTINGS

CMS Final Rule: Medicaid and Children's Health Insurance Program (CHIP) Managed Care Access, Finance, and Quality (CMS-2439-F)

On April 22, 2024, the Medicaid and Children's Health Insurance Program (CHIP) Managed Care Access, Finance, and Quality rule was finalized by the Centers for Medicare & Medicaid Services (CMS). The final rule was published in the Federal Register on May 10, 2024 and effective July 9, 2024. Myers and Stauffer is providing this client alert to ensure states are aware of several notable provisions specific to the in lieu of services and settings (ILOSs) standards.

For the full final rule text, see https://www.federalregister.gov/public-inspection/2024-08085/medicaid-program-medicaid-and-childrens-health-insurance-program-managed-care-access-finance-and.

The final ILOS rule revisions focus on requiring compliance with key principles. The principles require ILOSs to:

- Meet general parameters.
- Be provided in a manner that preserves enrollee rights and protection.
- Be medically appropriate and cost effective substitutes for State plan-covered services and settings. (Note: does not require budget neutrality.)
- Be subjected to monitoring and oversight.
- Undergo a retrospective evaluation, when applicable.

Background

CMS previously issued sub-regulatory guidance regarding ILOSs through the January 7, 2021, State Health Official Letter #21-001, the January 4, 2023, State Medicaid Director Letter #23-001, and through the November 16, 2023, CMCS Information Bulletin. The final rule codifies this into regulation through the revisions outlined below.

CMS developed a new section (§ 438.16) specifically for ILOS requirements to make it easier for readers to locate all of the ILOS provisions in one place and add flexibility to better organize the provisions.

1. ILOS Definition (§§ 438.2 and Conforming Changes 438.3(e)(2)(i) through (v), and 457.1201(e)).
2. General Parameters (§§ 438.16(a) through (d), 457.1201(c) and (e)).

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3. Enrollee Rights and Protection (§§ 438.3(e), 457.1201(e), and 457.1207).
4. Medically Appropriate and Cost Effective (§§ 438.16(d) and 457.1201(e)).
5. Payment and Rate Development (§§ 438.3(c), 438.7(b), and 457.1201(c)).
6. State Monitoring (§§ 438.16(d) and (e), 438.66(e), and 457.1201(c)).
7. Retrospective Evaluation (§§ 438.16(e) and 457.1201(e)).
8. State and CMS Oversight (§§ 438.16(e) and 457.1201(e)).

1. ILOS Definition (§§ 438.2 and Conforming Changes 438.3(e)(2)(i) through (v), and 457.1201(e))

"A service or setting that is provided to an enrollee as a substitute for a covered service or setting under the State plan in accordance with § 438.3(e)(2). An ILOS can be used as an immediate or longer-term substitute for a covered service or setting under the State plan, or when the ILOS can be expected to reduce or prevent the future need to utilize the covered service or setting under the State plan."

Based on the addition of the ILOS definition in § 438.2, conforming language changes are required to incorporate the downstream impact of the definition on language in §§ 438.3(e) and 457.1201(e).

Applicability date: Effective date of the final rule.

Applicability date § 438.3(e)(2)(v): The first rating period beginning 60 days on or after the effective date of the final rule.

2. General Parameters (§§ 438.16(a) through (d), 457.1201(c) and (e), and 457.1203(b))

CMS requires that ILOSs **must be approvable as a service** or setting through a State plan amendment, including sections 1905(a), 1915(i), or 1915(k) of the Act or through a waiver under section 1915(c); however actual approval through a waiver or State plan is not required. Exceptions will not be made for existing ILOSs that do not meet the included definitions. CMS limits the types of substitute services or settings that can be offered as ILOSs to ensure an ILOS is an appropriate and efficient use of Medicaid and CHIP resources. The only exceptions are to short-term stays or substance use disorder (SUD) treatment in an institution for mental disease (IMD) currently allowed under managed care regulations.

ILOS Cost Percentage

CMS limits allowable ILOS costs to a portion of the total costs for each distinct managed care program (i.e. non-aggregated across multiple programs or broken down by major service category), referred to as an ILOS cost percentage.

- The state's actuary is required to calculate and certify the projected ILOS cost percentage, the final ILOS cost percentage, and the summary report of actual managed care organization (MCO), Prepaid Inpatient Health Plan (PIHP), and Prepaid Ambulatory Health Plan (PAHP), ILOS costs annually, in the same manner as rates are developed consistent with generally accepted actuarial principles and practices.

- ILOS cost percentages are limited to five percent (excluding short-term stays in an IMD) of capitation payments distinctly for each managed care program, including state directed payments and pass-through payments in the denominator. This limitation is to prevent unrestrained ILOS cost growth.
- ILOSs costs may not include any third party management, operational, or ILOS infrastructure costs.
- The projected cost percentage is included in the annual rate certification.
- The State must submit the final ILOS cost percentage to CMS for review as a separate report concurrent with the rate certification for the rating period beginning two years after the completion of each 12-month rating period that includes an ILOS. This calculation, along with the summary report of actual MCO, PIHP, and PAHP ILOS costs is required as part of the submission. These submissions are not applicable for standalone CHIP. CMS indicated it will issue additional guidance on the standards and documentation requirements for this report. It also indicated it does not plan to publicly release the annual reporting, but will take it under consideration in the future.

Applicability date: The first rating period beginning 60 days on or after the effective date of the final rule.

3. Enrollee Rights and Protection (§§ 438.3(e), 438.10(g), 457.1201(e), and 457.1207)

CMS added language to state explicitly that all rights and protections afforded to an enrollee who is eligible for, offered, or has received an ILOS will remain. If the enrollee chooses not to receive ILOS, the enrollee retains their right to receive the service or setting covered under the State plan as if an ILOS was not an option. The enrollee handbook needs to clearly incorporate the rights and protections, if ILOSs are added to the managed care plan contracts and be posted on the managed care plan's website. ILOSs must be provided at the option of the enrollee and managed care plan and may not be retroactively implemented and offered to an enrollee.

Applicability date: Effective date of the final rule.

Applicability date § 438.3(e)(2)(v): The first rating period beginning 60 days on or after the effective date of the final rule.

4. Medically Appropriate and Cost Effective (§§ 438.16(d) and 457.1201(e))

Contract Requirements

State contracts are required to include each ILOS, along with standardization in name, definition, clinically defined target population, and other critical components necessary to clearly identify the State plan-covered services or setting for which each ILOS has been determined by the state to be a medically appropriate and cost effective substitute.

In addition, the contract is required to include that the process by which a licensed network or managed care plan staff provider determines and documents each ILOS is medically appropriate for a specific enrollee. Enrollee rights and protections are required to be included in the contract, as well as the requirement that managed care plans use specific codes established by the state that identify each ILOS in encounter data.

Risk-Based Approval Process

CMS will use a risk-based approval process in evaluating ILOS arrangements.

- States with projected ILOS cost percentages less than or equal to 1.5 percent is eligible for a streamlined review and less robust documentation requirements.
- Expanded documentation for ILOS in excess of 1.5 percent must be submitted concurrent with the contract submission for CMS review and approval.

Applicability date: The first rating period beginning 60 days on or after the effective date of the final rule.

5. Payment and Rate Development (§§ 438.3(c), 438.7, and 457.1201(c))

CMS requires that utilization and actual ILOS costs be included in determining final capitation rate development. Prior regulations required that the final capitation rates be based only on services covered under the State plan and additional services necessary to comply with Parity in Mental Health and SUD Benefits, but did not encompass ILOS costs. In addition, the rate certification is required to describe special contract provisions related to ILOS.

ILOS offerings and enrollee utilization should be closely and continuously monitored by the states and their actuaries, including assessments of whether any rate adjustments to their actuarially sound capitation rates are necessary when actual ILOSs utilization differs from the initial rate development assumptions.

Applicability date § 438.3(c): Effective date of the final rule.

Applicability date § 438.7(b): The first rating period beginning 60 days on or after the effective date of the final rule.

6. State Monitoring (§§ 438.16(d) and (e), 438.66(e), and 457.1201(e))

The 2016 final rule outlined existing requirements for managed care plan performance monitoring, which included approved ILOSs. To allow for appropriate monitoring of ILOSs, as mentioned above, CMS requires states to include contractual requirements that managed care plans use specific codes (e.g. Healthcare Common Procedure Coding System [HCPCS] or Current Procedural Terminology [CPT]) established by the state to identify each ILOS within the encounter data. CMS indicates requiring specific codes would ensure they can easily identify ILOS in Transformed Medicaid Statistical Information System (T-MSIS) data, support program integrity activities, and ensure the information is publicly available. This final rule also notes that the availability and accessibility of any ILOS is required in the Managed Care Program Annual Report (MCPAR), but notes capturing of this information alone is not considered sufficient monitoring and oversight of the ILOSs' fiscal impact on managed care expenses Also, these reporting requirements are not applicable for states with standalone CHIP.

Applicability date § 438.16(d) and (e): The first rating period beginning 60 days on or after the effective date of the final rule.
Applicability date § 438.66(e): Effective date of the final rule.

7. Retrospective Evaluation (§§ 438.16(e) and 457.1201(e))

For states with a final ILOS cost percentage above 1.5 percent for any given year within the first five-year period for each ILOS is authorized and identified in the MCO, PIHP, or PAHP contract and subsequent to applicability date of this final rule (i.e. new ILOSs), a retrospective evaluation, of that five-year period, for that ILOS will be required for submission to CMS two years after completion of the five-year rating period.

Previously authorized ILOSs with a cost percentage above 1.5 percent in any of the first five rating periods subsequent to the applicability date of this final rule would also be required to have a retrospective evaluation submission due two years after either the five-year period that the ILOS was included in the MCO, PIHP, or PAHP contract or the rating-period year that the ILOS cost percentage exceeded 1.5 percent, whichever is later.

The first five-year rating period of the ILOSs' contractual inclusion is the evaluation period. Additionally, CMS reserves the right to require retrospective ILOS evaluations for any ILOSs that exceed the 1.5 cost percentage subsequent to the distinct five-year rating periods identified for the new or previously authorized ILOSs, to ensure continuous monitoring of all ILOSs.

CMS encourages all states that include ILOSs in their managed care plan contracts to conduct a retrospective evaluation of all ILOSs. These evaluations should be completed for each managed care program, not across managed care programs or managed care plan contracts.

At a minimum, the evaluation must include cost, utilization, access, grievances and appeals, and quality of care for each ILOS. This must be completed separately for each managed care program that includes an ILOS. States are required to evaluate the impact each ILOS had on utilization of State plan-covered services and settings, including any associated savings. The state would also be required to evaluate the trends in managed care plan and enrollee usage of ILOSs. In addition, CMS proposes to require that states use encounter data to evaluate if each ILOS is a cost effective and medically appropriate substitute for the identified State plan-covered service or setting, or that each ILOS is a cost effective measure to reduce or prevent the future need to use the identified State plan-covered service or setting. Other required evaluation components would include the impact of each ILOS on quality-of-care and health-equity efforts, appeals, grievances, and state fair-hearings reporting.

CMS encourages, but does not require that states procure an independent evaluator for ILOS evaluations. CMS suggests that states can leverage existing EQR activities and a new optional external quality review protocol to help evaluate the ILOSs. **Because Myers and Stauffer qualifies as an EQRO, we can assist with this independent evaluation.**

Applicability date: The first rating period beginning 60 days on or after the effective date of the final rule.

8. State and CMS Oversight (§§ 438.16(e) and 457.1201(e))

If the state identifies an ILOS that is no longer medically appropriate or cost effective, or the state identifies noncompliance with the ILOS requirements, the final rule requires that CMS be notified within 30 calendar days. CMS, through its compliance oversight processes or through receipt of state notification, may require termination of the ILOS, thereby requiring the state to submit a transition plan to CMS within 30 calendar days from the date a state decides to terminate or MCO, PIHP, or PAHP decides to cease offering an ILOS to its enrollees. The plan would include beneficiary notification and timely access to medically appropriate State plan-covered services. The state would also need to remove the ILOS from managed care plan contracts and capitation rates. During the transition period, the terminating ILOSs are not allowed to be provided to new enrollees.

Applicability date: The first rating period beginning 60 days on or after the effective date of the final rule.

Next Steps

The final rule has a significant impact on the way states operationalize and monitor the above ILOS areas. States are required to review managed care plan contracts and ILOS documentation processes and begin discussions with the state actuary to determine the impact the changes may have on their current managed care programs.

For More Information

Myers and Stauffer partners with more than 20 states and CMS in ensuring proper oversight of managed care health plans and compliance with CMS regulatory requirements and is available to discuss any issues in the final rule. Myers and Stauffer is available to discuss any issues in the final rule. If you have questions or need assistance in assessing the impact of these changes on your managed care program, please contact the following members of our managed care engagement team.

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