CLIENT ALERT: IN LIEU OF SERVICES AND SETTINGS

CMS Proposed Rule: Medicaid and Children's Health Insurance Program (CHIP) Managed Care Access, Finance, and Quality (CMS-2439-P) in the Federal Register

On May 3, 2023, the Centers for Medicare & Medicaid Services (CMS) published a proposed rule titled: Medicaid and Children's Health Insurance Program (CHIP) Managed Care Access, Finance, and Quality (CMS-2439-P) in the Federal Register. 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 proposed rule text, see https://www.federalregister.gov/documents/2023/05/03/2023-08961/medicaid-program-medicaid-andchildrens-health-insurance-program-chip-managed-care-access-finance.

CMS' proposed ILOS rule revisions focus on requiring compliance with key principles. The principles would 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 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 and through the January 4, 2023, State Medicaid Director Letter (SMDL) #23-001. The proposed rule codifies this into regulation through the revisions outlined below. The effective date based on the SMDL was for contract rating periods beginning on or after January 1, 2024. However, this appears to be conflicting with effectives dates proposed within this rule.

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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 (iv), and 457.1201(e))
2. General Parameters (§§ 438.16(a) through (d), 457.1201(c) and (e))
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 (iv), 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 proposed to incorporate the downstream impact of the definition on language in §§ 438.3(e) and 457.1201(e).

Proposed applicability date: Upon effective date of the final rule.

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

CMS proposes to require 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 a waiver under section 1915(c). CMS notes there should be a limitation on 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 would be to short-term stays or substance use disorder treatment in an institution for mental disease (IMD) currently allowed under managed care regulations.

ILOS Cost Percentage

CMS proposes to limit allowable ILOS costs to a portion of the total costs for each managed care program, referred to as an ILOS cost percentage.

- The state's actuary would be required to calculate the projected ILOS cost percentage and final ILOS cost percentage annually, in the same manner as rates are developed and percentages need to be certified.
- ILOS cost percentages would be 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 was proposed to prevent unrestrained ILOS cost growth.
- The projected cost percentage would be included in the annual rate certification.

- A two-year period would be provided to perform the final cost percentage based on actual paid amounts reflected in the encounter data, which will be submitted in a separate summary report of actual managed care plan ILOS costs concurrent with the new rate certification submissions.

Proposed applicability date: The first rating period that starts on or after 60 days following the effective date of the final rule.

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

CMS proposes to add 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.

Proposed applicability date: Upon effective date of the final rule.

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

Contract Requirements

State contracts would be required to include each ILOS, along with the name and definition for each, and 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. The contract must also document the clinically defined target population(s) for each ILOS. In addition, the contract would be 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 would be 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 proposes to use a risk-based approval process in evaluating ILOS arrangements.

- States with projected ILOS cost percentages less than or equal to 1.5 percent would be 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.

Proposed applicability date: The first rating period that starts on or after 60 days following the effective date of the final rule.

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

CMS proposes to require ILOS costs be included in determining final capitation rate development. Existing regulations require the final capitation rates must be based only on services covered under the state plan and additional services necessary to comply with Parity in Mental Health and Substance Use Disorder Benefits, but do not encompass ILOS costs. In addition, the rate certification would be required to describe special contract provisions related to ILOS.

Proposed applicability date § 438.3(c): Upon effective date of the final rule.

Proposed applicability date § 438.7(b): The first rating period that starts on or after 60 days following the effective date of the final rule.

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

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 proposes to require states to include contractual requirements that managed care plans use specific codes established by the state to identify each ILOS within the encounter data. This proposed rule also notes that the availability and accessibility of ILOSs would be required in the managed care program annual report.

Proposed applicability date § 438.16(d) and (e): The first rating period that starts on or after 60 days following the effective date of the final rule.

Proposed applicability date § 438.66(e): Upon 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, a retrospective evaluation of the ILOS would be required for submission to CMS two years after completion of the first five-year period included the ILOS. CMS notes it encourages all states that include ILOSs in their managed care plan contracts to conduct a retrospective evaluation of all ILOSs.

At 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 would be 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 considered proposing to require that states procure an independent evaluator for ILOS evaluations. Included in the proposed rule is a new optional external quality review protocol, which could be used to help evaluate the ILOSs. CMS also seeks comments on whether it should require independent evaluation on the appropriateness of the proposed evaluation period length and timing.

Proposed applicability date: The first rating period that starts on or after 60 days following 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 proposed rule would require 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 15 calendar days. 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.

Proposed applicability date: The first rating period that starts on or after 60 days following the effective date of the final rule.

Next Steps

The proposed rule will have a significant impact on the way states operationalize and monitor the above ILOS areas. States will need to review managed care plan contracts and ILOS documentation processes and begin discussions with the state actuary to determine the potential impact the proposal may have on their current managed care programs. 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.

The proposed rule is open for comments until July 3, 2023. Submit formal comments here.

For More Information

Myers and Stauffer is available to discuss any issues in the proposed rule. If you have questions or would like help drafting formal comments, please contact the following members of our managed care engagement team.

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