On January 4, the Centers for Medicare & Medicaid Services (CMS) released a State Medicaid Director letter, SMD# 23-001, to provide additional guidance on the In Lieu of Services and Settings (ILOS) option for states to use in Medicaid managed care programs to reduce health disparities and address the unmet health-related social needs of Medicaid and Children's Health Insurance Program (CHIP) enrollees. The letter also clarifies previous guidance issued on January 7, 2021, in State Health Official (SHO) letter SHO# 21-001, "Opportunities in Medicaid and CHIP to Address Social Determinants of Health" and the 2016 Medicaid and CHIP managed care final rule requirements for ILOS.

Under the 2016 final rule (42 CFR § 438.3(e)(2)), ILOS may be covered under State Medicaid managed care program provided that:

1. States determine the ILOS is a medically appropriate and cost-effective substitute for covered services or settings under the state plan.
2. Enrollees are not required to use the ILOS.
3. An approved ILOS is authorized and identified in the managed care plan contract and offered to enrollees at the option of the managed care plan.
4. The utilization and actual costs of the ILOS are considered in developing the component of the capitation rates that represents the covered state plan services, unless a federal statute or regulation explicitly requires otherwise.

In SMD#23-001, CMS identifies six principles states must meet to obtain CMS approval of ILOS, which are discussed below. CMS also specifies that it will use a risk-based review process to review ILOS applications as part of managed care plan contract and rate reviews in determining whether a State's ILOS(s) meet these principles. Under this risk-based review process, the information States will be required to submit will vary depending on the ILOS Cost Percentage that applies to their managed care programs. CMS instructs States to use the following formula to calculate the ILOS Cost Percentage:

Total capitation payments attributable to all ILOSs, excluding short-term stays in an Institution for Mental Disease (less than 16 days) /
Total capitation payments specific to the managed care program (including all CMS-approved state directed payments and pass through payments) = ILOS Cost Percentage

Effective January 4, 2023, States using ILOS will be required to submit a projected ILOS Cost Percentage and, retroactively, a final ILOS Cost Percentage to CMS annually per managed care program. Documentation, monitoring, and evaluation requirements for states with an ILOS Cost Percentage that is less than or equal to 1.5% are streamlined, while states with higher ILOS Cost Percentages must adhere to additional requirements as outlined below. CMS will deny approval for any ILOS that does not meet the requirements in the guidance.

The Six Principles for ILOS Approval:

1. ILOSs must advance the objectives of the Medicaid program.
    a. ILOSs must not violate any applicable federal requirements, including general prohibitions on payment for room and board costs under Title XIX of the Social Security

Act, the Americans with Disabilities Act, Section 504 of the Rehabilitation Act, and the Emergency Medical Treatment and Labor Act.

b. ILOSs must be for services approvable through a state plan amendment (SPA), including sections 1905(a), 1915(i), or 1915(k) of the Social Security Act (Act) or waiver through 1915(c) of the Act.

2. ILOSs must be cost-effective.
    a. States must determine ILOSs are cost-effective substitutes for covered services or settings under the state plan.
    b. CMS believes there should be a limit on total expenditures for ILOSs to reduce inequities for beneficiaries across delivery systems and ensure appropriate fiscal constraints. As such, CMS specifies that the ILOS Cost Percentage per managed care program should not exceed 5%. CMS will require that both the projected ILOS Cost Percentage and final ILOS Cost Percentage be certified by states' actuaries and CMS will review the ILOS Cost Percentages developed as a component of the applicable rate certification review process.
    c. State actuaries must include the following information for each managed care program rate certification annually.
        i. A brief description of each ILOS in the Medicaid managed care program, and whether the ILOS was provided as a benefit during the base data period.
        ii. The projected ILOS Cost Percentage, including the aggregate projected ILOS Cost Percentage for the applicable managed care program, as well as the impact of ILOS(s) on rates based on materiality:
            1. For each ILOS that is expected to have a material impact on the rates, the actuary must provide the projected ILOS Cost Percentage, and a description of the data, assumptions, and methodologies used to develop it.
            2. For all ILOSs that are expected to have a non-material impact on the rates, the actuary may group those ILOSs together and provide a description of why the ILOSs were not considered to have a material impact, as well as the projected ILOS Cost Percentage.
        iii. A description of how the ILOS(s), material and non-material, were considered in the development of the projected benefit costs, and if this approach was different than any of the other services in the categories of service.
    d. If the projected ILOS Cost Percentage is greater than 1.5%, states must submit a description of their processes for determining that each ILOS is cost-effective, including a description of the key factors and data included in this analysis.
    e. The final ILOS Cost Percentage report for a program that uses a calendar year 2024 rating period must be submitted to CMS with the calendar year 2027 rate certification. The report must include, at a minimum, the following information:
        i. The portion of the total capitation payments attributable to ILOS(s), excluding a short term stay in an IMD, for the specific managed care program that includes the ILOSs and a description of how this amount was calculated.
        ii. The total actual dollar amount of capitation payments specific to the Medicaid managed care program that includes the ILOSs.
        iii. The final ILOS Cost Percentage specific to the Medicaid managed care program.

iv. A summary of the actual managed care plan costs for delivering ILOSs based on claims and encounter data provided by the managed care plans to states.

3. ILOSs must be medically appropriate.
    a. States must submit, at a minimum, the following information contained within their managed care contracts:
        i. The name and definition of each ILOS, and the covered Medicaid state plan services or settings for which they are substituted. The state must also include the coding to be used on claims and encounter data to identify each ILOS.
        ii. The clinically oriented definitions for the target population(s) for which the state has determined each ILOS to be a medically appropriate and cost-effective substitute.
        iii. A contractual requirement for the managed care plans to utilize a consistent process to ensure that a provider (either a plan's licensed clinical staff or contracted network provider) using their professional judgment determines and documents that the ILOS is medically appropriate.
    b. States have the option to impose additional provider qualifications, limitations, or protocols to ensure that ILOSs are cost-effective and medically appropriate.
    c. If the projected ILOS Cost Percentage of a managed care program is greater than 1.5%, states must provide a description of their processes for determining medical appropriateness. CMS notes that if the projected ILOS Cost Percentage is greater than 5%, the ILOS may not be approvable.

4. ILOSs must be provided in a manner that preserves enrollee rights and protections.
    a. Managed care plans are prohibited from requiring enrollees to utilize ILOSs or from mandating replacement of a state plan covered service for an ILOS.
    b. Managed care plans may not deny an enrollee a medically appropriate Medicaid covered state plan service or setting on the basis that an enrollee has been offered an ILOS, is currently receiving an ILOS, or has received an ILOS in the past.
    c. Medicaid enrollees have the right to file appeals and/or grievances regarding the denial or receipt of an ILOS.

5. ILOSs must be subject to appropriate monitoring and oversight.
    a. To demonstrate appropriate state monitoring, oversight, and transparency of ILOSs, states must submit the following information to CMS, at a minimum:
        i. An actuarial report provided by the state's actuary certifying the final ILOS Cost Percentage specific to each managed care program as outlined above. The report should demonstrate that the final annual ILOS Cost Percentage does not exceed 5%. Written notification within 30 days of determining that an ILOS is no longer a medically appropriate or cost-effective substitute or, if the state determines any other areas of non-compliance such as failure to protect enrollee rights.
        ii. An attestation to audit encounter, grievances, appeals, and state fair hearing data to ensure accuracy, completeness, and timeliness. CMS notes that, when possible, states should stratify ILOS utilization based on sex, race, ethnicity, disability status, and language spoken to inform health equity initiatives and mitigate health disparities.

iii. Documentation necessary for CMS to understand how the utilization and cost of an ILOS, as well as any savings, were considered in the development of capitation rates along with the associated rate certification.

6. ILOSs must be subject to retrospective evaluation, when applicable.
    a. All states with ILOSs are encouraged to complete a retrospective evaluation.
    b. States with final ILOS Cost Percentages of more than 1.5% are *required* to submit a retrospective evaluation for each managed care program no later than 24 months after the completion of the first five contract years.
    c. At a minimum, retrospective evaluations should include the following:
        i. Impact each ILOS had on utilization of state plan-covered services or settings, including the associated cost savings, trends in managed care plan and enrollee use of each ILOS, and impact of each ILOS on quality of care.
        ii. Assessment of whether encounter data supports the state's determination that each ILOS is a medically appropriate and cost-effective substitute.
        iii. The final ILOS Cost Percentage for each year.
        iv. Appeals, grievances, and state fair hearings data, reported separately and for each ILOS, including volume, reason, resolution status, and trends.
        v. Impact each ILOS had on health equity initiatives and efforts undertaken by the state to mitigate health disparities.

CMS expects states to provide supporting information and justify ILOS costs. Effective, January 4, 2023, CMS will not approve any state's managed care plan contracts that include new ILOSs that do not fully conform to this new guidance. States that currently include ILOSs in managed care contracts will have until the contract rating period beginning on or after January 1, 2024, to conform to this guidance.

Sellers Dorsey remains well-positioned to monitor CMS guidance directly impacting Medicaid programs across the country and is available to provide guidance for all Medicaid stakeholders. For more information or to discuss anything you've read here, please contact Leesa Allen, Managing Director, Consulting and head of Sellers Dorsey's Research and Policy team at lallen@sellersdorsey.com.