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All State Call Agenda

Agenda

- In Lieu of Services and Settings (ILOSs)
  - Background on ILOSs
  - Guidance on Use of ILOSs in Medicaid Managed Care (SMD 23-001)
  - Technical Assistance
  - Q and A
Background on ILOSs

- In the 2016 Medicaid and CHIP managed care final rule, CMS finalized 42 CFR § 438.3(e)(2) that formally recognized States’ and managed care plans’ abilities to cover in lieu of services or settings (ILOSs) that are substitutes for services or settings covered under the State plan. Managed care plans historically had flexibility under risk contracts to cover alternative services and settings to meet enrollees’ needs. CMS codified this practice in regulation to bring consistency to plans’ use of ILOSs and ensure enrollee protections.

- The key requirements in 42 CFR § 438.3(e)(2) are:
  1. States must determine that the ILOS is a **medically appropriate and cost effective substitute** for covered services or settings under the State plan;
  2. Enrollees cannot be required to use the ILOS;
  3. An approved ILOS must be authorized and identified in the managed care plan contract and may be offered to enrollees at the option of the managed care plan; and
  4. The utilization and actual cost of the ILOS is **taken into account in developing the component of the capitation rates** that represents the covered State plan services, unless a Federal statute or regulation explicitly requires otherwise.
Background on ILOSs (continued)

- One of the most commonly offered ILOS is inpatient mental health or substance use disorder treatment provided during a short term stay (no more than 15 days during the period of the monthly capitation payment) in an institution for mental diseases (IMD). When short term IMD stays are provided as an ILOS, the States must comply with 42 CFR §§ 438.3(e) and 438.6(e).

- Recognizing an increase in the use of ILOS, including new and innovative ILOSs that States and their managed care plans may choose to offer to Medicaid enrollees to address unmet health-related social needs (HRSNs), we determined additional guidance was necessary to clarify the nature of non-IMD ILOSs that can be offered and to outline related parameters.

- ILOSs is a separate option for States than section 1115 HRSN authority which authorizes covered services.
Overview of SMDL on ILOSs

- On January 4, 2023, CMS released a State Medicaid Director Letter (SMD 23-001) outlining guidance on the use of non-IMD ILOSs to:
  - Clarify the nature of ILOSs that can be offered, including to address HRSN; and
  - Provide parameters for ILOSs to ensure appropriate and efficient use of Medicaid resources.

- This guidance does not replace or alter existing Federal requirements for the use of short term IMD stays as an ILOS, or the availability of FFP for capitation payments to managed care organizations and prepaid inpatient health plans consistent with § 438.6(e).
Overview of SMDL on ILOSs (continued 1)

- ILOSs can be used, at the option of the managed care plan and the enrollee, as **immediate or longer term substitutes** for State plan-covered services or settings, or when the ILOSs can be expected to **reduce or prevent the future need to utilize State plan-covered services or settings**.

  - For example, offering medically appropriate and cost effective ILOSs, such as medically tailored meals for a clinically-oriented target population, may improve health outcomes and facilitate greater access to care for home and community-based services through community integration, thereby preventing or delaying enrollees’ need for nursing facility care.

- ILOSs could be utilized by States and their managed care plans, when consistent with the requirements, to address certain Medicaid enrollees’ HRSNs in order to reduce the need for future costly state plan-covered services. This can improve population health, reduce health inequities, and lower overall health care costs in Medicaid.
Overview of SMDL on ILOSs (continued 2)

- 6 Principles to ensure ILOSs are an appropriate and efficient use of Medicaid resources:
  1. ILOSs must **advance the objectives of the Medicaid program**;
  2. ILOSs must be **cost effective**;
  3. ILOSs must be **medically appropriate**;
  4. ILOSs must be provided in a manner that **preserves enrollee rights and protections**;
  5. ILOSs must be subject to appropriate **monitoring and oversight**; and
  6. ILOSs must be subject to **retrospective evaluation**, when applicable.

- CMS will utilize a **risk-based review process** for review of ILOSs based on a State’s **ILOS Cost Percentage**, and review and approval of ILOSs will occur as part of the managed care plan contract approval process.
Overview of SMDL on ILOSs (continued 3)

- This guidance is **effective with the date of publication** (i.e., January 4, 2023), though there are **some nuances**:
  
  - CMS will review States’ compliance with this guidance as part of our review of associated managed care plan contracts and capitation rates.
  
  - CMS acknowledges that States already covering ILOSs may need time to conform with this guidance. States with existing ILOSs will have until the rating period, beginning on or after January 1, 2024 to comply with this guidance for existing ILOSs. If these States elect to add new ILOSs, they must conform with this guidance for new ILOSs as of January 4, 2023.
Overview of SMDL on ILOSs (continued 4)

- Some State examples:
  - State X: (1) currently provides 8 non-IMD ILOSs; (2) does not intend to add new ILOSs; and (3) has a calendar year (CY) rating period. State X has until January 1, 2024 to comply with this guidance for the 8 non-IMD ILOSs.
  
  - State Y: (1) does not currently provide any non-IMD ILOSs; (2) wants to add a new ILOS effective 3/1/23; and (3) has a CY rating period. State Y must comply with this guidance for the new ILOS as of 3/1/23, and provide associated contract and rate amendments for 3/1/23-12/31/23.
  
  - State Z: (1) currently provides 4 non-IMD ILOSs; (2) intends to add a new ILOS effective 7/1/23; and (3) operates on a July-June rating period. State Z must comply with this guidance for the rating period beginning July 1, 2023 through June 30, 2024 for the new ILOS, and has until the rating period beginning July 1, 2024 to comply for existing 4 non-IMD ILOSs.
ILOSs Must Advance the Objectives of Medicaid

- ILOSs must **advance the objectives of the Medicaid program.**
- ILOSs must **not violate any applicable Federal requirements**, including but not limited to:
  - Regulatory requirements, such as 42 CFR § 438.3(e)(2); and
  - General **principles on payment for room and board costs** under title XIX of the Social Security Act;
- ILOSs must be approvable as a service or setting through a State plan **amendment** authorized through a section of the Social Security Act, including sections 1905(a), 1915(i), or 1915(k) of the Social Security Act, **or a waiver** under section 1915(c) of the Social Security Act.
ILOSs Must be Cost Effective

- States must determine each ILOS to be a cost effective substitute for a covered service or setting under the State plan. This must occur before ILOSs can be included as an option in the managed care plan contracts.

- **ILOS Cost Percentage**
  - All States are required to submit a projected and final ILOS Cost Percentage, certified by the State’s actuary, for each managed care program that includes non-IMD ILOS(s). The ILOS Cost Percentage is a calculation of:
    - The portion of the total capitation payments attributable to all ILOS(s), excluding short term stays in an IMD, for the specific managed care program (numerator); divided by
    - The total capitation payments specific managed care program (denominator), which must include all State directed payments in accordance with 42 CFR § 438.6(c) and pass-through payments in accordance with 42 CFR § 438.6(d).
  - The projected ILOS Cost Percentage is submitted annually in the applicable rate certification, and the final ILOS Cost Percentage is submitted retroactively no later than 2 years after the completion of the contract year that includes ILOS(s), along with a summary of actual managed care plan costs, as a companion actuarial report.
ILOSs Must be Cost Effective (continued)

- Since ILOSs are provided as substitutes for State plan-covered services and settings, CMS believes there should be a limit on the amount of expenditures for ILOSs to reduce inequities for beneficiaries across delivery systems and ensure appropriate fiscal constraints. As such, **the ILOS Cost Percentage per program should not exceed five percent**.

- If the **projected ILOS Cost Percentage is greater than 1.5 percent**, States must submit to CMS a **description of their processes for determining that each ILOS is cost effective**, including a description of the key factors and data included in these processes.
ILOSs Must be Medically Appropriate

- States must determine each ILOS to be a medically appropriate substitute for a covered service or setting under the State plan. This must occur before ILOSs can be included in the managed care plan contracts as an option.

- States must include the following in managed care plan contracts that include ILOS(s):
  - The name and definition of each ILOS, and the covered Medicaid State plan services or settings for which they substitute. The State must also include the coding to be used on claims and encounter data. For example, the State must note specific Healthcare Common Procedure Coding System (HCPCS) or Current Procedural Terminology (CPT®) codes that identify each ILOS.
  - 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.
  - A contractual requirement for the managed care plan to utilize a consistent process to ensure that a provider (either a licensed plan’s clinical staff or contracted network provider) using their professional judgment determines and documents that the ILOS is medically appropriate for the specific enrollee, based on the target population definition described above. This documentation could be included, for example, in an enrollee’s care plan or medical record.
ILOSs Must be Medically Appropriate (continued)

- If the projected ILOS Cost Percentage is greater than 1.5 percent, States must submit to CMS a description of their processes to determine that each ILOS is medically appropriate for the target population(s) (e.g., use of peer-reviewed research, randomized control trials where possible, clinical engagement, evaluations of existing pilots or programs, relevant analyses of State administrative data, evaluations from other States, etc.).
ILOSs Must be Provided in a Manner that Preserves Enrollee Rights and Protections

- The rights and protections guaranteed to Medicaid managed care enrollees under Federal regulations remain in full effect when an enrollee is eligible to be offered or elects to receive any ILOS. Enrollees retain all of the rights afforded to them in 42 CFR part 438. As just two examples:
  - The right to make informed decisions about their health care and to receive information on available treatment options and alternatives per 42 CFR § 438.100(b)(2).
  - The grievance, appeal, and State fair hearing provisions in 42 CFR part 438, subpart F, apply to enrollees and ILOSs to the same extent and in the same manner as all other covered services.

- ILOSs may not be used to reduce, discourage, or jeopardize Medicaid enrollees’ access to covered Medicaid State plan services and settings. If an enrollee chooses not to receive an ILOS, they always retain their right to receive the Medicaid covered State plan service or setting on the same terms as would apply if an ILOS were not an option.

- In accordance with 42 CFR § 438.10(g)(2)(ix), all enrollee handbooks must contain information on enrollee rights and responsibilities. States that elect to include ILOS(s) in their managed care plan contracts must ensure that each plan’s enrollee handbook clearly explains these rights and protections.
ILOSs Must be Subject to Appropriate Monitoring and Oversight

- States must perform **ongoing and robust monitoring and oversight activities** to ensure that ILOSs remain medically appropriate and cost effective substitutes for State plan-covered services and settings, and comply with Federal requirements. This includes:
  - **Evaluating compliance** with Federal requirements at least annually.
  - Ensuring that managed care plans submit **timely, complete, accurate, and validated encounter data** for ILOSs to the Transformed Medicaid Statistical Information System (T-MSIS), per 42 CFR § 438.242.
- These efforts also include some reporting requirements, including:
  - Submitting the actuarial report for the **final ILOS Cost Percentage** for each applicable program demonstrating that the final percentage does not exceed 5 percent.
  - Providing **written notice to CMS** 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 area of non-compliance.
  - Submitting an **ILOS transition plan** to CMS for approval, if an ILOS is terminated.
  - Submitting an **attestation to audit** encounter, grievances, appeals, and State fair hearing data to ensure accuracy, completeness, and timeliness. This audit effort will inform State obligations for monitoring, annual reporting, and encounter data consistent with 42 CFR §§ 438.66(b)-(c), 438.66(e), 438.242(d) and 438.818, and be used to evaluate the medical appropriateness and cost effectiveness of each ILOS.
  - Providing any necessary documentation considered in the development of capitation rates.
- If CMS becomes aware (through State notification or other means) that an ILOS is no longer medically appropriate or cost effective or if there are other issues of non-compliance, we reserve the **right to rescind** approval of the ILOS or require **corrective action**.
ILOSs Must be Subject to Retrospective Evaluation, When Applicable

- CMS encourages all States to conduct a retrospective evaluation of all ILOSs.
- If the final ILOS Cost Percentage is greater than 1.5 percent, States are required to submit a retrospective evaluation for the applicable managed care program.
- The evaluation must include five years of data and include:
  - Cost;
  - Utilization;
  - Grievances;
  - Appeals; and
  - Quality of care
- Evaluations are due 24 months after the completion of the first five contract years that include ILOS(s).
- If the retrospective evaluation shows that an ILOS is not a cost effective, medically appropriate substitute for State plan-covered services or settings, or identifies other substantive issues, CMS will consider corrective action or termination.
- If CMS determines that it is appropriate, a State may be required to conduct a second evaluation using an additional five years of complete, accurate, and validated data.
Technical Assistance on ILOSs

- CMS review and approval of ILOSs will occur as part of our review and approval of managed care contracts and capitation rates.

- If States require technical assistance on ILOSs, feel free to reach out to your Division of Managed Care Operations (DMCO) analyst and the MCOGDMCOActions@cms.hhs.gov mailbox.
Q&A on ILOSs