
SMD #: 23-001
**RE: Additional Guidance on Use of In Lieu of
Services and Settings in Medicaid Managed Care**

January 4, 2023

Dear State Medicaid Director:

This guidance addresses an innovative option states may consider employing in Medicaid managed care programs to reduce health disparities and address unmet health-related social needs (HRSNs),¹ such as housing instability and nutrition insecurity, through the use of a service or setting that is provided to an enrollee in lieu of a service or setting (ILOS) covered under the state plan.² On January 7, 2021, the Centers for Medicare & Medicaid Services (CMS) published a State Health Official (SHO) letter (SHO#21-001)³ that described opportunities under Medicaid and the Children's Health Insurance Program (CHIP) to better address social determinants of health (SDOH). Since CMS published that SHO, states have been working to implement changes in their Medicaid managed care programs to meet the HRSNs of Medicaid enrollees more effectively, including partnering with community-based organizations that routinely address HRSN. CMS is publishing this guidance to clarify an existing option that states can pursue to enhance and expand these efforts through the use of ILOSs.

ILOSs can be utilized by states and their managed care plans to strengthen access to care by expanding settings options and address certain Medicaid enrollees' HRSNs in order 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. 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 obviate the future need to utilize state plan-covered services or settings. Managed care enrollees always maintain the right to elect to receive an ILOS or the state plan service, and cannot be required by a managed care plan to use an ILOS. The investments and interventions implemented through ILOSs may offset potential future acute and institutional care and improve quality, health outcomes, and enrollee experience. 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, thereby preventing or delaying enrollees' need for nursing facility care.

¹ HRSNs are an individual's social needs — such as for housing and food security — that may exacerbate poor health and quality-of-life outcomes when they are not met.

² ILOSs are authorized in accordance with 42 CFR § 438.3(e)(2).

³ Opportunities in Medicaid and CHIP to Address Social Determinants of Health, <https://www.medicaid.gov/federal-policy-guidance/downloads/sho21001.pdf>

CMS believes states and managed care plans can use ILOSs to improve access to health care and help address many of the unmet physical, behavioral, developmental, long-term care, and other HRSNs of Medicaid enrollees. ILOSs can offer many benefits for enrollees, but we also believe that as states and managed care plans expand their use of ILOSs to better address HRSNs, it is necessary to clarify CMS' expectations for such ILOSs and provide a policy framework for states and managed care plans to ensure appropriate and efficient use of Medicaid resources. As states take advantage of this opportunity, CMS will monitor and evaluate results to identify and share best practices to help states effectively use ILOSs to achieve optimal outcomes for their enrollees.

Background on ILOS

In the 2016 Medicaid and CHIP managed care final rule,⁴ CMS finalized 42 CFR § 438.3(e)(2) that formally recognized states' and managed care plans' abilities to cover services or settings that are substitutes for services or settings covered under the state plan (also known as ILOS). As CMS acknowledged in its 2015 notice of proposed rulemaking,⁵ managed care plans historically had flexibility under risk contracts to cover alternative services or services in alternative settings to meet enrollees' needs, and CMS believed codifying the practice in regulation would bring consistency to plans' use of such alternatives, as well as ensure adequate enrollee protections. To do this, CMS finalized four requirements for the use of ILOS at 42 CFR § 438.3(e)(2):

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 must 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.

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 provided as an ILOS, the states must comply with 42 CFR § 438.3(e)(2)(i)-(iii) and 42 CFR § 438.6(e). Due to the statutory limitation on coverage of services provided in an IMD in accordance with language in subparagraph B following section 1905(a)(30) of the Act, our ability to permit states to claim federal financial participation (FFP) for a monthly Medicaid capitation payment for an enrollee who receives services in an IMD is limited as outlined in 42 CFR § 438.6(e), and uniquely based on the nature of risk-based payment (see 80 FR 31116 for further details on this policy). Other than as an ILOS, in accordance with 42 CFR §§ 438.3(e)(2) and 438.6(e), FFP is not available for any medical assistance under Title XIX for services provided to an individual, aged 21 to 64, who is a patient in an IMD facility. The guidance within this SMDL does not replace or alter existing federal regulations and sub-regulatory guidance regarding the use of short term IMD stays as an ILOS, or the availability of FFP for capitation payments to MCOs and PIHPs for

⁴ 81 FR 27498 <https://www.govinfo.gov/content/pkg/FR-2016-05-06/pdf/2016-09581.pdf>

⁵ 80 FR 31116 <https://www.govinfo.gov/content/pkg/FR-2015-06-01/pdf/2015-12965.pdf>

enrollees who utilize an IMD. Existing policy on short term IMD stays as an ILOS is explained in further detail in the 2016 Medicaid and CHIP final rule (see 81 FR 27555-27563).

As required in 42 CFR § 438.66(a) through (c), states must establish a system to monitor performance of their managed care programs. When ILOSs are included in a managed care plan's contract, they too must be part of the state's monitoring activities. As part of such monitoring, states must ensure that all ILOSs, including short term stays in an IMD, are medically appropriate, cost effective, and at the option of the enrollee and managed care plan.

Since the 2016 Medicaid and CHIP managed care final rule, states have utilized ILOSs, in accordance with 42 CFR § 438.3(e)(2), to strengthen access to care and ensure the effective and efficient use of Medicaid resources. For example, the use of short term IMD stays as an ILOS is utilized by some states to address specific concerns about ensuring access to and availability of inpatient mental health and substance use disorder services. Additionally, some states and managed care plans have begun to utilize ILOSs to support an array of new and innovative services and settings for their enrollees to address unique needs, enhance the benefits of other covered services or settings, or reduce or prevent utilization of other state plan services or settings. The 2016 Medicaid and CHIP final rule, including the preamble and related guidance,⁶ specified CMS' requirements for ILOSs, including short term IMD stays that are offered as an ILOS. At this time, we believe that additional guidance is necessary for other types of ILOSs, such as those ILOSs intended to reduce or obviate the need to utilize the state plan-covered services or settings in question over a longer period time and non-IMD ILOSs. This guidance clarifies the nature of ILOSs that can be offered and outlines appropriate parameters to ensure appropriate and efficient use of Medicaid resources. We note that this guidance does not absolve states and managed care plans from compliance with all applicable federal requirements for all ILOS, including short term IMD stays. This includes, but is not limited to, those requirements outlined in 42 CFR §§ 438.3(e)(2), 438.6(e), and 438.66.

Overview of ILOS Parameters

To help states effectively utilize ILOSs to improve access to care for the Medicaid population and the efficient use of Medicaid resources, CMS has developed clarifying parameters that are outlined in this guidance for states' use of ILOSs. CMS acknowledges that ILOSs can offer many benefits for enrollees, but also believes it is necessary to have overarching parameters to ensure adequate assessment of the alternative services and settings prior to use, ongoing monitoring for appropriate utilization and enrollee protections, and financial guardrails to ensure accountability and prevent inappropriate use of Medicaid resources.

The following six principles are critical to the appropriate and efficient use of ILOSs, and reflect CMS' goal of improving health outcomes and advancing health equity. Each principle specifies requirements that states must meet to obtain CMS approval of states' managed care plan contracts that include ILOS(s) in accordance with 42 CFR § 438.3(a).

1. ILOSs must advance the objectives of the Medicaid program;
2. ILOSs must be cost effective;

⁶ <https://www.medicaid.gov/federal-policy-guidance/downloads/faq08172017.pdf>

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.

These six principles are described in detail beginning on page 5 of this State Medicaid Director (SMD) Letter.

CMS believes it is appropriate to use a risk-based review process for the agency's review of ILOSs to minimize state administrative burden while ensuring fiscal safeguards related to ILOSs. To this end, the ILOS documentation states must submit to CMS, as well as the related activities states must complete, will vary based on a state's ILOS Cost Percentage for each managed care program.⁷ 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,⁸ for the specific managed care program (numerator) divided by the total costs for the specific managed care program (denominator), which must include all capitation payments, including all state directed payments in accordance with 42 CFR § 438.6(c) and pass-through payments in accordance with 42 CFR § 438.6(d). States are required to annually submit a projected ILOS Cost Percentage and retroactively a final ILOS Cost Percentage to CMS. Documentation, monitoring, and evaluation requirements for states with an ILOS Cost Percentage that is *de minimis* (i.e., less than or equal to 1.5 percent) are streamlined, while states with higher ILOS Cost Percentages must adhere to additional requirements. These parameters are explained further below. CMS reserves the authority to deny approval for any ILOS it determines does not meet the requirements in this guidance.

Effective with the date of publication of this guidance, CMS will expect states to provide the supporting information and justify their ILOSs costs in a manner consistent with this guidance. We acknowledge that many states are already covering ILOSs, and those states may need time to conform with this guidance, such as to make necessary procedural and contractual changes. Therefore, states using ILOSs clearly documented in an approved managed care plan contract as of the date of publication of this guidance will have until the contract rating period, beginning on or after January 1, 2024, to conform with this guidance for existing ILOS. If these states elect to add any new ILOSs (i.e., ILOSs that are not in an approved contract as of the date of publication), they must conform with this guidance for new ILOSs. For CMS to conduct its review of contracts that contain ILOS(s), states must submit an assurance that they comply with all applicable principles of the ILOS policy in this guidance and associated regulatory

⁷ The ILOS Cost Percentage is measured by the specific managed care program that includes ILOS. For example, if a state has a behavioral health program operated by prepaid inpatient health plans, a MLTSS program operated by managed care organizations and a physical health program operated by managed care organizations, the state should develop a separate ILOS Cost Percentage for each of the three programs. We believe the ILOS Cost Percentage must be measured distinctly for each managed care program as rate development typically occurs by managed care program and this would ensure appropriate fiscal safeguards for each program that includes ILOS(s). We do not believe it is appropriate to develop an ILOS Cost Percentage across multiple programs as this does not ensure appropriate accountability in each program.

⁸ The costs of short term IMD stays that are ILOSs are not included in the numerator of the ILOS Cost Percentage as these costs must not be used in rate development given the statutory limitation, and instead states must use the unit costs of providers delivering the same services included in the state plan as required in § 438.6(e).

requirements as well as provide the documentation outlined below. CMS may also request additional documentation from the state to aid our review.

ILOS Principles

ILOSs Must Advance the Objectives of the Medicaid Program

ILOSs must advance the objectives of the Medicaid program. CMS will review each application to ensure that they advance the objectives of the Medicaid program and make this determination as part of our review of the state's contracts and associated capitation rates in accordance with 42 CFR §§ 438.3(a) and 438.7(a). In addition:

1. ILOSs must not violate any applicable federal requirements, including 42 CFR § 438.3(e)(2), 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.
2. ILOSs must be approvable through a state plan amendment authorized through 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

In accordance with 42 CFR § 438.3(e)(2)(i), states must determine ILOSs are cost effective substitutes for covered services or settings under the state plan. States must demonstrate to CMS that the ILOSs are cost effective substitutes in order for CMS to consider the managed care plan contract and associated rate certification for approval in accordance with 42 CFR § 438.3(a) and 42 CFR § 438.7(a). CMS will review states' determinations of cost effectiveness to ensure compliance with this requirement and that they are reasonable; the agency reserves the right to ask for additional documentation to aid our review.

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, CMS believes that the ILOS Cost Percentage (defined on page 4) per program should not exceed five percent. CMS believes that an ILOS Cost Percentage at or below five percent would be consistent with ensuring ILOSs are used effectively to achieve their intended purpose to advance access to health care while still ensuring fiscal safeguards. Both the projected ILOS Cost Percentage and the final ILOS Cost Percentage must be developed and certified by states' actuaries. CMS outlines the requirements related to the projected and final ILOS Cost Percentages, as well as other necessary ILOS documentation, below.

CMS will evaluate the projected ILOS Cost Percentage developed and certified by states' actuaries as a component of our review of the applicable rate certification(s) in accordance with 42 CFR § 438.7(a). The projected ILOS Cost Percentage is calculated by dividing the portion of the total capitation payments that would be attributable to all ILOSs, excluding short term stays in an IMD, for the specific managed care program (numerator) by the projected total capitation

payments specific to the managed care program (denominator), including 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 must be developed in a reasonable and appropriate manner, consistent with generally accepted actuarial principles and practices. Any managed care plan contract for a program with a projected ILOS Cost Percentage or related documentation that is not deemed reasonable by CMS will not be approved under 42 CFR § 438.3(a).

As part of rate certifications, states' actuaries must estimate, document, and certify the projected ILOS Cost Percentage annually. Specifically, states' actuaries must document the items below in each rate certification applicable to the program(s) that include(s) ILOS(s). The detail provided should be commensurate with the projected ILOS Cost Percentage for each program. CMS also may request additional information as deemed necessary in accordance with 42 CFR § 438.7(d). If a rate certification includes rate development for more than one managed care program, the documentation described below must be provided separately for each applicable program.

1. 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.
2. The projected ILOS Cost Percentage, as defined above. To inform CMS' review of capitation rates that include ILOS projected benefit costs, as outlined in Section I, Item 3.B of the Medicaid Managed Care Rate Development Guide,⁹ the state will be required to provide the aggregate projected ILOS Cost Percentage for the applicable managed care program, as well as document the impact of ILOS(s) on rates based on materiality, as outlined below:
 - a. 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.
 - b. 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.
3. A description of how the ILOS(s) (both material and non-material impact) were taken into account in the development of the projected benefit costs, and if this approach was different than that for any of the other services in the categories of service.

As part of the managed care contract submission to CMS, states must also submit documentation regarding ILOS cost effectiveness. If the projected ILOS Cost Percentage as described on page 5 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 this analysis. States must submit this documentation separately for each Medicaid managed care program that includes ILOS(s) for CMS' review and consideration for approval of

⁹ <https://www.medicaid.gov/medicaid/managed-care/guidance/rate-review-and-rate-guides/index.html>

the states' contracts with its managed care plans, in accordance with 42 CFR § 438.3(a). Upon CMS' request, states must provide additional information if CMS determines that information is pertinent to the agency's approval of the contracts that contain ILOS(s), including the cost effectiveness of ILOS(s). CMS reserves the authority to deny approval for any ILOS it determines not to be a cost effective substitute.

Additionally, all states are required to submit documentation of the final ILOS Cost Percentage applicable to each program for CMS review. The final ILOS Cost Percentage is calculated by dividing the portion of the total capitation payments that is attributable to all ILOSs, excluding a short term stay in an IMD, for the specific managed care program (numerator) by the actual total capitation payments specific to the managed care program, including all state directed payments in accordance with 42 CFR § 438.6(c) and pass-through payments in accordance with 42 CFR § 438.6(d) (denominator). This information must be certified by states' actuaries and provided to CMS in a separate actuarial report with the future rate certification(s) required in 42 CFR § 438.7(a) for the applicable programs that include the ILOS(s). In addition to providing the final ILOS Cost Percentage, as defined above, we believe this actuarial report should include the actual plan costs for ILOSs for the specific managed care program to ensure appropriate transparency as this historical experience will inform prospective rate development. This actuarial report, including both the final ILOS Cost Percentage and the actual plan costs, must be submitted to CMS no later than 2 years after the completion of the contract year that includes ILOS(s). CMS believes this is adequate time to account for changes to the eligibility file and revised rate certifications for rate amendments which may impact the final capitation payments that are a component of the calculation. For example, 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 information specified below. CMS may also request additional information, as deemed necessary and appropriate. The following documentation must be provided separately for each applicable program:

1. The portion of the total capitation payments that is attributable to ILOS(s), excluding a short term stay in an IMD, for the specific managed care program that includes the ILOS(s) and a description of how this amount was calculated.
2. The total actual dollar amount of capitation payments specific to the Medicaid managed care program that includes the ILOS(s). This total capitation payment amount 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).
3. The final ILOS Cost Percentage specific to the Medicaid managed care program. This percentage is calculated by dividing the amount from Step 1 by the amount from Step 2.
4. 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.

ILOS Must Be Medically Appropriate

In accordance with 42 CFR § 438.3(e)(2)(i), states must determine ILOSs to be medically appropriate substitutes for state plan-covered services or settings. States must demonstrate to CMS that ILOS are medically appropriate to be considered for approval as a component of the managed care plan contracts in accordance with 42 CFR § 438.3(a). CMS will review the state's determination to ensure it is reasonable; CMS maintains the right to ask for additional documentation to aid our review. CMS reserves the authority to deny approval for any ILOS that it determines is not a medically appropriate substitute. For CMS to conduct its review, states must submit at least the following within their managed care contracts:

1. The name and definition of each ILOS, and the covered Medicaid state plan services or settings 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.
2. 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.
3. 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 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.

At their discretion, states may also choose to impose additional provider qualifications or other limitations and protocols to ensure that ILOSs are medically appropriate and cost effective.

Additionally, if the projected ILOS Cost Percentage of a managed care program is greater than 1.5 percent, states must provide 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.). If the projected ILOS Cost Percentage is greater than five percent, the ILOS may not be approvable.

ILOS 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, including, for example, 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). While ILOSs are offered to Medicaid enrollees at the option of each managed care plan, the provision of ILOSs is also dependent on the enrollees' willingness to receive the ILOS. In accordance with 42 CFR § 438.3(e)(2)(ii), managed care plans are strictly prohibited from requiring enrollees to utilize ILOSs or from mandating replacement of a state plan covered service for an ILOS.

ILOSs may not be used to reduce, discourage, or jeopardize Medicaid enrollees' access to covered Medicaid state plan services or 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. Managed care plans are not permitted to 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. 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 ILOSs in their managed care plan contracts must ensure that each plan's enrollee handbook clearly explains the rights and protections specified in this section to be considered for approval as a component of the managed care plan contracts in accordance with 42 CFR § 438.3(a).

Managed care plans' contracts must, pursuant to 42 CFR § 438.228, require each managed care plan to have a grievance and appeal system in place that meets the requirements of 42 CFR part 438, subpart F and 42 CFR part 431, subpart E, which require states to provide for state fair hearings under specified circumstances. 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 services covered by the managed care plans' contracts. As with all services in managed care, enrollees can request a *de novo* state fair hearing at the Medicaid agency level in accordance with 42 CFR § 431.233. The offer or coverage of ILOS(s) by a managed care plan in no way alters or diminishes an enrollee's rights pursuant to 42 CFR part 438, subpart F. For example, pursuant to 42 CFR § 438.404, managed care plans are expected to provide notice of an adverse determination to enrollees if ILOS(s) offered by their Medicaid managed care plan are not authorized for an enrollee because of a determination that it was not medically appropriate. Additionally, consistent with 42 CFR § 438.402, Medicaid enrollees also retain the right to file appeals and/or grievances with regard to the denial or receipt of an ILOS.

ILOS Must be Subject to Appropriate Monitoring and Oversight

To ensure that ILOSs included in managed care plan contracts remain medically appropriate and cost effective substitutes for state plan-covered services or settings, states must perform ongoing and robust monitoring and oversight activities. Such activities must include evaluating compliance with federal requirements; using appropriate quantitative and qualitative measures, at least annually; and 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. Encounter data should be the foundation of many monitoring activities, and ensuring that the data are an accurate representation of all services used by enrollees is imperative.

To demonstrate appropriate state monitoring and oversight of ILOSs as well as related transparency, states must submit at least the following to CMS:

1. **An actuarial report provided by the state's actuary certifying the final ILOS Cost Percentage specific to each managed care program as outlined above.** This report should demonstrate that the final annual ILOS Cost Percentage has not exceeded five percent. This information must be certified by the state's actuary and provided as a

separate report with the applicable rate certification submission. This report should also include 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.

2. **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.** CMS reserves the right to rescind its approval or require corrective action to address deficiencies for any ILOS if it 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. If CMS determines that termination of some or all of previously approved ILOS(s) is warranted, the state must submit an ILOS transition plan to CMS for approval. The plan should include a transition of care policy to phase out the applicable ILOS(s) while ensuring access to contractually required services with minimal disruption to care for Medicaid enrollees. Transition of care processes generally will not exceed 12 months from the date of the written notice from the state or the date of the rescission notice from CMS. The state should ensure the transition plan includes a process to notify enrollees of the termination of an ILOS that they are currently receiving as expeditiously as required by the enrollee's health condition. The state must also amend its managed care plan contracts to remove the applicable ILOS, and if necessary, amend rate certifications to adjust its capitation rates to remove applicable ILOS costs, as necessary.
3. **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. Additionally, encounter data, when possible, must include data necessary for the state to stratify ILOS utilization by sex (including sexual orientation and gender identity), race, ethnicity, disability status, and language spoken to inform health equity initiatives and efforts to mitigate health disparities. Audited data will be used to evaluate the medical appropriateness and cost effectiveness of each ILOS continually.
4. Documentation necessary for CMS to understand how the utilization and cost of an ILOS, as well as any savings resulting from the use of an ILOS, were considered in the development of actuarially sound capitation rates. This documentation must be submitted with the associated rate certification.

ILOS Must be Subject to Retrospective Evaluation When Applicable

All states that include ILOSs in their managed care plan contracts are encouraged to conduct a retrospective evaluation of all ILOSs. However, states with final ILOS Cost Percentages greater than 1.5 percent are required to submit a retrospective evaluation for each managed care program that includes ILOS(s) to determine its overall impact on furthering the purposes of the Medicaid program, and demonstrate that each ILOS is a medically appropriate and cost effective substitute for identified state plan-covered services and settings. A retrospective evaluation must be completed using accurate and validated data for the ILOS. The state must utilize this data to

evaluate cost, utilization, access, grievances, appeals, and quality of care. Evaluations must be submitted to CMS no later than 24 months after the completion of the first five contract years that include ILOS(s).

At a minimum, each evaluation should include the:

1. 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;
2. Assessment of whether encounter data supports the state's determination that each ILOS is a medically appropriate and cost effective substitute for identified covered services and settings under the state plan;
3. The final ILOS Cost Percentage for each year, consistent with the actuarial report described on page 7;
4. Appeals, grievances, and state fair hearings data, reported separately and for each ILOS, including volume, reason, resolution status, and trends; and
5. Impact each ILOS had on health equity initiatives and efforts undertaken by the state to mitigate health disparities.

If the retrospective evaluation shows that a ILOS is not a cost effective, medically appropriate substitutes for state plan-covered services or settings, or identifies other substantive issues, CMS may determine whether to permit the state to take corrective action to remedy the deficiency or terminate the ILOS, if warranted. If CMS determines that it is appropriate, the state may be required to conduct a second evaluation using an additional five years of complete, accurate, and validated data.

If CMS determines that termination of some or all of the ILOSs is warranted, the state must submit to CMS a transition of care policy for approval as described on page 10.

Closing

CMS remains committed to supporting state efforts to strengthen access to care and better address the HRSNs of Medicaid beneficiaries while also ensuring the effective and efficient use of Medicaid resources. ILOSs provide states with an opportunity to address many health disparities and unmet physical, behavioral, developmental, long-term care, and HRSNs of Medicaid managed care enrollees. Effective with the date of publication of this guidance, as outlined above, CMS will not approve any state's managed care plan contracts that include new ILOS(s) that do not conform to this guidance. States that use ILOSs, as clearly documented in an approved managed care plan contract as of the date of publication of this guidance, will have until the contract rating period beginning on or after January 1, 2024, to conform with this guidance for existing ILOSs.

CMS looks forward to continuing to collaborate with states on the implementation of ILOSs under this policy framework. If you have any questions or need additional information, please contact John Giles, Director, Division of Managed Care Policy, at 410-786-5545 or John.Giles1@cms.hhs.gov.

Sincerely,

/s/

Daniel Tsai
Deputy Administrator and Director