

What do you or your organization perceive as potential benefits of the proposed changes for the 4th Edition? Please provide as much detail as possible.

Answered: 125 Skipped: 0

#	RESPONSES
1	clarification of level 3.7, expansion of outpatient service levels
2	The inclusion of monitoring services in level 1 to support the concept of substance use as a chronic condition that requires on going supports over time.
3	It depends on how the adopted language clarifies the areas that are now unclear or those you wish to make clear. The changes need to be specific, straight forward and dispel as much ambiguity as possible.
4	<p>More emphasis is needed on psychological aspects of addiction. Level 1.0 should address psychological counseling in addition to medical management.</p> <p>3.7 Medically Monitored Intensive Residential Services should also include psychological management and appreciation for the patient's psychological pain responses. Overmedication can contribute to reinforcement of addiction behaviors.</p> <p>Trauma assessment is important for everyone with addiction issues. Homelessness, family alienation, prostitution, exploitation of others can all contribute to trauma and PTSD that must be addressed with addiction.</p>
5	<p>1.7 - I would like for ASAM to give guidance about the OBOT model and requirements for in-person vs telehealth. With the expansion of telemedicine, we are getting numerous providers wanting to implement a telemedicine only model for treatment of OUD. My concern is this feels more like a for profit move vs meeting the needs of individuals in treatment and recovery.</p> <p>3.7 - this aligns with the systems in VA, many are inpatient psychiatric units of acute care hospitals offering this level of care.</p> <p>Recovery Residences - we recently began certifying these in VA. This alignment with ASAM will help us in better utilizing these resources as well as how they best integrate along the ASAM Continuum.</p> <p>Rebundling WM into the levels of care - this aligns with how VA implemented the model so this will be very supported to have this aligned with the ASAM Criteria. I am not aware of any stand-alone models that are Medicaid providers.</p>
6	<p>The science of care grows our understanding. Our assessment and criteria instruments should evolve in alignment. Specific points:</p> <p>(1)In general, we believe the proposed changes will strengthen the ASAM level of care criteria and further push the substance use treatment field forward as a health care service set. The existence of ASAM itself has been a foundational aid to the establishment of quality SUD services.</p> <p>(2)Renaming 3.7 as "residential" versus "inpatient" will create consistency with the language used in Colorado. As this modification is made, we are hopeful that the expected staffing associated with</p>

the 3.7 level of care will be more explicit. There is a misalignment in the definition of 24-hour medical care in our state, with some providers and regulators interpreting the standard to be met with medical staff available by phone 24/7 and others interpreting this to mean 24/7 nursing on the site. We believe that 3.7 programs that do not have medical staff on-site result in a mismatch between the needs of patients who are assessed to require a 3.7 level of care based on Dimensions 1, 2 or 3 and the availability of medical care needed to address these factors. We believe that more explicit standards about the kinds of medication conditions and associated medical interventions that are needed in the treatment of substance use disorders will strengthen treatment.

(3) We view the inclusion of recovery residences as a part of the continuum of residential care as worth considering. However, this may come in conflict with the recent establishment of a regulatory body (CARR) for SUD recovery living. The confounding of setting where treatment occurs and the intensity of treatment can be confusing for providers, policy makers, and the public. We support any clarification of the role of recovery support in the continuum of care and support the strengthening treatment requirements for level 3.1 residential in order to better distinguish it from recovery residences.

(4) We support additional clarification regarding justice-involved clients and level of care criteria. In addition to outlining levels of care in justice-settings, we believe more discussion is needed about how public safety concerns fit into the determination of residential levels of care in the community. It is clear that there are populations who require a secure, supportive setting due to risk for re-offense and child welfare related concerns who may not otherwise meet traditional medical necessity criteria for residential care. Any clarification about how these risk factors should be factored into dimensional assessment would be very helpful in our state.

(5) We further support the plans to bolster the adolescent standards. In fact, it might be helpful to segregate the adolescent standards from the adult standards as it is currently challenging to get a clear picture of the continuum and related level assessment when they are integrated with the adult standards.

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- 7 Splitting 1.0 into 1.0, 1.5, and 1.7 has the advantage of folding in both OTP and OBOTs (such as primary care settings / FQHCs that offer MAT) explicitly into the ASAM Criteria and create opportunities for ASAM to define service standards for these settings. I think making WM an explicit component of 1.7 and 2.7 has the advantage of emphasizing that ambulatory withdrawal management should be offered in settings with the capacity to offer this care (i.e. make ambulatory WM an expected component of outpatient care) Agree with folding biomedical capabilities into 1.7, 2.7, and 3.7 LOCs since biomedical enhancements weren't consistently understood. Agree in principle with increasing the minimum services associated with 3.1 to 9 hours to align with 2.1 LOC. Organizing the admission criteria with a "dimension forward" approach making explicit which dimensions drive admission to each level of care and which dimensions need to show improvement to support transition to a less intensive level of care is a great step forward, and having the criteria drive treatment planning will also be a big step forward. I agree with eliminating 3.3 LOC contingent upon the criteria making co-occurring capabilities and expectations across the continuum of care. An ASAM Criteria-driven explanation of specific UM and medical necessity documentation will also be helpful at reducing the considerable ambiguity surrounding how various payer UM units apply the criteria to coverage and payment decisions. The proposed use of MBC and standardized UM tools is a great step forward, as is an explicit linkage to how recovery residencies align as a component of the Criteria.
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- Ohio Managed Care Medical/Clinical Directors applaud efforts to “Support Better Communication” of Medical Necessity
 - Support the expansion of Medically Monitored Intensive Residential Services to include the integration of biomedical services to better align with and meet the needs of patients.
 - In support of the work to clarify the role of recovery residences to fit within the continuum to place individuals in the appropriate care setting and addresses a key determinant of health.
 - In support of the integrated care model and the expansion of primary care providers as agents to treat substance use disorders. However, true integration requires that individuals also be referred to or enrolled in supportive programs that address their social and emotional needs.
 - Explore the continued needs of our evolving social structure and reflect those needs in healthcare design and delivery.
 - Support the inclusion of justice-involved individuals, however consideration must be given to ensure equity is achieved with the population.
 - Support the decision to separate adolescent treatment from the adult standards to account for the needs of the developing brain.
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- Idaho Medicaid believes the suggested changes make sense. We appreciate the focus on transitions, the emphasis on communication of medical necessity, and additional attention to particularly vulnerable populations, such as criminal justice-involved individuals, individuals with cognitive impairments, and adolescents.
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- We support much of the changes that further clarify the criteria.
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- All Levels of Care are interpreted by regulatory agencies as a medically necessary level of care. It would be helpful to delineate some programs, or facilities as part of the continuum of care, but not a medically necessary level of care. “Recovery Residences” and DUI programs would be part of the Continuum of Care, but not be part of a Level of Care. General Comments & Issues To be Addressed Coordination of care requires the elimination of Fed CFR 42 (part 2). Members are not willing to allow for this coordination of care. In this world of easy access to highly dangerous meds and combinations of meds, particularly opiates and benzodiazepines, it is vital that all providers be able to be made aware of the current situation of the member and not fall to the role of free-drug provider. There has been a request for scoring similar to LOCUS/CALOCUS Co-occurring care should be care that improves the member’s/client’s ability to resist using. It should not increase their vulnerability. The program should work to stabilize mental health symptoms but not treat these issues either in groups or in individual sessions, especially trauma related issues in depth. Members in early recovery do not have the inner and outer resources to cope with this level of stress. In outpatient management of PTSD, we do not encourage deep discussion of the trauma unless the member can tolerate the discussion.
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- Developing more standardized medical necessity criteria as well as standards for medical necessity documentation.
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- Incorporating withdrawal management with ongoing treatment - Incorporating cognitive concerns in the level of care
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- #1 The editorial team is proposing that the clinical requirements align with Level 2.1 (9 or more hours of clinical services per week) and that structured services (including mutual support and other recovery support services) are offered 7 days per week. I think this is a great improvement in this LOC and a much smoother step down from Residential 3.5. The provider should also have equitable reimbursement for this LOC, currently they are trying to fill in this gap with PHP 2.5 with an housing option. #2 (These were some critical elements that Dr. Welch and Pelt delineated in the Utilization Management Course) I feel that this is taking the Criteria up to the next level and shaping the behavior of the provider to provide better standardized High-Level treatment. Better Implementation Support for the ASAM Criteria Standards Clearly delineating the assessment and treatment planning process by: -Describing standards for an intake assessment -Providing a standardized tx template -Dev. of ITP based on the 6-Dimensional Assessment -Standards on how the Tx Plan should be updated
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15	Agree emphatically that criminal justice-applicable criteria have to be expanded. I am Co-Chair of ASAM Criminal Justice SIG
16	Broader delivery of service to the patient; better comprehension of treatment to the whole person.
17	Better emphasis on the medical and nursing care requirements for withdrawal management across the continuum of care.
18	Providing a second manual for adolescences, removing level 3.3, adding a trauma subdimension, and clearly identifying WM across the continuum all seem to be appropriate changes. As the state, we already had our 3.3 and 3.5 provide the same levels of authorization and collapsed 3.7 WM and 3.7 into one level.
19	ASAM has bene very influential in creating national SUD standards and to ensure standards by which payment for services can be justified.
20	lacking treatment lengths definition - not modalities but lengths of treatment suggested for each modality
21	Better decision making on appropriate levels of care, particularly for patients who may not require or want higher levels of care.
22	- ASAM's proposal to require a standard treatment plan template, standardized language, and "more standardized medical necessity criteria as well as standards for medical necessity documentation" is a positive change that will improve provider documentation as well as simplify utilization management reviews. - Although we applaud ASAM from moving into offering a supporting guidance for CJI populations, there are also other underserved populations including pregnant, and parenting women, homeless populations, that could benefit from specialized treatment approaches/considerations.
23	- Addition of Level 1 - Long-term Remission Monitoring: This will allow for the ongoing support often needed by individuals with SUD to manage recovery and minimize relapse. It could be challenging to address medical necessity for this level of care in order to receive payment for these services. - Addition of recovery residences: Safe housing supportive of recovery is highly needed. This is an important addition to meeting the integrated needs of individuals with SUD. Standards of quality for recovery residences should be included. - Increasing clinical service times: Aligning 3.1 clinical hours with Level 2.1 (9 or more hours of clinical services per week), and specifying that structured services are to be offered 7 days per week will increase the therapeutic benefit of residential treatment services and better prepare individuals to transition to outpatient care. - Dimension forward approach: Identifying which dimensions drive admission to each level of care and which dimensions need to show improvement to support transition to a less intensive level of care will increase consistent application of placement criteria and enhance transition planning. - Separate volume for adolescents and transition age youth: This will give much-needed focus on the developmental needs of these populations.
24	The proposed changes provide more clarity for the identified levels of care. In addition, the elimination of 3.3 in particular will help to reduce the confusion with providers' use of level 3.3 as a step down level of care. We believe the additional recommendations are positive and would support those changes.

25 I believe the proposed changes may be helpful in strengthening the continuum of care and bridging the existing gaps.

Additional guidance will be needed for those who have been granted by courts a path of treatment that avoids incarceration, but who have been in that treatment for long intervals with little true evidence of improvement or benefit. Some of them have been maintained in treatment for years, but for political reasons the justice system and treatment providers working with the justice system seem to prefer seeing them minimally engaged in treatment rather than declare them as treatment failures and resort to alternative solutions. This provides for another enabling mechanism that should be eliminated and replaced with something that works.

26 -Appreciate plan for admission assessment template and other standardized tools because the quality of information received from programs varies widely. (Note: will this include requirements/expectations re: COWS/CIWA? Because there are programs that have told us: "We don't do CIWA.")
-Appreciate the emphasis on mental health treatment, as this is often overlooked or not dealt with fully by certain programs.
-Agree with removal of Level 3.3 because I really don't know where this type of program exists.
-Clarifications of medically managed settings and residential programs also appreciated, as these are often areas of confusion when doing reviews for admission and for medical necessity.

27 •Several perceived benefits are recognized with the proposed changes. We support the breakdown of the level 1 services into three parts. As a managed care organization, we are looking for a way to reward providers for maintaining stable clients and enhancing payment for providers that induct and maintain medications, which would be resolved through the separating out level 1 services and embedding withdrawal management into levels of care, rather than keeping it separated out. Our company reinforces that biomedical care needs to be incorporated in substance use disorder treatment and believe the proposed changes would enhance indicators we already have in place as provider expectations. We are promoting collaboration with the justice system and believe the proposed changes would help support our work in this area. As an insurance company, we support anything related to clarification of medical necessity and promote standardized tools as part of the assessment process. Having a clearer idea of medical necessity and the use of standardized tools will help ensure consistency across multiple insurance providers and decrease provider burden. With the distinction of 3.7-WM, we found that some providers are denying admissions if a person is not willing to participate in 3.5 after the 3.7-WM treatment. The integration of withdrawal management into treatment services, instead of making it standalone will mitigate some of the admission challenges with follow-up requirements.

28 Benefits in managed care include creating a shared language and increasing the consistency among regions of care. Also, I believe the efforts made by ASAM and the adoption by a majority of states is raising the expectations and level of care that can be provided in addiction treatment.

The changes to level 1 and the integration of withdrawal management represent practical and important steps forward in the field. With the emphasis on MAT during the pandemic, the benefits of having a national evidence-based level of guidance to ensure these are not provided outside the continuum of addiction treatment is important at this juncture.

Also, in NC, 80% of the potential opioid settlement funds will be managed by counties, who are often unfamiliar with addiction treatment. I think ASAM's new and existing role will be essential in providing guidance to bridging these conversations between politicians and providers, identifying gaps, and helping to destigmatize addiction.

In addition, the changes for residential treatment have important implications as many of the rural areas in particular may have individuals being placed into housing supports without adequate clinical support. This guidance and recommendations in the 4th edition will help eliminate those well-intentioned but inadequate efforts, as well as prevent the drops offs in care that are historically common.

29 Many of the changes look well thought out and in great support of the patient. I am wondering if there is any movement on the commercial payers supporting 3.1?
I will likely have more comments but right now I want to make sure I am interpreting this correctly - it seems that 2.0WM is no longer a level of care for ASAM Ambulatory Detox?

30 n/a

31 I am requesting to view the proposed changes and be a field reviewer for the document, as I was able to do for the 3rd Edition. From my staff of 70 clinicians within the courts, I would select a small group (8-12); we would each review the document in full as field reviewers and provide one set of feedback to you for consideration, thereby augmenting your input on justice involved clients.
Thank you

32 I think it is great that the criteria are going to further consider and attempt to include recovery residencies (these have significantly expanded in our community and have been a great benefit) and the level one addition to monitor recovery. Data supports that the longer we stay engaged with people the better, and sometimes this is not possible when insurance will not cover ongoing services. Having ASAM support such care I believe would help ensure benefits.

33 N/a

34 I do much consulting for payors and provider groups, as well as civil and criminal cases in addiction medicine. People continue to die because level 3.7 is used for withdrawal management without daily medical oversight from a physician / APC who is acting as an Attending and Captain of the Ship. There are a staggering amount of 3.7 programs where an absentee Attending allows grossly under-trained and under-supervised LPN and unlicensed counselling staff to run the treatment using 'standing orders' is obscene. Medically managed withdrawal at Level 4 in hospitals with 24/7 physicians on site is needed for treating impending and actual DTs, but Medically Monitored 3.7 MUST spell out daily rounds by an Attending, consistent not with a SNF but with an acute inpatient physical rehab or free-standing acute psych hospital. It is unconscionable to allow programs to harm patients by failing to medically monitor patients in acute alcohol and benzo withdrawal - and Nursing Monitoring by LPNs /RNs is NOT Medical Monitoring by an MD/DO (or qualified APC). PLEASE make this clear, because too many people are seizing and dying in "Level 3.7 Detox programs" due to utter lack of real, patient specific daily monitoring by medical (MD/DO/APC) rounding staff.

35 The increased details on standards at Level 1, the updates to adolescent treatment, and the better communication for medical necessity are most beneficial.

36 ATAC is submitting an extensive analysis to the president of ASAM, William F. Haning, III and the president elect, Brian Hurley, as well as the president of CSAM, Karen Anne Miotto.

37 I believe that the changes to Level 1 are important, specifically adding a way to capture maintenance care and medication assisted treatment, however, I don't think that the proposed 1.7 level of care really captures the reality of how medication assisted treatment should be delivered. It seems to me that it should be an intervention that is independent of level of care. The use of medications in the treatment of substance use disorders can, and should, occur in conjunction with all levels of care.

I agree that level 3.7 is better renamed residential, especially in the face of block grant prohibitions on the use of funds for inpatient care. I further agree with better integration of biomedical services in the continuum. One concern for Colorado that could be addressed in the new edition is that there is confusion about whether 24-hour nursing care is "required" in 3.7 programs. When I read programming, staffing and the Dimension 1,2,3 criteria together, I do not see how patients meeting the criteria could be safely treated in a program that does not have on-site nursing care. However, until recently our state has not been aligned with ASAM in regulation, so there are financial implications that result in watered down programming.

While I agree with unbundling of withdrawal management, it seems that withdrawal management and medication assisted treatment are similar in that a patient can be in ambulatory WM or even have episodes in 3.7 WM and still be appropriate for a 2.7 or 1.5 level of care. Maybe some explicit direction about how to think about WM as it relates to treatment needs would be helpful. In our state, 3.2WM programs are almost always stand-alone programs that serve both a public safety and an individual safety role. We need to more strongly emphasize the treatment role of these programs as it relates to determining level of care needs and making the most appropriate referral.

I strongly support addressing recovery residences and believe that this cannot be done without looking at the 3.1 level of care. This level of care, as currently written, is really a recovery support level. The treatment requirements are lower than 2.5 and it is the supervised environment and intensity of recovery support that makes it a more intensive level of care, not the treatment intensity. Again, I am not certain that increasing treatment (as opposed to recovery support) intensity is the best option or not. It seems like 3.1 could be conceptualized as a level of care similar to recovery housing—maybe the distinction would be that treatment is provided on-site (integrated 2.5 rather than parallel as with recovery housing).

I agree that more operationalization of the programming/services within each level would be helpful. I routinely use the residential credentialing manual to help my clients with this but having more direction in the main publication would be great. Again, being explicit about 24/7 nursing care would be really helpful for our state.

I further agree about the need for clarification related to 3.3. In my experience, states are using that level of care, largely, to capture services with costs that exceed 3.5 such as residential women and children's programs and co-occurring programs. There is a grave need for more specialized services for people with cognitive delays, including those with long term methamphetamine and alcohol use and this level of care is both under used and under-appreciated. [continued in next response]

38 The development of standards of care at Level 1 we see as beneficial. We also see as benefits the integration of biomedical services in the continuum, clarifications of how recovery residences fit in the continuum, updating the standards to reflect more integrated care for co-occurring mental health conditions by incorporating standards for co-occurring disorders; inclusion of the social determinants of health, diversity, equity, and inclusions; the recognition of the impact of trauma; updates to the language to reflect evolving terminology in the field. We like the idea of describing standards for an intake assessment to make determinations for initial patient placement versus a full biopsychosocial assessment used for treatment planning purposes.

39 It looks to expand the existing structure to provide additional options to meet people where they are, which includes Medication Assisted Treatment, affording them a level of care that fits their experience.

40 PLEASE NOTE - Due to the volume of comments, we were unable to use this form as it cut off our submission. To access our comments, please find them at the following link:

https://www.dropbox.com/s/m6948hcqaa9mhxs/ASAM_Feedback_IABH_2-7-22.docx?dl=0

41 provides more detailed and comprehensive data

good for medical audiences and other postgraduate level students

42 the inclusion of long term remission adds benefit to the inclusion of recovery support services along the continuum and the needs for assessment, planning for this care.

It is strongly encouraged to include 0.5 under Level 1 like long term remission as this service will be provided by outpatient levels to at risk youth as early interventions services. Leaving it out poses issues. There also needs to be at risk asam assessment considerations and leaving it as 0.5 does is not inclusive of assessment. In addition, this will allow for the integration of services to address mental health needs in dimension 3 and recovery support needs in dim 6.

There also needs to be better integration of telehealth, mobile services, and digital therapeutics can be incorporated into the continuum, including early intervention and monitoring (new level 1.0) besides treatment.

43 There are a number of benefits for the proposed changes for the 4th edition. Focus on substance use that are not opioids is a critical area of focus and need AS WELL AS supporting clinicians in implementing evidence based treatments, both behavioral as well as MOUD (such as identifying optimal pharmacotherapy for a given patient).

Another potential benefit (but also risk that I will outline below) is that ASAM Criteria are often used by provider organizations/treatment providers as well as payers and policymakers what are quality standards and practices. The benefit is that there is a go-to resource for what quality standards, guidelines, evidence, and best practices should be utilized. Many organizations use ASAM Criteria to support decision-making to engage or not engage, to pay or not to pay, or to support or not-support certain activities.

44 Hopefully the 4th Edition will be simplified. Additionally, we would like early intervention, like screening, brief intervention and referral to treatment, to be highlighted as an entry point for care. Specifically, Consistent with 0.5 Early Intervention, and the best practices of care coordination, encourage universal implementation of SBI as a standard of care associated with the early identification and prevention of SUD. Fundamentally, SBI can act as the "front end" mechanism for identifying substance use risk (often alongside both mental and physical health issues), and SBI provides the appropriate questions and information needed for primary care providers engage patients with services that ideally are proximal to primary care (e.g. integrated behavioral health specialists). SBI is an approach that can help coordinate the appropriate level of care and can prevent the onset of disease (SUD).

The Fletcher Group is most excited about the alignment with Recovery Housing and recognition of the need to incorporate the concept and treatment of chronic diseases and social drivers of health throughout all levels of care. By incorporating these two factors it is also important to address the range of effective programs and services that incorporate a social recovery model. Thus, there is a blending of a medical model with high reliance on licensed professionals, and a social model with an emphasis on lived experience, peer support, and building recovery capital.

Recovery housing programs and services expand the approaches important to address substance use disorders and the opioid crisis, as Blanco (2022) states: “approaches narrowly focused on the treatment domain have considerable limitations.” (Blanco, C, Wall, MM, Offson, M. (2022) “Expanding Current Approaches to Solve the Opioid Crisis.” JAMA Psychiatry. 79:1; 5-6.). Recovery housing provides a service option that coordinates with medical and clinical practitioners and specifically addresses social drivers of health as well as the chronic nature of substance use disorders after an initial intervention that addresses withdrawal symptoms, craving, and untreated pain, See Thakrar, AP. (2022) “Short-Acting Opioids for Hospitalized Patients with Opioid Use Disorder.” JAMA Internal Medicine, January 31. A recovery house program represents a service model that provides long-term, six or more months in a structured living environment, to support the individual's ongoing recovery by addressing SUD as well as social drivers of health in promoting employment and stable housing.

Recovery housing fits within a recovery ecosystem in providing safe housing that reinforces abstinence, it offers a long-term program, which is essential for brain healing and development of recovery capital to maintain recovery from this chronic health condition. Because it is a long-term intervention with support service, recovery housing works to develop an individual's knowledge and skills to establish the resources needed in managing this chronic health condition. The program is consistent with the Stanford chronic condition management program (see for example: Lorig, K., Holman, H., Sobel, D., Laurent, D., Gonzalez, V., and Minor, M. Living a Healthy Life with Chronic Conditions, 3rd Edition, Bull Publishing (2006).

Individuals who are also experiencing homelessness or involvement with the criminal justice system and have limited community support resources (social drivers of health) recovery housing serves an important role as a resource for jail diversion, or re-entry from jail or prison. Recovery housing also serves as transitional care from acute inpatient treatment or from an acute medical detoxification in which acute inpatient care is not required because of limited co-occurring physical or other severe mental illness conditions. Recovery housing may also serve as an adjunct to an intensive outpatient program.

The health care system is becoming increasingly responsive to social drivers of health and the importance in taking these factors into consideration in establishing a system of care. See for example: Beyond Health Care: The Role of Social Determinants in Promoting Health and Health Equity (kff.org) ASAM criteria that is significantly influenced by determining the medical necessity of a specific level of care, without taking into consideration social drivers of health is likely to create barriers to programs and financial supports to establish a holistic continuum of care. It is important for criteria to take into consideration housing, employment, social connections, socioeconomic, physical environment, and access to services across the continuum. Likewise, in establishing criteria for a chronic health condition each component of the system of care reinforces the knowledge and skills for the individual to respond to the chronic health condition.

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- 46 We appreciate the continuum of care updates and believe that maximum flexibility/broadest possible range will be particularly helpful in terms of meeting the needs of patients in under-resourced settings.
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- 47 Improved organization of the level system will allow more nuanced care, especially in these areas: 1)Attention to co-occurring conditions (childhood and adult traumas and their current symptomatic expression; depressive illnesses, social anxiety, etc.). 2)Recognition of the importance of systematic, organized long term disease management similar to chronic care of diabetes or hypertension. PHPs have been working in this area for decades, collaborating with participants to support them as they transition from high-intensity formal health care services through lower intensity services and, ultimately, to supported self-management. 3)Updating the section on safety-sensitive workers is essential to ensure that the rehabilitative needs of this special population are addressed. Stigma and bias differentially impact safety-sensitive workers and present unique challenges and scrutiny that bear on successful return to work. The obvious impact of COVID-19 on the healthcare workforce underscores the critical importance of ensuring that these special needs, and public safety, are not overlooked or compromised. Our expertise in the organized, team-based management of substance-related chronic illnesses in healthcare professionals has positioned us to provide experience and data that may be extrapolated and applied to the population at large.
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- 48 this is really more advocacy for A&D Counselors
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- 49 -We agree that more enhanced criteria for WM services at all levels is a positive change – separate and distinctly defined levels would better serve individuals with different needs and perhaps prevent overuse of withdrawal management
- By recognizing the need to assess and address biomedical issues, the new ASAM will support integrated BH and PC care.
 - We like the idea of identifying subdimensions that should be the focus of assessment and treatment and organizing the admission criteria with an “dimension forward” approach by level of care
 - Considering the high correlation between cognitive impairments and SUD, we believe that incorporating care for individual with cognitive impairments across the continuum will improve access and patient outcomes
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- 50 Patients with hemophilia appear to have the same access to short-term, Level 4 treatment facilities as everyone else. However, in talking with several Level 3 treatment facilities, they believe that they are not able to take patients on IV infusion medications, even when the patients are fully-functioning, biomedically stable, and capable of self-administering their medication. After reviewing the criteria detailed in ASAM’s Matrix for Matching Adult Severity and Level of Function with Type and Intensity of Service, it is possible that the facilities’ reluctance to accept patients on IV infusion medications may be due to an overly broad reading of the criteria. As you are aware, Risk Rating 4 on Dimension 2 states, “The patient is incapacitated, with severe medical problems (such as extreme pain, uncontrolled diabetes, GI bleeding, or infection requiring IV antibiotics.)” As such, it is possible some facilities may read this language to include all patients who require IV infusion medications, and therefore give all patients with hemophilia a risk rating of 4, regardless of the stability of their condition.

Today, most patients with hemophilia self-administer their IV infusion medications prophylactically two or three times per week. The entire infusion process takes 2-10 minutes and involves a simple syringe “push.” The process does not require any infusion pumps, specialized durable medical equipment. or medical supervision. NEHA hosts an annual summer camp to teach children with

hemophilia how to self-infuse their IV medications starting at age 5, which aims to give them the confidence to infuse anywhere. Infusing IV medication for a person with hemophilia is as routine as brushing their teeth. People with hemophilia who take their IV medication prophylactically are considered medically stable and lead full, healthy, and productive lives.

We recognize that in a SUD treatment facility, patients who use IV medications may need to have additional staff supervision to ensure that their infusion is consistent with their SUD recovery journey. However, most hemophilia patients do not require any medical staff or medical assistance to successfully administer their medication. Our understanding of the ASAM criteria suggest that stable patients with hemophilia that are able to self-administer their medications should not be excluded from Level 3 facilities on the basis of Dimension 2, even if they require brief staff supervision during their self-administration.

We respectfully request clarification of the above referenced language in the ASAM Criteria 4th Edition. By clarifying this, patients in the hemophilia community with SUD would be able to access appropriate placement and treatment for their SUD.

51 From the brief synopsis provided by ASAM, Ohio sees the following as potential benefits of the 4th Edition of the ASAM Criteria:

- 1)Integration of the behavioral health disciplines (SUD and MH) along with integration of physical healthcare via the x.7 levels of care. The occurrence of comorbid conditions (MH or physical) in populations of people with SUDs is a common occurrence and the advancement to treating the whole person in as few settings as possible is paramount.
- 2)Focusing on reintegration of withdrawal management to alleviate “steep drop-offs”.
- 3)The clarifying of “recovery residences” is a welcomed objective as this is an area of extensive complications and confusion, at least in Ohio. The partnership with NARR is crucial to achieving this objective.
- 4)The addition of long-range remission monitoring helps build understanding of wellness management beyond acute care strategies and settings.
- 5)Simplified presentation to improve clarity and support implementation to greater fidelity supports quality practice, furthers the use of the criteria as a standard of care, and promotes consumer protection. This may be enhanced by the focus on more standardized medical necessity criteria and documentation. Taking this from paper to practice will require extensive training provided by capable and competent trainers.
- 6)The promotion of SUD treatment into general healthcare, both in primary care and emergency departments, promises to promote a more complete continuum of care with support for ongoing care.
- 7)Incorporating principles of measurement-based care may help with age-old policy question about consistent measurement progress and successful outcomes beyond sobriety.
- 8)Additional resources for justice-involved individuals and adolescent treatment can support advancement of practice for individuals in these specialty groups and settings.
- 9)Will there be more discussion of the link between level of care criteria and prescribing medications for SUD in OBOT settings to support practitioner and consumer education?

Those are just a few examples and Ohio looks forward to reviewing additional details as the editorial committee progresses with the 4th Edition.

52 I am writing on behalf of the American Association for the Treatment of Opioid Dependence, representing more than 1,200 opioid treatment programs (OTPs) in the United States. We are grateful to ASAM for inviting us to comment on the ASAM Criteria 4th Edition. We are also encouraged that Dr. R Corey Waller will serve as the head of the new editorial team given his expertise in this area.

The following comments provide some context with regard to this new edition.

Shifting Characteristics of An Opioid Epidemic

As ASAM knows, the current opioid epidemic began with an overprescribing of prescription opioids without proper follow up. It then morphed into increasing heroin use, which evolved into fentanyl being the primary opioid used as patients entered treatment. There is a complicating factor with the increased use of stimulants, notably methamphetamines.

We have been receiving feedback that many OTPs have been challenged with stabilizing patients with methadone hydrochloride products for those, who are primarily using fentanyl as a reason for entering treatment. Illustratively, most of our patients would stabilize on an 80-120 mg regimen of methadone maintenance treatment prior to fentanyl use.

At the present time, we continue to get reports from OTPs throughout the United States, stating that patients need upwards of 160-180 mg of methadone to achieve stability. This is directly related to the use of fentanyl given its potency as an opioid.

It is understood that the ASAM criteria must anticipate further changes in how a patient presents to treatment. This is but one recent challenge but it is important for the editorial committee to consider such matters.

Major Changes Proposed for the Fourth Edition
Updating the Continuum of Care to Reflect the Evolving Treatment System

Expanding Levels of Care within Level 1

Level 1.0 – Long-term Remission Monitoring

We certainly support changing criteria so that there can be appropriate levels of care when a patient decides to end medication - assisted treatment. We understand that what is being proposed could include patients remaining in medication-assisted treatment toward a greater degree of stability and toward remission monitoring. The unintended consequence here might be the challenge of having state Medicaid reimbursement fund this level of service delivery and that should be kept in mind. ASAM is especially aware of such matters, given its prior publications on how third-party reimbursement aligns with the services being provided.

Level 1.5 – Outpatient therapy

We understand the proposed level of care would include specialty office-based practices including OTPs and DATA 2000 practices. At the outset, it is important to underscore the differences in how these particular treatment models differ. While they do utilize medications to treat opioid use disorder, OTPs are regulated at federal and state levels while DATA 2000 practices are not. There is more of a team effort in the structuring of OTPs and how they treat the patient as compared with DATA 2000 practices. There are no team requirements or regulatory requirements in how DATA 2000 practices function. In effect, changes in the ASAM criteria should reflect such realities and draw on evidence whenever possible.

Updating Level 3.7 (Medically Monitored Intensive Residential Services) to Reflect Care in Residential Settings

It is important to point out that many residential substance use disorder treatment facilities do not permit the use of medication - assisted treatment for their residents. There are a number of reasons for this including ideology and what is reimbursed. In this instance, the criteria for the fourth edition should keep this matter in mind. Additionally, many halfway houses and skilled nursing facilities in addition to senior care facilities do not provide medication-assisted treatment while the individual patient is housed within their residential treatment facilities.

53 CCAPP is very pleased to see Level 1.0 – Long-term Remission Monitoring being added to the criteria. As such, we would like to provide some resources for the committee to consider as follows:

- 1.Strengths Planning for Building Recovery Capital (Best, Counselor Magazine 2018)
- 2.8 Dimensions of Recovery Capital – Do You Know the Basics?
- 3.Recovery Capital Pathways (Cano and Best, 2017)
- 4.William White Interviews David Best (Best and White, 2012)
- 5.Recovery Capital, A Primer for Professionals (White and Cloud, 2008)
- 6.Recovery Capital as Prospective Predictor of Sustained Recovery (Laudet and White, 2008)

We believe that framing this element in a more "patient-driven" respect would be most fruitful. The concepts of recovery capital should be included as a model for this level of care.

Upon review and consideration of the proposed modifications to the ASAM for issuance of Edition 4, OBH and HCPF, in consultation with providers and Managed Service Organizations (MSOs) and Regional Accountable Entities (RAEs) who jointly oversee statewide benefits and coverage for the publicly funded delivery system, agree the proposed changes have the potential to strengthen the ASAM level of care criteria and further push the substance use treatment field forward by ensuring improved continuity of care, consistency of assessment criteria, and addressing gaps for populations that have historically been underserved.

Increased emphasis on the biomedical dimension and service requirements should improve the quality of care and align it more with medical standards of care. As part of this increased alignment, we would observe that it would also be beneficial to have more detail on minimum standard treatment hours (or ranges of treatment hours) for each level of care.

For medication-assisted treatment and withdrawal management, we offer the following observations:

The current way in which medication-assisted treatment is portrayed can be misleading; we are concerned about MAT being added as a level of care. Medications are an intervention that can, and should, be considered at every level of care. While long-term maintenance is well established in the outpatient setting, without the proper emphasis on the use of medications as an intervention across the continuum, these effective tools may be underused in residential and intensive outpatient levels of care.

It is anticipated there will be an impact to OBH licensing. OBH currently requires a special license for OTP/OMAT services. Clarifications to the criteria for OTPs to also have/provide ambulatory WM should be considered. Changes to regulatory criteria will require system changes including financing and licensing.

We strongly support the emphasis on withdrawal management as an entry point to treatment and therefore support requirements for stand-alone withdrawal management programs to have qualified individuals on staff to assess level of care needs prior to discharge and facilitate admission to the level of treatment indicated by the ASAM.

Conceptually, bundling withdrawal management services into other levels of care is nuanced. We suggest adding requirements to all WM levels of care for an ASAM assessment prior to discharge and to facilitate access to ongoing treatment. For 3.7WM and 3.7 for example, consolidation merely acknowledges the present state.

We support the combining of 3.7 and 3.7WM into one level of care and request that specific medical staffing requirements for 3.7 are clearly defined, reducing ambiguity between medical staff available by phone 24/7 and 24/7 nursing staff on site. Most WM in Colorado is at the 3.2 level. The impact of integrating clients needing 3.7WM into existing 3.7 residential facilities may cause some challenges for bed management as the WM clients may greatly reduce lengths of stay.

However, we are concerned about the elimination of 3.2WM as a freestanding level of care. In Colorado, 3.2WM is frequently used as a harm reduction intervention, giving people a few days free of alcohol/drug use along with some motivational and supportive interventions. Failing to recognize the 3.2WM level of care will result in payers discontinuing payment for this level of care. While we agree that clarification of the 3.3 level of care is needed and that this level of care has been underused in Colorado, we believe that there is a need for a 3.3 level of care that addresses the needs of people who have cognitive delays as a result of their drug/alcohol use. Eliminating this level of care will discourage specialized settings for people with cognitive challenges which focus on behavioral evidence-based practices rather than the cognitive-behavioral interventions commonly used in other residential treatment settings. In addition, if the 3.3 level of care were

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- 55 1. I believe increasing the requirements of a level 3.1 is absolutely necessary. I have found limited if any benefit for clients needing treatment.
2. I also agree that a more systematic transition from one level of care to the next is needed. Too often clients completing a level 3.5 or higher are dropped to a level 1.0. This seems like too much of a drop in the level of services being provided. I think levels 1.7 and 2.7 would be highly beneficial.
3. Providing "standards for assessing trauma within Dimension 3 and how to determine what services need to be delivered based on the assessed needs in this subdimension" would be very helpful. Many evaluators miss recommending co-occurring treatment keeping the mind set they are there for a SUD and not MH is lacking in treating the whole person.
4. I believe we need to "incorporate treatment of individuals with cognitive impairments across the continuum" and not just 3.3. I agree when making a recommendation for 3.3, we are unable to get a person the treatment they need because programs deny access based on their lack of ability to provide this level of care.
5. Providing a clearer standards and implementation for "the care of justice-involved patients and the treatment of behavioral addictions" would greatly benefit the treatment providers as well as our clients.
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- 56 Added outpatient levels helps better represent what is out there.
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- 57 We like the emphasis on 1.0 as Recovery Support Services; the reintegration of Withdrawal Management into the Continuum of Care; the emphasis on Special Populations (incarcerated, LGBTQ+) and the emphasis on greater integrated care.
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- 58 It appears the use of BIO and/or WM with a residential 3.7 designation may assist in gaining coverage for SSH inpatient services. Many insurers label the care at SSH at "residential 3.7" but the facility is licensed as inpatient, not residential. The unfortunate consequence of labeling SSH services at "residential 3.7 with WM and/or BIO," as opposed to "inpatient 3.7 and/or 4.0" is a reduced per diem rate, as the hospital does not charge by line item. Daily physician services are separately charged by treating physicians but all other services are inclusive of the per diem rate.
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- 59 Inclusion, reflects updated practices in the field, expanding criteria for marginalized groups, treatment plan template!!, expansion of continuum for extended care.
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- 60 I am the Executive Utilization review nurse with my organization and have been studying ASAM for several years now and have noticed such a subjective approach across the board. The clear delineation of the assessment and treatment planning process will hopefully allow more concrete placement into appropriate levels of care. I also like that you will be Describing standards for an intake assessment to make determinations for initial patient placement versus a full biopsychosocial assessment used for treatment planning purposes. I really like that ASAM will be Describing standards for how the treatment plan should be updated based on reassessments. We have been attempting to educate our clinicians to look at the entire 6 dimensions when updating weekly and meeting with clients weekly. Hopefully this will provide a clearer picture for them. I am also responsible for obtaining pre-authorizations for out level 3.5 and 2.1 programs and at times (before the COVID when we were actually doing utilization review) you would have to argue your point with the MCO and they would still deny services, hopefully organizing the admission criteria with a "dimension forward" approach focusing on which dimensions drive admission will help this as well as help with the transition to less intensive level of care. Funny didn't even realize that 3.3 was specific for patients with cognitive impairments I have just been focusing on the levels of care we provide, but I believe adding this chapter would be a great benefit for not only our program but others because we have had numerous clients with cognitive impairments that have participated in our 3.5 program with a lot of one on one support. This would probably help our clinicians. I also am interested to see what the standardized medical necessity criteria will look like.
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- 61 The wish list ASAM describes in their proposed changes seem excellent. We need details to fully understand the proposed changes.
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- 62 I wish there was more detail provided to stakeholders to make thoughtful comments.
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- 63 No
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- 64 I have not seen the changes
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65 Because Fellowship Hall operates over the entire continuum of care, we see the fact that withdrawal management services are being integrated into the continuum as a good thing. At Fellowship Hall, we recognize that withdrawal management is just the very beginning of treatment. We are very gratified to see ASAM recognizing the need for further treatment past withdrawal management. We feel that level 3.7 (medically monitored intensive residential services) and level 2.7 (medically monitored intensive outpatient care) would be appropriate levels of care for guests currently receiving withdrawal management at Fellowship Hall. Also, because Fellowship Hall does offer care at all levels throughout the ASAM continuum, we see the emphasis on being able to move a patient through all continuums as a great thing. For facilities who don't offer the entire continuum of care, we hope that we may be able to partner with some of them so that they can best serve their patients. For example, we would like to be able to offer all of our lower levels of care to a person who was detoxed at an outside hospital or crisis center where the other lower levels of care are not available.

We are also excited to learn more on how ASAM plans to incorporate the need for recovery residencies into the levels of care. At Fellowship Hall, we have multiple recovery residencies on our campus. We also have close relationships with many of the oxford houses (sober living houses) in the local area.

66 Better patient management. Fair distribution of insurance funding

67 The benefit is to separate the subcategories within each dimension. Provide more guidance for how to identify interventions that directly address ASAM goals. Guidance on better follow-up on clients that have completed treatment.

68 1.We appreciate the planned delineation between assessment for initial patient placement ("intake assessment") and a more comprehensive "...biopsychosocial assessment used for treatment planning ...". (Note please see related Unintended Consequences comment below relating to relationship between multidimensional assessment and biopsychosocial assessment).

2.We appreciate the concept of expanding levels of care and more detailed standards in Level 1 to support a variety of ambulatory settings. (Note please see related Unintended Consequence comment below regarding barriers to flexible service delivery in proposed Level 1 services).

3.We appreciate the plan to describe standards for how the treatment plan should be updated using reassessment (Note please see related Unintended Consequences comment re standardized treatment planning template below).

4.We appreciate the plan to incorporate the principles of measurement based care throughout treatment.

5.We support the concept that 5 hours of structured services may be too low for this licensed level of care, however, rather than increasing the amount of structured 3.1 services to 9 or more hours, we support consideration of the concept as described in the paragraph on facilitation of care within programs to allow organizations to (become licensed to) deliver multiple levels of care within their programs for example being able to offer simultaneous, reimbursed Level 1 or Level 2.1 services for persons newly transitioning from residential treatment instead of referring those residents to outside services.

6. We appreciate the confusion and overlap regarding Level 3.3. Note that in some instances (for example in Maryland), this level is used for specific populations, such as pregnant women and women with children, however, not generally for persons with cognitive disabilities. Perhaps Level 3.3 can be reframed to support specific populations of need without being entirely eliminated. Please note comment on related unintended consequences below.

7. Clarification of the important role for recovery residences in a recovery continuum will be very

- 69 Benefits may include better delineation of what each level of care is offering
- 70 Improved continuum of care for patient transitions from different levels of care w/in and with/out Kaiser HMO.
- 71 Further emphasis on variability in program resources within level 1 more accurately reflects the reality of ambulatory addiction care and begins to address the disproportionate emphasis placed on levels 2+ in the criteria.
- 72 For the new level 1.0 patients, we are currently required by the state to do regular (ongoing) therapy for patients receiving buprenorphine - even if they have been on it for years. While UDS and other diversion mitigation strategies make sense (to ensure that diversion is not occurring) requiring therapy for stable patients is an undue burden on them.

Further, most care we offer for outpatients will fall under level 1.7. I would need to evaluate the new criteria for level 3.7 in more detail provided to give a comment there.

- 73 We currently do not have services above Level 1, but we refer across the continuum. The benefits of the increased clarity will be to further standardise the treatment received by our patients and reduce the financial barriers to placement.
- 74 As stated above, The various providers have their own interpretations of criteria for approving ongoing IOP sessions. We often have to "fight" for our clients to receive the treatment that they need after completing 50-70% of the IOP. The reason for this is that the client no longer meets medical necessity and the definition of medical necessity is different from one insurance carrier to the next, and this definition is often NOT disclosed to us. Having standard criteria for ongoing services will make providing our clients with services much more conducive to client-centered treatment.
- 75 I think the reinforcement of "continuity of care" is very valuable to our clients. All the research we have read over the last 20 years indicate the longer an addict is in residential treatment, the better his/her chance of successful outcomes. Insurers in California are cramming down the LOS to the point where RTC has become less effective as a treatment tool. If ASAM could make a suggested LOS for RTC, similar to what Pennsylvania has (all RTC must be a minimum of 30 days), the clients would benefit significantly.
- 76 I was shocked at the number of people who were being directed toward inpatient care so will be happy to see the outpatient levels of care expanded
- 77 I cannot speak for agency
- 78 My favorites are the addition of the .7 MAT intervention to the various care levels, as well as the increased emphasis of care levels at the 1.0. These are going to be extremely helpful!
- 79 Better differing levels of care and monitoring. Also, better metric system for measuring outcomes.
- 80 I monitor patients that have been stable for years, sometimes decades, using MAT (buprenorphine). This is a common scenario. I would consider this level 1.7. Some are in counseling. Some are in 12 steps programs. All are encouraged to pursue life long support. Is this reasonable for ASAM guidelines?
- 81 The criteria should be specific about the use of medicine for OUD and even AUD. A majority of rehabs and even some detox are not using buprenorphine in the USA.

Also tobacco use disorder and Hepatitis C are often not treated . Please be specific about including medical care when treating a SUD.

- 82 Long term maintenance, which is a problem
- 83 It is much more straightforward. It is excellent to finally see the integration of psychosocial treatment and medical treatment. Will levels 1.7, 2.7, and 3.7 include ALL forms of MAT, or just MAT for opioids??
- 84 Greatly appreciate the addition of nuance to level 1.0 care and the addition of a "BIO" distinction. Wholeheartedly agree with the acknowledgement that most patients in level 3.1 would need more than 5 service hours/week.

85 I appreciate the attempt to better describe the role of an Opioid Treatment Program ("methadone clinic") by adding Level 1.7.

86 If I am reading this correctly, it states that there will be an almost-doubling of the services required for 3.1 halfway houses, to have them reflect 2.1 level service intensity with housing. I feel this defeats the purpose of that level of care. As of now, for patients in a 3.1 halfway house who are stable, they only need to receive 5 hours of service. But if they destabilize, their services can be bolstered by simultaneous referral to an IOP program. We have in the past used this extensively in our program. Our program has both an outpatient clinic (Level 1, Level 2.1 and OTP), and a 3.1 halfway house. Patients are treated simultaneously in 3.1 and outpatient. 3.1 clinical services are more oriented toward integration into the community, fostering eventual independence, securing stable housing, and residential milieu/process issues. Services in our outpatient program for less stable patients involves more traditional services like relapse prevention, anger management, trauma-centered groups, MAT management, etc. We are working with our State Medicaid office to allow 3.1 plus 2.1 billing together. The services are provided in separate locations (our hospital-based outpatient level 1,2 program and community-based level 3.1). This works out well so that their outpatient treatment can be chronic and long-term – years when necessary; while their residential services at 3.1 level of care is provided only while they are living at that facility. In our experience, since residential treatment is more transient, and sometimes patients suddenly leave those facilities (e.g., for major rule violation putting residents at risk – threats, violence, bringing substances in), it is critical that the ongoing outpatient treatment continues uninterrupted.

In the absence of allowing 3.1 to be combined with 2.1 or 2.5, what happens to destabilized patients is that they need to be put into 3.7 at the expense of continuity of care at the 3.1 and outpatient program, or for care continuity to continue, but at lower numbers of hours than is indicated.

I worry about increasing the clinical minimum hours/days for 3.1 from 5 hours to 9 hours for 2 reasons:

It reinforces the disallowance of some payers for letting patients stay in 3.1 plus intensive outpatient or partial hospitalization programs, and/or

Not all 3.1 residents need 9 hours of services per week – for more stabilized patients, it would be better that they focus on other recovery tasks. It is always possible for 3.1 programs to offer more

87 I think the proposed changes will give the substance use field more delineation when it comes to direct care.

88 The ASAM is used for to help us assess addiction and the appropriate continuum of care for our client's. I think that these changes does not hurt what we do but should enhance what we do as it relates to help the clients we serve.

89 However, we need no diagnosis to be clear. Many people miss interpreting no diagnosis.

90 I do not see all the levels of care, so TC's may have a hard time figuring out what is offered and what if anything has changed for our situation. We offer an mental health overlay with clinical guidance from program directors for men and for women housing situations, and some medical management within certain guidelines of what medications will be acceptable and not feed the addiction problems. The components have a medical manager who overrseas this area .

91 I appreciate the delineation for assessment and treatment planning. I also like the inclusive language and terminology, particularly for LGBTQ. The addition of level 1.0 will be interesting, particularly in my work environment and possible implications this could have (soldiers).

92 The proposed changes do help clarify the individual levels of placement.

93 The changes proposed appear to offer the flexibility to provide services called for at almost any level of care. For example, I've always looked at 3.7 and 3.7WM as the same level of care with services planned to meet patient needs as symptoms improve or deteriorate, and MAT and other medical care can be incorporated in most levels.

94	I feel that consideration of Harm Reduction Philosophy adds to the education and practice of providers in treating individuals with addiction. The additions allow for appropriate continuum of care despite the complexity of the person's condition. The addition to level 3.7 is crucial to address the progress of physically addictive substances in our society.
95	Good additions
96	With the increase in telehealth services, this is a needed change. I believe it will help insurance companies see the need for treatment and hopefully they will be more willing to authorize additional sessions.
97	Serenity is a dual intensive residential treatment center for substance abuse (SUD) - with co-occurring mental health diagnosis. Prior to 2020, We were licensed at 3.7 LOC, and due to the precious changes we has to switch to 3.5 LOC, because we didn't have a Dr, employed fulltime. This adjustment may be beneficial to us in getting back to 3.7 LOC as we already provide this level in the curriculum
98	<p>The additions to the continuum of care in Level 1 is helpful to us because we serve a lot of clients that may have low substance use, or substance use in remission, and we want to serve them based on that particular level while focusing more on their mental health concerns. When substance use is present but not their primary concern, we can indicate as such on the ASAM and make the proper recommendations. It is important to be able to screen for sobriety maintenance and remission and be keep that in mind while focusing on more prevalent mental health concerns. The proposed changes give better consideration to these low levels of use and/or remission. It may also give clinicians an opportunity to identify low level substance use earlier, and treat it earlier in a preventative manner. Early prevention and intervention should get more focus in clinical care, and including that in the level-of-care continuum is helpful.</p> <p>The ASAM could be improved by including culturally competent care and traditional healing practices, in addition to the bio-medical model.</p> <p>Telehealth practices need more research to determine efficacy and that information should be shared with clinicians, as since the pandemic, most services are being offered via telehealth, and this is likely to continue.</p> <p>Another potential benefit is more integration of practices to address co-occurring disorders, as mental health and substance use are more often co-occurring than not.</p>
99	Integration of withdrawal management services at all levels of care. Integration of management of co-occurring medical conditions at all levels of care.
100	<p>Facilitate transitions of care within programs</p> <p>Disruptions in the continuity of care often occur as patients transition from one program to another. The editorial team plans to align standards within Levels x.1, x.5, and x.7. For example, aligning standards for staffing and scope of practice requirements within Levels 1.7, 2.7, and 3.7 to facilitate and encourage a given facility or organization to deliver multiple levels of care within their programs. This convention would also hold true for 1.5, 2.5, and 3.5, as well as 2.1 and 3.1. I view this change as greatly needed. Finding placement for patient's on MAT and with MH disorders exiting our facility has been very challenging. The cause for not accepting them relates directly back to what I believe these changes are trying to fix. It will be beneficial for NARR to get involved and the residential care for this population to be greatly expanded.</p>
101	No additional comments
102	Due to limited stakeholder feedback window, our feedback is focused on concerns.

103 I agree with the proposed integration of BIO service standards into the continuum of care within Levels 1.7, 2.7, as well as 3.7 since it provides a similar benefit in outpatient settings that provide Ambulatory Withdrawal Management without and with extended on-site monitoring.

I like the minor revision for individuals with opioid use disorder who have co-occurring psychiatric disorders related to a more comprehensive assessment including determination of mental health status and suicide risk. A better determination of mental health status and suicide/homicide risk and whether the patient is stable is an improvement since many patients would be better served in a hospital setting. The major revision and recommendations for pharmacotherapy in conjunction with psychosocial treatment without a delay in pharmacotherapy for those who decline psychosocial treatments or when they are not available. Also of benefit is the major revision to consider ACT services for patients with co-occurring schizophrenia and opioid use disorder who have a recent history of, or are at risk of, repeated hospitalizations or homelessness.

104 Expanding on Level 1 and Level 2 which is our main placement for patients is great, it will assist us in what we offer to each patient. Such as, if an individual patient needs a little more than just outpatient but not as much as intensive outpatient.

105 Requirement of continuity of care from acute care facilities so that the patients are not kicked out after they run out insurance allowances.

Substance induced cognitive impairments - a good concept. I suggest that we eliminate the term of 'co-occurring disorders.' This name implies addiction is medicine and others are psychiatry. This separation is political or administrative, not scientific.

A vast majority of withdrawal management can be safely done in an outpatient setting.

106 The added breakdown of categories, assuming that one knows what the numbers stand for, are very helpful and do a better job at identifying the treatment level. I think it is particularly helpful in looking at treatment options across the continuum. The changes may help the medical pieces fit better into the ASAM.

107 I see the changes will help identify a more updated continuum of care programs/referral sources. I also liked clarifying recovery residents fit into treatment, as we utilize those types of resources the most in South Carolina due to limited access to quality care identified and needed.

I also think providing more tools for standardized intervention will be helpful to promote the inclusion of treating SUD in primary care and hospital settings.

108 More specific, adds more detail to patient/client placement.

109 I think the proposed changes were long overdue and will fill gaps that the previous edition had.

110 Understanding the needs of each instead of clumping things together.

111 The Ascension RS team finds great value in many of the edits ASAM is proposing in the 4th Edition.

Specifically, there is benefit in the elimination of steep drop-offs in the intensity of services between levels of care. We support the recommendation to increase the clinical hours in 3.1 to align with 2.1 (from 5 to 9 hours).

We find great benefit in ASAM incorporating how recovery residences fit into the continuum of care in collaboration with the National Association of Recovery Residences.

112 With more collaboration with the NAADAC and NAATP there will be a better edition. I would like to see genetic testing, TBI Hx, the role of PRSSs, and specific language for monitoring of non opioid replacement therapies (Naltrexone, Acamprosate). I would like to see length of care recommendations at each level. I would like to see frequency of care at level one. There should be a discount program for the CONTINUUM software for low income HCP and agencies.

113	i like what i say reimbursement for medical withdrawal in hospital setting with medicade is difficult without unattached " medical diagnosis " ie gastritis/hepitis/seizure/encephelopaty-toxic
114	Bundling has been helpful for the detox. Ratings3,7, etc with Peer Riewers uneneducared, minds made up is Maddening!! Waste of time...,bad for everyone !
115	* I am very glad to see emphasis on diverse populations (racial, gender). * "Justice-involved individuals" are sadly underserved in our state. (The term "Justice-involved individuals" is an example of the opaque language that I reference above.) * We do need to work seamlessly for patients with substance use, psychiatric, and medical problems.
116	better definition on criteria
117	LA County (with population 10 million) only has two level 3.7 providers. The move of 1.7, 2.7, and 3.7 to medically monitored is good if the county and state are willing to sign off and fund them. If not, these new levels only act as barriers to treatment. Insisting on at least 9 hours plus of Clinical Care at level 3.1 is welcome. Eliminating level 3.3 seems appropriate, as no one in our county seems equipped to care for them and it acts as a barrier to treatment. Special care for formerly incarcerated and LGBT populations is appreciated.
118	The ASAM criteria is an immensely influential publication, changes to which will affect patient care for the foreseeable future. I thank the editorial team for the opportunity to provide feedback on the proposed changes. The ASAM Criteria has increasingly been adopted by third party payors, institutions and jurisdictions to be used as a guideline or standard for coverage and reimbursement decisions. The proposed changes can help insure that judgements made thus are appropriately tailored to the needs of patients at the various levels of care. I applaud the expansion of levels of care at Level 1 to provide more detail. The Long Term Remission Monitoring level will have the advantage of including those who may have in the past fallen under the radar in terms of data collection and monitoring of clinical progress for services that may be of less frequency or intensity for those in long term remission. I also commend the editors for updating the standards to reflect evolving priorities of the field, in particular the recognition of the role technology is increasingly playing in treatment. It is incumbent on ASAM to play a leadership role in the use of digital modalities of treatment. These are gaining momentum in the marketplace in response to the vast unmet medical need for effective treatments. The ASAM Criteria updates have an opportunity to provide a framework and by extension drive education and development of protocols for the appropriate use of such technology.
119	This update provides a much-needed clarification with Level 1 to expand to 1.0, 1.5 and 1.7. This will clear up a lot of what we have already intuitively been seeing in terms of counseling requirements, frequency of appts and so forth. Our agency provides a full continuum of care from level 0.5 to 3.7 currently, with a wide breadth of integrated services including PCP, psychiatric and substance. Clarification provided will assist in appropriate designation of services as well as expanding services for our clients.
120	Improved understanding of the role of recovery homes, outpatient care, integration of social work and behavioral health; consideration of care for justice-involved patients

121 I would like to see more thrifty, targeted, evidence-based use of resources. The benefits I expect to see from that are cost savings, waste reduction, and improved outcomes.
Rigorous methodology sounds great.
Expanding Level 1 is appropriate.
The integration of biomedical services is appropriate. I often have to manage medically complex patients. Providing care to those patients requires special systems to manage them and should be rewarded by higher compensation.
More recognition of withdrawal management at multiple levels is great. This is a lot more work, and requires a lot of special services at every level.
Supportive housing needs to fit in, but they also need to be held to following evidence-based practices. Many do not, such as excluding buprenorphine.

122 I believe the potential benefits of the changes listed in the 4th edition include the following:

- 1) Increased integration of withdrawal management services throughout the continuum of care I think will greatly benefit providers in their ability to appropriately assess and respond to withdrawal symptoms across treatment settings.
- 2) Attention to unique treatment needs of lesbian, gay, bisexual, and transgender individuals
- 3) The increased distinction between treatment needs for adults and adolescents I also think will be of benefit to tailoring treatment needs for adolescents

123 Primary benefits of the proposed changes are (1) emphasizing the role of primary care clinicians in the management of stable SUD; (2) supporting the role for outpatient management of alcohol or opioid withdrawal, which will enable many more patients to receive this treatment; and (3) addressing the clinical utility of telehealth and digital therapeutics, to expand access for patients -- both geographically and temporally -- to evidence-based behavioral treatments, which are underutilized due to a lack of trained providers, cost, and self-stigma.

124 Level 1.5 would be very important because there is such a wide variety of treatment programs implementing many different types of interventions. Some are not relying on evidence-based practices and I think it is important to be very clear about basic standards of care and what is expected for organizations who claim to provide quality care.

Withdrawal management services are so important because this is a chronic relapsing brain disease. When people relapse is usually because they were in withdrawal after a trigger cause them to return to the drug of choice. Others may be in withdrawal for other reasons but whether this is a reentry or the first entry to point of care we have to be very specific about what that should look like an level 1.7, 2.7, and 3.7.

Eliminating steep drop-offs in the intensity of clinical services will be important because insurance companies must be held accountable and spend the money to help patients get into recovery and remain in recovery. Ultimately this is better for patients relieve suffering a family is in the community and saves money although insurance companies tend to be shortsighted. The ASAM criteria can help change that.

Diversity equity and inclusion are priorities and so many organizations now (public and private). I am so happy to see as include people with cognitive impairments gbtq individuals and others so we can bring everyone into the fold. As I wrote earlier everyone is a person (not just the patient) and everyone deserves quality care at the same level in the same locations by people who do their best to understand their own implicit biases. Having the same criteria include a more diverse group of individuals deserving of care will have a great deal of meaning in our society.

Justice involved individuals have been victims of discrimination since the beginning of my practice and addiction medicine. Judges have told patient they must stop buprenorphine in order to satisfy the criteria for the probation and patients have been victims of abuse by the courts and ways that other individuals brought before the court are not treated. I think it is crucial that we include a lot of details about how the justice system should be approaching the disease of substance use disorder and being much more clear about the fact that people who are in withdrawal may not be thinking rationally and certainly cannot be read Miranda rights and expected to be abiding by something that they could not fully appreciate at that moment.

Agree that long-term remission monitoring is essential and by recognizing its necessity, ASAM provides guidance to support ongoing treatment despite years of remission.

125 Another potential benefit is with regard to better integration of withdrawal management services. Presently our experience is that we do lose a significant number of patients to care once through the acute withdrawal period. This also can present as guidance for ER to community transitions.

What do you or your organization perceive as potential unintended consequences of the proposed changes for the 4th Edition? Please provide as much detail as possible.

Answered: 125 Skipped: 0

#	RESPONSES
1	not enough detail to answer this question.

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- 2 I would like to see the incorporation of more objective measures of progress for patient's in care. To the extent that the criteria can strongly recommend providers use tools such as a PHQ-9 or the GAD to assess a patient's mental health status for dimension 3, that would allow for objective data points to track progress. In addition, any objective rating scales specific to substance abuse such as the Brief Addiction Monitor (BAM) to track progress would be welcome. Many providers continue to use set schedules (eg 30 day residential programs) to guide when a patient needs to move between levels of care vs individualized progress measures which include objective measures.

 - 3 Costs---purchase of news software/manuals, staff training, development of inter-rater reliability testing, assurance of supervisory capabilities at the provider levels.

 - 4 We currently are seeing extensive residivism with the current criteria.

 - 5 We have struggled with providers willing to open higher level residential settings. Could ASAM include sectoin on how best to use ASAM Level 3.1 and 2.1 or 2.5 to meet the equivalent of the higher levels - would help to expand treatment capacity.

Changes to the ASAM Criteria will impact managed care contracts, state plans for medicaid, regulations, policy manuals and may also have a budgetary impact. It would be helpful to prep states in advance so we can begin leveraing our legislature and budget requests to be able to support the transition and implemetation of the changes. Also will need to provide additional training to ensure the provider community, state agencies and MCOs are knowledgable and have the skills and abilities to implement successfully.

(1) It would be helpful to have more detail on minimum standard treatment hours for each level of care, especially for residential (3). As it stands now, 3.7 indicates 20 treatment hours/week. There isn't a number specified for 3.5 (it should also be at least 20 hours, just without the medical supports). For 3.1, the minimum amount of treatment hours is currently 5 hours per week. This is a big step down from 20 hours weekly in 3.7 and 3.5 levels of care. Someone could get more support in an IOP level of care (minimum of 9 hours per week) coupled with sober living. If 3.1 remains "clinically managed low intensity residential services," it should provide more support and treatment than a lower level of care and allow for a smoother transition from higher levels of care to help ease the client back into the community.

(2) It would be helpful if ASAM publish a standardized form template for the actual ASAM itself. We still see many different formats, use of numerical risk ratings vs. mild, moderate, severe, etc., and some with little to no justification. Perhaps a more standardized format from ASAM would help with continuity of care and services from provider to provider and payor to payor and level of care to level of care.

(3) While we agree that the current way in which medication assisted treatment is portrayed is misleading, we are not convinced that adding a new sub-level of care makes sense for each level. We believe that medications are an intervention that can, and should, be considered at every level of care, and integrated thusly. While long term maintenance may be done in an outpatient setting, we believe that without the proper emphasis on the use of medications as an intervention across the continuum, these effective tools will be underused in residential and intensive outpatient levels of care.

(4) While we understand the rationale for bundling withdrawal management, conceptual. For 3.7WM and 3.7, for example, we think the consolidation merely acknowledges present state. However, it is not clear where or how 3.2 WM will fit in this conceptualization. In Colorado, 3.2WM is heavily used for its public safety role. While this is not ideal for many clients, there are people who would never have a chance to experience a short period free of alcohol and drug misuse coupled with supportive, motivational interventions, without this level of care. While it may not be consistent with the current conceptualization of the match needed between BIO needs and medical care, it does perform a harm reduction role in our communities. We strongly support the emphasis on withdrawal management as an entry point to treatment and therefore support requirements for stand-alone withdrawal management programs to have qualified individuals on staff to assess level of care needs prior to discharge and facilitate admission to the level of treatment indicated by the ASAM. We do believe that failing to recognize the 3.2WM level of care will result in payers discontinuing payment for this level of care which serves a critical harm reduction role in our communities.

(6) We hope that during this revision, ASAM takes the opportunity to further standardize the structure of the publication, making it easier to use. While the level of care criteria are presented in a standardized way, the descriptions of the programming and staffing elements at each level of care are not consistent across levels. This makes the publication difficult to use.

(7) In Colorado, this will result in significant re-write of rule for OBH (soon to be BHA). This will be a major effort. It also seems to impact greatly the newly expanded SUD Medicaid benefit, and would seem to materially alter the managed care regulations governing it. It would take significant time and expense for the State to adopt it.

There is a major drawback to creating a 1.7 and 2.7 LOC that silos away medical services into these LOCs. In the third edition of the Criteria, OTS (aka MOUD) was promoted as a longitudinally accessible service which should be available at all LOC. Creating a 1.7 / 2.7 will imply that programs offering 1.0, 1.5, 2.1, and 2.5 LOCs can avoid offering MOUD because 'they aren't a 1.7/2.7 certified site.' The entire concept of OTS need to be broadened to medication management for multiple SUD indications (various intoxication syndromes, AUD management, OUD management, TUD management, off-label StimUD/CUD/etc management), and access to medication management needs to be available throughout the continuum of care, the way non-SUD mental health systems of care makes, generally, medication services available at all LOCs (even if not offered in every practice setting). In Southern California there is considerable disagreement among various payers and providers about whether WM LOCs are appropriate for patients with stimulant induced intoxication symptoms or withdrawal features (without alcohol/opioid withdrawal syndromes that are typical admission criteria). ASAM clarifying that LOCs should establish access to medication management (even if comfort meds) for patients with stimulant intoxication/withdrawal syndromes (beyond standard alcohol or opioid withdrawal protocols) will be important at resolving this ambiguity. As such, if ASAM proceeds with establishing a 1.7 / 2.7 medically monitored LOC, it would need to explicitly state how patients at all other LOC must have access to medication management at any point in their treatment such that 1.7/ 2.7 can serve as a continuity resource for patients admitted to other LOCs (which would currently read as a bit confusing: a patient in long-term recovery on a maintenance MOUD admitted to a 1.0 and 1.7 LOC at the same time). While I agree in principle with increasing the minimum services associated with 3.1 to 9 hours to align with 2.1 LOC, currently programs can't bill CA's Medi-Cal program for mutual self-help attendance and other services not delivered by a state-registered counselor (or other certified/licensed clinician), and it would require the CA Medi-Cal system to clarify that the currently non-billable self-help hours would reasonably count against the 9 hours a week service requirement as part of required weekend structure and support for the 3.1 LOC. While I agree with eliminating 3.3, there is a major risk of actually being perceived as de-prioritizing co-occurring capabilities, so it'll be important to emphasize standards for addressing cognitive impairments (and other co-occurring mental health disorders) within any level of care in the continuum to mitigate this loss of visibility on what previously might have been offered in sites that designate themselves as 3.3. Also, in LA County, 3.7-WM are hospital LOCs and not considered residential LOCs, so making 3.7 a non-hospital residential LOCs will be a change for the 3.7-WM settings in LA County. However, depending on how ASAM defines the service standards, this could facilitate more non-hospital and higher-intensity residential settings to offer 3.7-WM if they don't need hospital licenses. Two other key omissions: A. folding tobacco services into the LOCs: confirming that smoking treatment (meds and counseling) need to be explicitly part of the specialty SUD system of care and the standard for this care. This would do two things: 1. Make payers and regulators responsible ensuring that these services are available and pay for them and 2. Suggest the explicit articulation of clinical standards describing intensifying tobacco treatment in clinical situations where patients motivated to change their tobacco product use (high readiness on Dimension 4) not responding to lower intensity smoking treatments are offered higher intensity smoking treatments (which aligns with ASAM's interest in the Criteria guiding treatment planning). B. Inclusion of harm reduction approaches as engagement strategies. 0.5 Prevention and early intervention language is too focused on primary intervention, and I'd suggest reworking this as: 'early identification of risk and low threshold engagement' which implies a broader set of possible services which should be part of the SUD care continuum (and which payers should cover).

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- Clinicians often offer repetitive/dated ASAM Dimension content across multiple reviews which does not address the here and now for the individual being served. Additionally, clinicians are not consistent with including evaluation of the individual's level of functioning in each dimension. Please consider providing additional guidance on how to improve fulfilling each dimension in the "here and now" for clinicians.
 - Outdated Individual Treatment Plans which may result in unnecessary denials. Please consider including additional guidance on importance of updating treatment plans to allow for a true representation of current individual needs/strengths/agreement.
 - Limited ability to factor patient motivation/participation in treatment. Clinicians will often use lack of motivation and negative attitude as evidence of medical necessity for continued stay. Need guidance on discharge for obstinate refusal to participate in treatment.
 - Clinicians focus on a fixed length treatment despite claiming otherwise. Again, please consider providing additional guidance for clinicians on evaluating individuals moving through stages of change vs a fixed length of stay.
 - Limited to no details surrounding pursuit of medical issues identified, other than to offer a diagnosis.
 - Leave of absence from Residential Level of Care requiring 24/7 supervision
 - Court Ordered does not equal medical necessity
 - Late or No Transition of care planning. Evidence of involving individuals in conversations regarding movement to the next level of care is deficient. Furthermore, there is lack of evidence for long term housing plans. Please consider including additional guidance for solid transition of care planning for clinicians.
 - Clinicians "Fit" individuals into offered Levels of Care vs. appropriate Level of Care
 - Failure to clearly state individualized time-lined goals and objectives and report on progress
 - Emphasis on patient barriers to recovery without stating provider interventions to ameliorate. Consider adding a requirement in each Dimension that highlights what exactly the Provider is doing to address the identified patient issues.
 - Minimal to absent incorporation of measurement-based care to support a patient-centered approach to symptom and progress monitoring
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- 9
- Idaho Medicaid's main concern has to do with relabeling level 3.7 medically monitored intensive inpatient services a residential service. Medicaid can only pay for room and board in inpatient settings. Residential services are not considered inpatient services. If level 3.7 medically monitored intensive inpatient services were relabeled a residential service, Medicaid reimbursement for this service would have to exclude room and board. This would mean that reimbursement for level 3.7 would fall significantly and that Medicaid patients could end up losing access to this level of care. As well, free-standing psychiatric hospitals and chemical dependency units in acute care hospitals may choose not to provide this level of care, if it cannot be reimbursed as a hospital-based service.
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• Review methodology lacks the rigor of the American Psychiatric Association (APA) Practice Guideline for the Pharmacological Treatment of Patients with Alcohol Use Disorder (<https://ajp.psychiatryonline.org/doi/10.1176/appi.ajp.2017.1750101>) or the thoroughness of Medications for Opioid Use Disorder Save Lives (<https://www.nap.edu/catalog/25310/medications-for-opioid-use-disorder-save-lives>). ASAM used more rigorous evaluation methods to evaluate drug testing (Appropriate Use of Drug Testing in Clinical Addiction Medicine <https://pubmed.ncbi.nlm.nih.gov/28557958/>) Best practice in guideline development is summarized in the Guideline for Pharmacological Treatment of Patients with Alcohol Use Disorder: “. . . process intended to be consistent with the recommendations of the IOM 2011 report, the Principles for the Development of Specialty Society Clinical Guidelines (Council of Medical Specialty Societies, 2012) and the requirements of the Agency for Healthcare Research and Quality (AHRQ) for inclusion of a guideline in the National Guidelines Clearinghouse.”

• The Proposed Updates would benefit from a stated commitment to updating and improving patient and caregiver information. • The ambulatory care service proposal is an improvement. Incorporating information that aligns with coding (CPT and HCPCS) expectations, especially documentation requirements (see <https://www.cms.gov/files/document/medicare-mental-health.pdf>) • The proposal is not aligned with harm reduction strategies. These include but are not necessarily limited to approaches like improved availability of naloxone for individuals with opioid use disorder, overdose prevention centers that allow supervised use of illegal drugs and reduced alcohol consumption initiatives. Harm reduction can be incorporated into Level 1.7. <https://www.whitehouse.gov/wp-content/uploads/2021/03/BidenHarris-Statement-of-Drug-Policy-Priorities-April-1.pdf> • ASAM should publish the systematic literature reviews that are conducted to support criteria revision, especially reviews related to treatment of adolescent substance use disorder and criminal justice system treatment. Publication of systematic reviews in peer reviewed journals is a critical aspect of guideline development transparency. This type of publication is characteristic of most other professional organization guideline development, Systematic reviews support the ASAM future orientation noted in the methodology section. • It would be useful to receive further clarity on Level 3.1 and how it can be billed so that it includes the clinical treatment component. Moreover, there is a need to revamp Level 3 Residential/Inpatient; there is confusion between different levels within Level 3, confusion with the use of “Inpatient” for 3.7 • There is a need for more provider education (ASAM criteria, application across various ASAM levels of care)

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- 11 Level 1 Outpatient Services: Would be helpful to further define level 1 services. Examples OTP, OBOT, routine OP group/ind/medication services Would be helpful to address the “ambulatory detox” programs who are not following evidence based practices on use of MAT Address use of medication only services and Tele- MAT, and the rise of digital self help programs that may or may not include medication. Level 2.1 Intensive Outpatient: Majority of IOP programs offer services 3 hours a day/3 times a week to get to 9 hours however we do see IOP being offered 1.5 hours a day 7 days a week and being called IOP which creates an unnecessary financial burden on the member to pay a cost share 7 days a week. These programs state that this aligns to 2.1. Please clarify daily minimum clinical hours vs non clinical recreational/social services Please clarify what license level should deliver the services as we see many program services being delivered by addiction counselors and peers with licensed staff in a supervisory capacity only. Please add commentary on supporting/educating on medication assisted treatment options in a 2.1 setting. Please add time frame for completing assessments and treatment plan. Please add time frame to complete a physical examination, if a medical condition is identified. Please add use of standard, validated instruments to gauge member response to treatment and a change in the treatment plan as a result of non response. Level 2.5 Partial Hospitalization Services: Any clarity that can be provided about offering evidence-based services vs. unproven or experimental therapies (ie: animal assisted, brain mapping, Navy Seal Training, adventure therapies) that could guide facilities on creating a more robust evidence based curriculum. Please clarify the number of clinical hours vs non clinical/recreational hours provided in a day rather than a 20 hour per week. There is no mention of medication assisted treatment as a best practice in 2.5 services. Specify how soon the assessment and treatment plan development should occur. Please add time frame to complete a physical examination, if a medical condition is identified. Specify what license level can complete the assessment. Please add use of standard, validated instruments to gauge member response to treatment and a change in the treatment plan as a result of non response. Level 3.1 Clinically Managed Low-Intensity Residential: ASAM 3.1 states that programs must have the ability to arrange for pharmacotherapy (page 224) and then says that programs should include “Addiction pharmacotherapy” (page 225). Does this mean programs must provide pharmacotherapy or just need to be able to arrange it if needed? Does the patient self administer medication in a 3.1 setting? Level 3.1 programs offer at least 5 hours per week of low-intensity treatment of

substance related disorders. Pg 222. Can this standard be reconsidered considering that level 2.1 requires at minimum of 9 hours of treatment per week and is technically a lower level of care? Is 3.1 a step up from level 1 or 2 services (page 225) or is this used as a step down from 3.5 or 3.7 services? Specify how soon the assessment and treatment plan development should occur. Please add time frame to complete a physical examination, if a medical condition is identified. Please add use of standard, validated instruments to gauge member response to treatment and a change in the treatment plan as a result of non response. Specify what is a reasonable timeframe to obtain a physical examination (page 226 and 227) If the patient is also attending IOP/2.1 while residing at the 3.1 how do the programs communicate and coordinate the treatment plan.

Level 3.2 WM Clinically Managed Residential Withdrawal What is considered "appropriately trained staff" and "appropriately credentialed staff?" (pg 137) A physical examination by an MD, PA, NP is only required if self administered medications are to be used? Add requirement for laboratory or toxicology tests. Who determines if the patients intoxication/withdrawal signs are sufficiently severe to require 24-hour structure and support (page 137) without a physical examination? Shouldn't there be a validated withdrawal scales used at admission and at intervals during the stay? Page 138- the addiction focused history reviewed with the physician- can this occur telephonically without the physician ever seeing the patient? Level 3.3 Clinically Managed Population Specific Can this service occur within a specialty track at a 3.5 or a 3.7 setting? If services occur within a medical/neuro rehabilitation setting then how many clinical hours should be provided within the treatment day. Level 3.5 Clinically Managed High Intensity Residential Please clarify requirements for clinical license types that are appropriate to be providing initial assessment, level of care determination, treatment plan development, and clinical services. For ASAM 3.5, the number of clinical hours per day and per week are not noted in ASAM 3rd Edition. A concrete number or range would be very helpful in requesting more robust clinical programming for facilities who provide very meager evidence-based services in their RTC schedules, especially on the weekends. Can we assume this is a more intensive level than ASAM 2.5 which requires a minimum of 20 hours per week? Can you please provide clarification of guidelines for THC/medical marijuana use in facility-based levels of care; as well as any other experimental services such as EEG brain mapping and use of hallucinogens. Level 3.7 Medically Monitored Intensive Inpatient Services The naming convention for this level of care is confusing because

inpatient refers to hospital based programs and not free standing residential facilities. The majority of 3.7 programs occur in free standing residential treatment programs. Can this be clarified in the naming convention. For all levels of care: When (by what day) should a Biopsychosocial Assessment be completed? Currently this is stated as "at the beginning of treatment." We have had several providers use this as a loophole to wait several days prior to completing the assessment. For all levels of care: When (by what day) should the initial and master treatment plans be completed? We see create variability - some providers wait up to 30 days or longer prior to plan creation. Others create the treatment plan immediately. For all levels of care: Please provide clarification for phrasing such as "is available" which could be replaced by more objective language particularly regarding physician, nursing, and other licensed clinical oversight. For example: ASAM Level 3.7WM expects that a physician, physician's assistant, or nurse practitioner is available to provide on-site monitoring of care and further evaluation on a daily basis (page 139). A registered nurse or other licensed and credentials nurse is available to conduct a nursing assessment on admission (page 139-140). For all levels of care: Please provide clarity regarding staffing requirements at each level of care that are less subjective for example: ASAM Level 3.7WM, expects that programs have appropriately licensed and credentialed staff available to administer medications in accordance with physician orders (page 140). The number of clinical hours per day and per week are not noted for ASAM 3.7 WM. A concrete number or range (which could at least be offered to those in withdrawal that are healthy enough to attend) would be very helpful in requesting more robust clinical programming for facilities who provide very meager evidence-based services in their RTC schedules or offer more recreational hours than clinical programming. For all levels of care: When should a treatment plan review be completed (in days) when a patient transitions from one level of care to another?

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- 12 1. Increasing the amount of information that could be considered to be ASAM standards. This will make medical necessity determinations more confusing and difficult unless actual medical necessity criteria and medical necessity documentation are very clearly called-out, and separately from all other text. (2) No longer identifying withdrawal management as separate levels of care. Although there is no disagreement with the need for ongoing treatment after withdrawal management, (a) many persons choose to not do that, and incorporating withdrawal management into other levels of care in a set of standards is not going to magically change that; and (b) withdrawal management is a separate type of service with separate medical necessity criteria and separate reimbursement, so that conflating it with other levels of care with create further challenges for health insurers. (3) Updating Level 3.7 to reflect care in residential settings. This will effectively eliminate the level of care of hospital inpatient rehabilitation (as distinct from Level 4 acute inpatient treatment). To the extent that 3.7 is envisioned as comparable to acute inpatient rehabilitation facilities and long-term acute care hospitals, 3.7 is a sub-acute hospital level of care, not a residential level of care.
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- 13 - Negative perception if person first language isn't used (see page 5 "lesbian, gay bisexual and transgender" - When the "standardized tool" is referenced, clarification of what a "standard medical necessity" form would entail, how standard medical necessity is being defined, and how it would specifically be used by providers. Concerned that providers would rely too heavily on a form instead of considering the dimensions/unique situations for each individual they are assessing.
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- 14 Unfortunately, I think that the good structured changes with the treatment planning template and development of the ITP based on the 6-Dimensional Assessment, and standards on how the Tx Plan should be updated will conflict with some the states departments of Medicaid outdated policies that have been crafted by its provider groups and lobbyists.
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- 15 Although mutual aid programs do not, under strict definition, constitute "treatment" and thus do not fall under the purview of the ASAM Criteria, mutual aid meetings and such approaches as 12-Step facilitation or CBT are often integral to recovery programs, in- and out-patient. Since candidates for treatment have a wide spectrum of temperaments, values, religious and spiritual values, thinking styles, etc., elective admission should include an assessment of same and a clear declaration of what approaches in this arena are available or implemented. This is not trivial. The same goes for whether an institution is congenial to, neutral towards or antipathetic to MAT and/or OAT specifically. Although JACH evaluation criteria are explicit that patient choice in terms of types of approaches that are available to prospective clients/patients must be available and offered, websites and presentations of services are seldom explicit on the issue of what type of treatment is offered and whether or not MAT/OAT is potentially available.
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- 16 I would like to see the incorporation of, or suggesting, the ability of the addiction treatment provider, specifically the physician, physician assistant, or nurse practitioner being able to act as a bridge to primary care for the patient while working to move them along the continuum of ambivalence with willingness to the action of actually going. I believe the language proposed on page 5, "Promote better integration of SUD treatment into general healthcare. For example, emphasizing the role of primary care providers in managing patients with stable SUD..." could deter capable physicians and treatment providers from offering general medicine services and care delivery because it's "not ASAM guidance."
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- 17 I sincerely hope that payers and State Insurance Commissions and Medicare and Medicaid programs will recognize and pay for levels of care appropriately. I hope that Medicaid and Medicare will provide coverage for addiction treatment across the continuum of care.
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- 18 My critique would involve highlighting the language in this proposed framework. At one point they mention this: "Addiction is a complicated biopsychosocial illness." And then later make the following statements.
At bottom of page 4: "Clearly delineating the assessment and treatment planning process by: Describing standards for an intake assessment to make determinations for initial patient placement versus a full biopsychosocial assessment used for treatment planning purposes."
And this statement on pg. 5 when discussing 'evolving priorities': "Promote better integration of SUD treatment into general healthcare. For example, emphasizing the role of primary care providers in managing patients with stable SUD and the role of emergency departments in initiating treatment and supporting engagement in ongoing care."
And just below this last point they state: "Define standards within each level of care for providing coordination of biomedical services (e.g., referrals to primary care or specialty care, coordination with those providers, overseeing medication adherence, etc.)."
The primary focus of this change in ASAM appears to be a harking back to the biomedical approach and a step toward forgoing the advances of incorporating behavioral health clinicians in overseeing and directing patient care. Although few would disagree that the biomedical approach is unequivocally insufficient in treating individuals with SUD, the ASAM changes appear to desire a biomedical first model.
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19 The proposed changes seems very positive, however my feedback is that they do not go quite far enough to help payment systems understand which types of treatment may be necessary (and should be paid for) to support individuals at any point in time. I hope that level 1 can be conceptualized as both a level of a variety of services that can be paired together to sustain recovery but also a very of harm reduction services that could be paired together to maximize wellness for clients that are using. I also hope that ASAM can help us explain to payers that although we envision a world were medical and non-clinical SUD services are integrated in one program, often they aren't today. In CA DMC-ODS has implemented payment in ways where they are tied to a "program." I hope that ASAM helps move the nation's payment system away from programmatic payment models and instead payment based on pairing of services across a health system. This would allow flexibly of SUD healthcare system design and optimization of limited workforce resources depending on the availability in communities. For example, centralized case management services and centralized MAT/WM is not available in CA's DMC-ODS payment model. I hope that ASAM makes it very clear that the concept of "program" across the continuum doesn't mean that it all the services must be linked to the same legal entity or program for payment. And that any services across legal entities could be paired together to create the level of care descriptions on the continuum. It seems that this is the spirit of ASAM but payment systems are interpreting the discrete levels too strictly to justify payment.

20 Without treatment lengths better defined in Outpatient to IOP 1-2 levels defined,

Agencies think that a client should get a WOP (sending agency sent assessment for WOP) Certificate after 3 months Cog skills. ??? WOP 9 months ? 6 months min?

Without this it splits staff and agencies because everyone has a different idea of what the offender needs.

1. The conflict in agencies begins by Parole (client just paroled after 1 - 3 years incarcerated or More) or Case management at 1/2 way house telling the client only needs maybe one group?? and the offender has multiple hot UA's for heroin and Meth-

- even in our facility, there is a propensity to discharge the client completed WOP when the client only completed 12 weeks of cog skills after being sent for level 1 (EOP - WOP) treatment episode for hot UA for Heroin or meth while incarcerated in 1/2 way house. ???

Problem:

Case managers, Parole, Probation

We all:

Define Lengths of treatment differently- we need a guideline

ie

wop 6-9 months per assessment? (EOP 3- 4 months, IOP 4 to 8 weeks)

bulleted list of what is required to move to the next level

ie., do not move to EOP from IOP if the Client has hot UA's and is not attending sober supports in the community-

21 I may be missing it, but do the Criteria address what are usually considered harm reduction approaches? Do the Criteria address prevention approaches for family members in treatment?

I worry about "Behavioral Addictions." Are we getting ahead of the science?

22 - ASAM's proposed separation of levels of care (LOC) into 1.7, 2.7 etc. creates an unnecessary division between social model vs. medical model treatment that may ultimately impact the progress made within publicly funded SUD system during the last several years. The reason is because the bifurcation of levels of care that offer MAT and those that don't validate the current construct that social models of addiction care should be able to coexist with more medical models of addiction care, whereas the evidence-based perspective is that we must have biopsychosocial models of addiction care where MAT is available in all ASAM levels of care. The ultimate goal of SUD treatment should be the seamless integration of pharmacologic treatment such that all patients have the option and ability to access medication for addiction treatment (MAT) whenever indicated, regardless of level of care. We are very concerned that this proposal to separate out levels of care that offer MAT from those that do not will unintentionally result in further fragmentation of SUD systems. Furthermore, there is a risk that patients have stable SUD and may be ready to step down to a lower level of care but remain "stuck" in a given LOC due to medical issues that make discharge (or transfer) problematic. Recommend not separating out ASAM levels of care that offer MAT and instead requiring that all levels of care offer pharmacologic treatment options, including by referral if those settings cannot immediately offer pharmacologic options now and need to grow into that capability.

- Recommend that ASAM clarify how recovery residences fit into the continuum of care.

23 - Treatment planning template: This could lead to cookie-cutter treatment plans that are not individualized to the strengths and needs of individuals.
- Adding trauma under Dimension 3: Could possibly narrow focus of trauma rather than promoting trauma-informed approaches within all dimensions.
- Integration of Withdrawal Management: While ensuring continuity of care is a positive of this approach, it might also dilute the standards for providing safe and effective WM.
- General comment: In order for these important standards to reach the widest possible audience, ASAM is encouraged to consider making more of your materials available to public systems and non-profit treatment providers free of charge.

24 While the changes suggested may offer clarity, continual updates and modifications to the levels of care can create a more complex understanding of implementation and utilization for providers. For example, the 3rd edition of the ASAM criteria, while having more content, becomes more challenging simply because of the sheer volume of material. This would be especially challenging when a provider is offering more than one level of care and is attempting to crosswalk the staffing requirements, settings and supports. The chart used in the ASAM 2nd edition revised was much easier to use.

25 The industry will have to adapt to the new iterations and assign specific codes to each level of care. It may take a while before we will all speak the same language.

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- 26 -Am not certain of the need for Levels 1.0 vs 1.5. Can these 2 conditions be combined? I would think that part of remission-monitoring can very well include regular OP therapy, individual or group-based.
- Regarding the inclusion of telehealth, will this include specific standards/expectations if care is provided primarily in that format? ex: how to perform urine drug screens; safety parameters; whether assessments should be done face-to-face
- Regarding the legal/forensic consideration: how will it be addressed/advised re: court-ordered treatment? Very often, court-ordered tx does not necessarily align with MNC criteria--ie, judge orders 90-days of IOP when pt has already been sober x2 months and is maintaining in community.
- Points that don't seem to be addressed but need to (whether or not the 4th edition is the place to address it I'm not certain):
- (1) Over-use of urine drug screens by many programs--ordering multiple days in a row; ordering when no clearly defined evidence of possible relapse; ordering quantitative assays for no clear reason.
 - (2) Emphasis on discharge planning (step-down options, placement) from early on in tx course--much like is emphasized in MH programs.
 - (3) Addressing programs that have set program lengths (30 day or 60 day) which impacts medical necessity discussions as well as discharge planning, because programs expect the patient will be there x30 days and so don't try to address disposition issues until later, when MNC may already be no longer present for that LOC.
 - (4) Emphasis on fact that 1 relapse (ie, drinking ETOH on the weekend) does not automatically qualify one for HLOC. Emphasis should be on fact that relapses are part of recovery process, should focus on learning from situation and revising treatment/relapse prevention plan rather than automatically emphasizing what went wrong and deciding patient can't be maintained at that LOC.
 - (5) How to manage fact that THC is becoming legal in more and more states while still not legal federally--harm reduction approach? Addressing positive THC on urine drug screens?
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- 27 •There are a couple of potential unidentified consequences. MAT has not been universally adopted in our state with some even being anti-MAT, and they may present barriers with state implementation of the integration of the withdrawal management services, including the 1.7 level of care. Another potential unintended consequence may be related to the cost of materials and accreditations: Some of the providers in our network sought out accreditations for ASAM levels of care and may have to renew them because of the update, which would be a cost incurred. Additionally, if there are costs associated with use of the medical necessity paperwork or tools, it could be a burden to the provider community. Neither the current ASAM text nor the proposed changes include a treatment expectation related to hours of services for levels 3.7 and 3.5. The proposed changes include further definitions and increasing treatment services in a 3.1 facility. The unintended consequence in our treatment system with the update is that people in a 3.1 facility may receive more treatment service hours than people in a 3.5 or 3.7 level of care, if their treatment service hours remain undefined.
-
- 28 The additional training and depth of application provided will be a challenge when agencies and providers see this as an added significant expense. Also, there exists a current shortage of providers so I would anticipate challenges at the system and individual level in the logistics and cost of training existing and new providers in a way that allows for comprehensive, consistent and effective implementation.
-

29 We just spent nearly one year advocating for a center in Georgia to Anthem and Ambetter as a gap in services was identified and the center wanted a contract before they decided to open their doors. The payers were onboard and even offered site visits. The state has licensed them. The service is facility based ambulatory detox with extended on-site monitoring. The center has an in-house pharmacy. The entire program was created around Level 2WM - which it looks like has been eliminated. Eliminating a level 2.0 also eludes to assumption that ambulatory detox is only done in an office and that the severity of withdrawal management services is not significant enough to require observation. The facility we are working with would have to use 1.7 which I don't think would be a fair assessment of the services they are providing

30 The proposed changes use the word "provider" as an all-purpose word that seems to include physicians. Note that the AMA has strict guidance on this in that physicians are NOT providers. "Provider" is a term that came from the insurance industry as a way to simply bulk all clinicians into a single bucket as if there are no differences among our various groups. Feel free to use "clinician" or "healthcare professional" if you wish as those terms are not pejorative as "provider" is, but the preference would be to use "physician" where the individual referred to should be a physician, and to use the other terms only where anyone from LPC or LICSW up to MD would be perfectly acceptable.

Perhaps the word "provider" was simply used for expedience in the description of proposed changes, and won't appear in the 4th Edition at all, in which case I am not concerned (beyond simple annoyance that we used "provider" as a term at all).

31 While I support most of the changes I read above (especially the .7 delineation), I'm concerned that the 4th Edition will be so detailed that clinicians will not even read it. Additional manuals may render the ASAM even further out of reach for many/most.

32 While I cannot articulate this well, and it may not be the source of any unintended consequence at all, I believe that some standards pertaining to skilled nursing, withdraw management, and the integration of other biomedical interventions is, of course, needed (especially from an addiction medicine organization), but I continue to notice how organizations in my area who use the ASAM criteria and do not have medical staff (nursing, NP's, MD's) or have to try and contract with those at times struggle with some of the criteria.

33 I'd like to see changes that reflect digital interventions which now have evidence, and to what extent care can be delivered virtually.

34 Historical programs can be expected to chafe at any increase in requirements for them to better professionalize, but that is only problematic for those who are disinterested in ensuring quality of patient care that is consistent with the standards of care.

Many states still have licensing criteria from the PPC-2 on the books. States and payers will need to step up to update their regs and policies. They may be expected to complain about this, but when DSM gets updated by the APA, or the CPT or ICD products update, they simply must adapt.

One unintended consequence may be that patients and their families will have greater transparency into what care should be provided - and may then have great ability to advocate for such care in ways we have not seen before in the field.

35 The proposed changes do not incorporate certified peer recovery specialists (CPRSs) at all. While this maybe a larger systems' issue and I understand that services received by CPRSs are not considered formal treatment, it is worth mentioning.

I think the placement of CPRSs on the Continuum should be considered. Maybe at a Level 0.75 or 1.0? CPRSs provide ongoing support and assistance to individuals with substance use disorders. In RI (and I'm sure in other states), CPRSs are critical in reaching populations for whom formal healthcare/behavioral healthcare systems never have contact.

36 ATAC is submitting an extensive analysis to the president of ASAM, William F. Haning, III and the president elect, Brian Hurley, as well as the president of CSAM, Karen Anne Miotto.

37 [Continued from above] There is a need for clarification about all populations where there are "public safety" or other non-individual medical necessity considerations including justice-involved, child welfare-involved and children/adolescents where their safe living environment is outside their own control. We have attempted to establish clinical necessity criteria for criminal justice involved populations and residential women and children's programs that help the state and providers with other considerations that are not well covered in a medical necessity model. This includes risk to reoffend and risk to children. This is a critical area that needs to be addressed for states to meaningfully use the ASAM without wholesale adaptation.

Finally, I agree that more attention is needed to adolescent standards. It seems that it might be more useful to have a separate publication or section for adolescents. I find the publication very difficult to use for a number of reasons and one major reason is that you have to search through all the adult content and piece together the adolescent content.

In general, ASAM level of care criteria are very useful to the field and frankly push the addiction treatment field past the mental health treatment field in creating a shared understanding of intensity of care and setting. The publication itself is hard to use—feels like it is written by many different authors. On the whole, it would be helpful if every section were structured with a consistent outline so you can find exactly which services are provided in each level of care, and what the staffing requirements are.... I think the criteria themselves are pretty well standardized, it is the program level sections that could use some additional standardization.

I worry that if ASAM only goes partly down the road of discussing "public safety" or "clinical necessity" in further expanding sections for justice- involved populations, it will create more confusion. I think this discussion is central to the whole "medical necessity" concept. I don't think it can be easily done without a comprehensive look at whether "medical" necessity is the goal here or "clinical" necessity or some other term is the goal.

38 In Maryland, we use ASAM criteria as the medical necessity criteria for authorization of services and billing. The elimination of 3.3 will have an impact on our pregnant women and women with children programs and our court-ordered residential treatment programs since most of the specialty programs provide this level of care. Some of the changes will result in changes to our regulations and incorporation of new levels into our ASO (Level 1.7) that are not included at the present time. The requirements for jail-based and prisons, will require training since many of these facilities are not utilizing ASAM or have staff trained in ASAM assessments. We are interested in obtaining more specifics on what drives down to a lower level of care. How does ASAM see the changes tying into billing? More information on what co-occurring capable looks like and will there be more specifics on addressing pain medication and addiction treatment. We support collaboration between recovery residences and treatment providers and consider them important parts of the continuum, however we are not recommending recovery residences provide treatment. Requiring treatment and additional staffing may result in recovery residences going out of business. We do recommend recovery residences utilize the NARR standards. We are also in support of ASAM level 3.1 providers rendering additional clinical services (9 hours) and providing services on the weekend. However this may have an impact on programs, particularly with the workforce shortages. In Maryland, we will need to make regulatory and billing (rate) changes if the hours should change. We also interested in learning if ASAM will provide more guidance on services that are needed for children that are in treatment with the parent, particularly medical services, educational services, and age-appropriate recreational services.

39 We see a potential for greater error, as the selection of levels are a bit unclear; the increased number of choices could not only result in selection error, but also cause the process to be more time consuming. These additional levels will also require specified training that will most likely require additional follow up as well. Restructuring our web-based data system could be cost prohibitive because of enhancements and system upgrades that will likely be incurred.

40 PLEASE NOTE - Due to the volume of comments, we were unable to use this form as it cut off our submission. To access our comments, please find them at the following link:

https://www.dropbox.com/s/m6948hcqaa9mhxs/ASAM_Feedback_IABH_2-7-22.docx?dl=0

41 getting to be so specific in details, that is lessens the simplicity of the product makes it more difficult to teach to undergraduate students/trainees the more complicated (detailed) the lesser chance of having counselors utilize it properly--suggest a "short form" for use by non-medical counselors--AND another level for Clinical Supervisors--possibly using INCASE to develop undergrad, grad and post grad versions--for academic educators.

42 Leaving out these areas has major unintended consequences including system access to care gaps for youth and young adult populations.

43 As a physician-scientist/developer of prescription digital therapeutics (PDTs) - including the only FDA-authorized treatment for patients with substance use disorder due to cocaine, cannabis, stimulants (such as meth) (called reSET) as well as reSET-O which is intended to be used with MOUD for patients with OUD - it is critical that sufficient information is shared in ASAM Criteria to support clinicians, provider organizations, and payers.

If ASAM does not provide sufficient information on digital health and particularly PDTs, given the > 20,000 prescriptions of reSET and reSET-O, hundreds of HCPs prescribing, and payers covering (including commercial and Medicaid) payers - then:

(a) Clinicians may not have awareness and understanding of appropriate use and inappropriate use based on their FDA label and clinical evidence

(b) Payers may claim that lack of reference to digital health and PDTs such as reSET and reSET-O in the ASAM Criteria as a rationale for not paying for PDTs and/or digital health

ASAM providing up-to-date and accurate information on digital health and PDTs is critical to avoid problems as clinicians, providers, and payers utilize. It is important for practitioners to be aware of the evidence-base supporting CBT, CM, their use and inappropriate use which ASAM Criteria can be an important tool.

It appears that PDTs could support treatment across several care settings, from early intervention on (levels 0.5-3.7). Medically monitored outpatient withdrawal management (1.7) may especially benefit from the use of PDTs and the features available through the HCP dashboard (e.g. visibility in patients' self-reports and module progress, as well as entering UDT data). PDTs can work effectively in a hybrid care model encompassing both live and telemedicine visits. In the context of the ongoing pandemic, PDTs offer a means of expanding patients' access to evidence-based behavioral treatment.

As background: PDTs are software-based treatments that deliver evidence-based mechanisms of action and/or treatments such used either alone or in combination with pharmacotherapy. PDTs are designed to deliver based on the latest scientific evidence, software is manufactured under

good-manufacturing practices, and then evaluated in randomized clinical trials. Upon completion of clinical trials, the manufacturing and clinical trial data is submitted to FDA and reviewed as a software-as-a-medical device (SaMD), to comply with the Food and Drug Cosmetic Act of 1973, and if FDA decides to grant market authorization and/or clearance, then provides a label on the indication and intended use and how to appropriate use. Subsequently the manufacturer must comply with post-market surveillance monitoring for adverse events. Real-world evidence and healthcare economic outcomes research is conducted to evaluate generalizability and value to the health ecosystem.

reSET is an FDA-authorized PDT for patients with substance use disorder due to alcohol, cannabis, cocaine and/or stimulants. It is the only FDA-authorized treatment for patients with cocaine, cannabis and/or stimulant use disorder (such as methamphetamines) as no pharmacotherapy exists.

FDA link: https://www.accessdata.fda.gov/cdrh_docs/reviews/DEN160018.pdf and <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/denovo.cfm?id=DEN160018>

reSET-O is an FDA-authorized PDT for patients with opioid use disorder and is intended to be used alongside the MOUD buprenorphine. reSET-O received Breakthrough Status from FDA.

FDA link: <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?id=K173681>

reSET and reSET-O both have RCTs, real-world evidence and health economic data that is published, please reach out & these data+manuscripts can be shared.

NIDA supported reSET and reSET-O's development and lists them on their treatment option website: <https://nida.nih.gov/publications/drugfacts/treatment-approaches-drug-addiction>

44 The unintended consequence could be that third party payors misinterpret the guidelines and use them to deny people care. The guidelines could be too restrictive and prescriptive which would limit clinical judgement. Our organization has several questions:

Level 1.0 – Long-term Remission Monitoring: Will this include recovery communities, sober living and mutual support groups? Will this level also include peer health monitoring programs, such as many states have for professionals with substance use and concerns?

Level 1.5 – Outpatient therapy: Will this level delineate between individual and group therapy?

Level 1.7 – Medically Monitored Outpatient Care: Will this include MAT for opioids and other medication assisted therapies such as Campral, Naltrexone, Vivitrol and Anatabuse?

Will there be a condensed placement assessment rather than a complete biopsychosocial at the time of initial contact?

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- 45 The following is a list of considerations we foresee needing attention to avoid unintended consequences:
- Need to provide clarity and direction on provider types, roles, and accountability
 - Considerations around “medicalizing” a social model:
 - A medical model that focuses on medical necessity and does not incorporate the social drivers of health and the value of a social recovery model is likely to continue to create silos and a fragmented system of care
 - Adherence to treatment in chronic diseases is impacted most often by social factors that are not addressed in the medical model alone
 - The need to provide education and guidance on the level of credentials necessary to perform functions related to the social, cultural, and/or community elements of “services” versus “treatment”; the combination of which supports adherence and long-term recovery
 - Payment structures that support alignment across housing, clinical, medical, institutional, and social service settings.
 - Added functions in which is unclear who is responsible or qualified to provide; or activities that are required for which the financial model does not address.
 - Training for various use cases (eg. managed care, providers, operators, policy decision makers) and necessary language considerations and field experience/translation necessary to implement
 - Current system does not fully support linkage and implementation of the full continuum of care that incorporates recovery housing and social drivers of health to more effectively address the long-term chronic nature of SUD
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- 46 We recommend specific verbiage around the importance of culturally competent care in addiction. While broad verbiage around "diversity, equity, and inclusion" is helpful in terms of inclusivity, providing specifics can often pave the way for improvement, as many people may not be familiar with what this might look like in practice.
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- 47 *We encourage the update to include focus on the evidence and benefits of formal and informal, cohort specific, peer support systems. PHP participant outcomes, and participant feedback reveal a strong benefit of peer-to-peer support and the power of shared experience that often begins while in residential treatment and continues throughout the PHP process. An environment built upon compassion and care is created through long term follow up with the PHP and builds recovery skills, reduces internalized stigma about being ill, reorients the individual to better self-care skills, and ensures that participants build a strong base in health and recovery. *We also encourage the update to focus on how this can be created as a patient moves across all levels of care, providing discussion of when patients especially need this type of assistance and mechanisms to ensure appropriate reimbursement. *The important and indeed the very necessary recent focus on the use of medications in the treatment of addiction risks oversimplification of a complex disease that requires collaborative, multimodal, chronic disease management. Emphasis on the critical importance of team based systems of care, will reduce unintentional marginalization or alienation of the multi-modal treatment providers and peer supports who are central to effective disease management.
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- 48 see above
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49 We believe that the following issues require clarification to reduce confusion about new standards.
*Level 1.0 – Long-term Remission Monitoring
What criteria will it include if not tied to specific location?
Medication only or other services?
*BioMedical
Address whether an “unstable biomedical condition” have to be present in addition to withdrawal or are withdrawal symptoms sufficient for placement
*Better Implementation Support
How are standards for intake assessment vs. biopsychosocial different from the LOCI? Doesn't the LOCI already provide a standard for intake assessment?
Will the medical necessity form indicate what issues should be addressed in which dimension and guide placement like the LOCI does now? How will this be different from the LOCI?

50 We believe that a possible unintended consequence of the existing language in the ASAM's Matrix for Matching Adult Severity and Level of Function with Type and Intensity of Service, Dimension 2, Risk Rating 4, is that stable, patients with hemophilia able to self-administer their IV infusion medications are excluded from Level 3 facilities and their access to treatment is limited to Level 4 facilities.

We are grateful for your consideration and urge you to clarify the ambiguous language related to IV infusion therapy in the ASAM Criteria 4th Edition.

51 One of the major potential unintended consequences is the possibility that the 4th Edition may become expensive for providers (individuals and organizations) to implement, especially in these times where workforce issues have become exacerbated.

Organizations providing stand-alone withdrawal management programs will likely encounter significant challenges given that affiliation with other providers/programs would need to occur.

Current 3.1 programs may be challenged by the changes in hours of service delivery as the proposed changes represent fairly significant "upgrades".

52 It is understood that the editorial team is proposing to provide some greater degree of clarity in Level 3.7 care in a residential setting.

If the residential facility, as identified above, does not provide access to medication-assisted treatment, we believe that the criteria should take note of this and make recommendations. A recent illustration has emerged in the state of Massachusetts, where skilled nursing facilities do not allow a currently methadone-maintained patient, who is receiving care in an OTP, to continue such care while the patient is treated in the skilled nursing facility.

In such matters, the OTP in conjunction with the State Opioid Treatment Authority, must do its best to persuade the managers of the skilled nursing facility to allow the OTP to deliver medication to the patient. In this case, the Drug Enforcement Administration and its regulations governing the OTP is not the issue at play. It is in the hands of the administration of the skilled nursing facility.

Encourage Improved Continuity of Care Along the Continuum

We understand that the editorial team is recommending that more hours of clinical services should be provided per week in structured services, including recovery support. The recommendation is to increase the requirement for providing such services from five hours per week to nine hours per week. It is understood that developing such clinical criteria cannot adjust to the current level of workforce shortage in substance use disorder treatment facilities, however, that is a reality that must provide context for such recommendations.

One of our Board members has pointed out that this will represent an almost “doubling of the services required for 3.1 halfway houses, to have them reflect 2.1 level service intensity with housing”. He points out that this may “defeat the very purpose of that level of care”. Additionally, it is important to keep in mind that when developing such criteria, one must be mindful of how such services are likely to be reimbursed by the third-party payors, especially Medicaid and private insurance carriers. Additionally, it is very possible that stable patients do not need or want this increased level of care. We collectively advise the editorial team to be mindful of patients and their

response to treatment in addition to the workforce shortages as noted above.

Updating the Standards to Reflect Evolving Priorities of the Field

We agree that patients being treated for opioid use disorder must receive the necessary care to respond to their specific needs. We also agree with the importance of treating this chronic disease with team-based chronic care “including incorporating standards for remission monitoring as discussed above.” The question for the ASAM team is to evaluate where such team building practices exist. As the team knows, this is required for OTPs but is not required in DATA 2000 practices. In our judgment, the ASAM criteria must determine how its new 4th Edition criteria will be utilized in a field with such disparate differences. We certainly support changes to reflect evolving needs of patients, but we are in an era where much of our public policy seems to be moving away from medication-assisted treatment to medication-only models of care. Additionally, there are many practices outside of the scope of OTPs that have the practitioner working in isolation. It has been found through research that this becomes a dampening factor when a practitioner, even those that take an eight-hour training course, decide not to be active in treating opioid use disorder with buprenorphine in a DATA 2000 practice. Once again, such contextual policy issues should be kept in mind as the editorial team carries forth with its goals.

Summary

Thank you once again for allowing our Association to provide comments as ASAM develops its 4th Edition with updated criteria to provide guidance to our field. It is my hope that the above recommendations provide some value.

53

Level 1.0 – Long-term Remission Monitoring

Our concern is that it may focus too strongly on MAT/MAR, as opposed to a broader set of community supports. Will this level encompass non-medication support or help through recovery community centers (RCCs), for example (<https://www.recoveryanswers.org/resource/recovery-community-centers>)? There should be multiple gateways to recovery that support the individual’s choice to pursue recovery with or without medication. RCCs are non-clinical and typically offer peer support for individuals that choose MAR and for those who do not.

Level 1.5 – Outpatient therapy

We believe that this should be outpatient counseling and not only therapy. This level of care should follow along and support the broad umbrella of counseling - not limited to private therapists.

Recovery Housing

CCAPP has been a leader in fighting local government bans on this type of housing. As the NARR affiliate for California, we work closely with our national partners and are supportive of ASAM’s decision to include this necessary part of the continuum in the update. We are available to discuss potential impacts to zoning that the new version may bring about so that our local government conflicts are not exacerbated.

Integration

As mental health and SUD treatment become more integrated, we are concerned about what impact this will have on professionals who specialize in SUD treatment. California is set upon a path under Cal-AIM to formally integrate these systems. It would be helpful if the criteria spoke more to the competencies of those delivering the services in general.

54 length of stay and pace of programming would need to be modified across facilities to serve the needs of individuals with cognitive deficits and adjusting programming to serve both populations simultaneously would be confusing and burdensome for both programming and program management.

We support strengthening treatment requirements for level 3.1 residential to better distinguish it from recovery residences. 3.1 "clinically managed low intensity residential services," should provide more support and treatment than a lower level of care and allow for a smoother transition from higher levels of care to help ease the client back into the community. We support the increase in treatment hours of 3.1.

Colorado agrees with the inclusion of improvements for continuity of care and extended service offerings that operate after hours and on weekends to meet an appropriate level of intensity and duration of service provision. Alignment of clinical hours between 3.1 and 2.1 will mitigate the reduction of interventions for clients.

Colorado agrees with the updated standards to reflect evolving priorities of the field and encourages consideration of the unique treatment needs of pregnant and parenting individuals across the domains." EX: Gender-responsive treatment in the context of a birthing parent, dyadic assessments and considerations, and specific considerations for someone post-partum should be considered.

Inclusion of recovery residences as a part of the continuum of residential care is worth considering and Colorado welcomes input on considering how levels of recovery supportive housing may be integrated into the continuum of care. Colorado has a recently established regulatory body (CARR) for SUD recovery living residences in Colorado. Establishing clear criteria will be important when confounding the setting where treatment occurs and the intensity of treatment can be confusing for providers, policy makers, and the public.

Additional clarification regarding justice-involved clients and level of care criteria is needed and we support this enhancement. Furthermore, we would advocate for more discussion about how public safety concerns fit into the determination of residential levels of care in the community.

Clarification about how re-offense should be considered when evaluating risk factors in dimensional assessment would be very helpful. It is clear there are individuals who require a secure, supportive setting due to risk for re-offense who may not meet other traditional medical necessity criteria for residential care. Considerations for how "risk" is assessed between criminal justice organizations that are primarily focused on risk of re-offending and "risk" to self or others in the behavioral health field should be taken into consideration. Managing these two definitions of "risk" within a milieu should be factored into the criteria for various treatment settings.

We support the plans to bolster the adolescent standards and further delineation of adolescent standards is crucially important. We would suggest consideration for the segregation of adolescent standards from adult standards to increase clarity of each continuum. Family support and interventions are vital for this population and we would encourage inclusion of criteria that address the family system and the dyad for pregnant and parenting caregivers. Consideration of juvenile justice and/or family child welfare involvement should be considered factors and ask for clarification of how this may be addressed within the ASAM dimensions.

Additional Comments: Further standardizing the structure of the publication would improve usability. While the level of care criteria are presented in a standardized way, the descriptions of the programming and staffing elements at each level of care are not consistent across levels. It would be helpful if ASAM published a standardized form template for the actual ASAM itself.

55 1. If a "standardized treatment planning template" is provided I can see people becoming complacent and accrediting agencies (CARF) not agreeing with a standard template.

56 The evidence for the criteria is weak to non-existent and so decisions based on this tool may not have supporting evidence. Including strength and quality of evidence statements for each substance and each recommendation would be helpful in placing the PPC in perspective. The PPC is a helpful heuristic and not the gospel that ASAM and many jurisdictions seem to believe.

57 Very few of the traditional providers will be able to achieve the 1.7, 2.7 or 3.7 levels of Care. In Los Angeles County, with 12 million residents, there are only two 3.7 Treatment providers for Medicaid funded participants. These levels of care will continue to be grossly unavailable, and patients will be turned away because "they need a higher level of care."

58 Please refer to "The ASAM Principles of Addiction Medicine," 6th edition, chapter 70, Aversion Therapies for detailed description of the services provided at SSH.

The treatment services provided at SSH, including chemical counterconditioning treatment (CCCTX) and Rehabilitation Interviews (RI) AKA "amytal interviewing" or "drug assisted interviewing" are the core treatments that distinguish treatment at SSH from all others, and the only such treatment program in North America. All patients at SSH receive a combination of counterconditioning treatments (CCTX) and RI unless there is a medical contraindication.

SSH requests that the next edition of "The ASAM Criteria" acknowledge and support the unique offerings at SSH that do not easily fall into the current nor proposed criteria changes. CCCTX and RI cannot be provided at other than a 3.7 BIO or 4.0 level safely, and are not available from any other provider at any level of care.

SSH requests that "The ASAM Criteria," mandate that treatment at SSH be considered at 3.7 with WM and/or BIO or at a 4.0 level by insurers, and that if patients meet DSM-V SUD diagnostic criteria at the moderate to high severity level this treatment be covered without qualification otherwise.

Treatment may or may not include withdrawal management as a necessary service prior to rehabilitation but the treatment program itself is never less than 10 initial days, rarely 11 or 12, but never more than 12 days. Post-discharge reinforcements, i.e., readmission for 1 night, 2 days at 30 and 90 days post initial discharge are not charge for, and are a powerful form of contingency management enhancing program effectiveness (abstinence).

59 N/A

60 Well when we were preparing for our credentialing some of the information within the ASAM level of care certification manual was subjective and I am hoping adding additional things does not complicate our practice. For example • Define standards within each level of care for providing coordination of biomedical services (e.g., referrals to primary care or specialty care, coordination with those providers, overseeing medication adherence, etc.). I hope by doing this it doesn't add alot of additional policies, procedures, practice adjustment for what we are currently doing.

61 Not sure--need details of the changes.

62 We are not sure. We request that ASAM provide us the proposed standards for an intake assessment to make determinations for initial patient placement. Also, please provide your proposed standardized treatment planning template.

63 There will be confusion across agencies as some will accept the new changes and others are so tired of the constant change that they are going to stick with current edition.

64 I have not seen the changes

65 Fellowship Hall see the integration of biomedical services into the continuum as a good thing. However,, there are also potential unintended consequences. While we do provider services at the 3.7 level of care (medical monitoring and 24 hour nursing) other facilities looking to transfer individuals may get the wrong odea of the medical acuity that we can handle. For example, we are still unable to handle guests in need of IV therapy or cardiac monitoring.

Another potential unintended consequence to these changes could be that insurance companies pick up on the expansion of level 1.7. Specifically, if the role of medically monitored outpatient services is expanded, then insurance companies may be more hesitant to pay for a higher level of care even though it may be what is most clinically indicated.

66 I'm waiting to see how much the detox is affected.

67 Additional admin time. It feels that it may be asking us to integrate more services than we can provide. It is not as clear when to refer out vs when we have to add more services to clients that meet the other subcategories (.1 vs .5 vs .7).

68 1.We are unclear from this overview of proposed changes, which expanded level 1 service could support a patient with mild SUD and in an early stage of contemplation. An unintended consequence would be if the “delineated expectations” in level 1.5 resulted in a barrier to offering diverse Level 1.5 services, i.e. services to a patient not in long term remission (Level 1.0) and not in social detox (Level 1.7), perhaps still using some substances but not others who wishes to enter outpatient treatment.

2.We are concerned about the potential for unintended consequences in use of a standardized treatment planning template. We recognize that that many aspects of SUD treatment could benefit from further clarification and support, however anything related to imposing standard treatment plans has more potential harm for programs to return to one-size-fits all thinking. Perhaps there are other ways that ASAM Team can support implementation of the Criteria within treatment plans rather than provision of templates.

3.In referencing “collaboration with the patient to develop a treatment plan based on... multidimensional assessment”, we are not clear what is being recommended where, in terms of patient placement assessment, biopsychosocial, or a multidimensional ASAM assessment. There is potential for delineation and integration but also potential for unintended consequences of overlap and confusion. We are also concerned about any changes which have the unintended consequence of enabling both public (Medicaid) and commercial insurance companies to focus primarily on Dimensions 1, 2 and 3 to assess medical necessity while giving less weight to problems in Dimensions 4, 5 and 6. In our experience, insurance uses medical acuity to ration care by focusing on signs of withdrawal and ongoing medical issues – in the context of ASAM Dimensions, Severity and Risk Ratings. The result is someone with an OUD and a history of relapse, with no significant medical symptoms once a few days of detoxification is accomplished, but who dies from an overdose, without ever meeting medical necessity. Unintended consequences will occur unless there is focus on the chronic nature of SUD in the 4th Edition, particularly as assessed through Dimensions 4, 5 and 6. It is not clear in the proposed changes that the 4th Edition will support comprehensive use of all six Dimensions throughout the process of providing treatment and support to persons with SUDs from initial assessment, admission, authorization, goal setting,

treatment planning, utilization review, to discharge, aftercare and recovery planning.

4. Addition concern would be any unintended consequences resulting in “unfunded mandates”. With Medical Assistance reimbursement not covering actual expenses for residential levels of care – in particular those with medical monitoring and nursing staff - and with Commercial Insurance rationing care by limiting number of coverage days, requiring frequent reauthorization, and by excluding certain levels of care from coverage, we hope that the 4th edition be wary about potential loopholes for insurance providers to avoid or place further limitations on authorization of treatment. Examples for your consideration are any ASAM standards which bundle services to support more comprehensive treatment but due to regulatory limitations on combinations of services, and governmental silos between SUD and MH, result in lower insurance reimbursement rates instead of improved service delivery.

5. We appreciate that much effort went into development of these proposed standards and that this document is only an overview of a plan. We are aware that many providers were/are unaware of these suggested changes. We suggest that a further round of stakeholder comments be held after this initial feedback on the proposal is synthesized and that a longer, more comprehensive statement on the proposed changes be offered to stakeholders including further clarification.

69	unsure
70	Diferent stakeholders have different agendas, so legal referrals may have issues of compliance only for patients vs medical model treatment needs for pts in and out of hospital or residential care. Pts have ideas of what is best, by seeking social media information, not knowing the ramifications of their requests. Example of this is requesting residential care when outpatient can be sufficient.
71	I question the designation of 'BIO' being applied only to 1.7 within level 1. Most opioid treatment programs in my experience are inferior at addressing co-occurring biomedical needs compared to primary care homes that address addictive disorders in concert with patient biomedical needs. Prohibiting care levels 1.0 and 1.5 from receiving the BIO designation I'm afraid will fail to recognize the capabilities of adept office-based program which can exceed those of OTPs handily when done well.
72	Reduction in payment for regular outpatient or an increase in denials for care payments as payers impose new rules for the new criteria.
73	The only unintended consequence will be the perception that these changes are not significant (when they are).
74	To be honest, I expect that the insurance companies will develop new loopholes to make it difficult for those who need SUD services to obtain them. I realize that this sounds negative, but my experience thus far has been that finding ways to stop providing payment seems to trump the provision of needed services. I think that the best-case scenario would be that once someone has been approved for 90 days or IOP they should be allowed to complete this.
75	In California there has been mass confusion created by insurers. The California Department of Healthcare Services ("DHCS") licenses ALL "residential treatment facilities". They recognize detox (withdrawal management) services, residential treatment ("RTC") and Intensive Outpatient (they do not differential between PHP and IOP). They do NOT license ASAM 3.7 (WM) level of care. That level of care is licensed by the California Department of Public Health. However, insurers like Optum, Cigna and Aetna, refuse WM authorizations UNLESS you tell them, as a provider, that you do provide ASAM 3.7 LOC. But, IF you make that representation and/or actually provide that level of care, you violate you DHCS facility license for "operating outside the authority of your license". Your proposed changes to include ASAM 3.7 in "residential treatment" classification would require ALL California treatment providers (2,500 or so) to get licensed by two different agencies. We have 9 buildings and each one would have 2 licenses, which would be an unreasonable burden on our operation.
76	For the type of outpatient care that we provide, none are anticipated
77	I cannot speak for agency

78	Just what I mentioned above, the label of 1.0 as "long term remission monitoring may divert cases that can be managed initially there. Not everyone being treated has end stage disease and has to start at 3 or 4!
79	Maybe confusing for the rookie addiction provider.
80	State regulations don't recognize this approach. They expect everyone to receive the same level of care. Any suggestions? This approach is being introduced in Michigan.
81	MOUD will be still under used
82	Don't know
83	None. Recommend consideration of levels: 2.35 Long term sober living (i.e. halfway house) with ongoing outpatient therapy AND 2.37 Long term sober living with ongoing outpatient therapy and medical monitoring.
84	While I agree that it makes sense to integrate WM along the continuum, there are some standalone WM facilities that do an excellent job of setting up outpatient follow up. For example, the Chemical Dependency Unit at Johns Hopkins Bayview is a level 4WM for appropriate patients who present to the Emergency Department. While many patients follow up after discharge at the Bayview Comprehensive Care Practice (Level 1.0, delivering both primary care and SUD treatment), other patients may have insurance that dictates they get their long-term care elsewhere. Still, having the ability to get linked to care after presenting in the ED is valuable, as the Bayview ED has a well known name and serves a high-needs area of Baltimore. Compared with, for example, a typical general medical ward at any hospital, the Chemical Dependency Unit may be better equipped to link patients with long-term SUD treatment services. I would suggest that the revised criteria be careful to protect these types of facilities by giving them the opportunity to demonstrate their process of linking patients to long-term care, while at the same time avoiding overly burdensome documentation requirements. In addition, I would like to see the revised criteria provide more specific guidance on how to recommend an appropriate level of care when the exact level dictated by the criteria is not locally available.
85	not sure
86	I outlined the above. In summary, 1) Loss of flexibilities in service intensities within level 3.1 2) Potential over-scheduling more stable resident, leading to them prematurely discharging or limiting their community involvements 3) Refusal of payers to allow for simultaneous billing for 3.1 plus either 2.1 or 2.5 levels of care, which at this point is allowable per ASAM criteria.
87	We will need to update all the ASAM forms to include the proposed updates.
88	I'm not sure at this time but we look forward to using this 4th edition.
89	NONE
90	We do not have a nursing staff. We do have some oversight by an MD when needed.
91	As noted about the level 1 step down for maintenance monitoring. This may be specific to my work environment. Spacing and logistics for further groups to support the change may be challenging
92	I'm just curious if the ASAM is necessary for providers to truly decide which level of care is best for their clients or if it is just another step for billing purposes only. It seems there are more and more "hoops" that providers have to make "fit" for their clients to justify the level of care they believe will be the most helpful for their clients. Most providers have received a lot of training and are licensed to help with these decisions when they work one-on-one with their clients. I'm not convinced they need a chart or assessment to determine the level of care that they feel will be the most helpful for their client. I realize this will not be a popular opinion but felt it is worth at least stating as I'm sure I am not the only provider who has this opinion.

93 I believe that the biggest problem with this logical increase in flexibility will come from determining how services will be paid for. A per-diem rate may not be able to accommodate as symptoms improve or deteriorate as service needs change in the same setting, and a fee for service model may not financially support consistent staffing to meet the flexibility allowed for; it may also motivate a justification for the delivery of more services to make the reimbursements match the cost.

Mark, et al. (2021) found that ASAM implementation was associated with a 9% improvement in retention with treatment that began in a residential setting. They were unable to find any significant association between the use of ASAM and successful treatment completion. You can anticipate increased retention (defined here as 30-days) in residential facilities which can easily account for the 9%. And, it would appear from this study that the application of ASAM criteria may have an unpredictable relationship with actual treatment outcomes.

As written, this summary also continues to describe the boxes at the same time it moves in the direction of eliminating them which I think makes sense. It does not address the actual treatments applied beyond MAT. I do applaud the intention to incorporate social determinants of health as being integral to prognosis; measures to monitor progress; and, a “patient-centered” approach as being central to quality care. Relationships with patients have been found to be the key drivers of outcomes in both organizational and individual therapy settings (Goldberg, et al., 2016; Norcross & Wampold, 2019).

Goldberg, S. B., Babins-Wagner, R., Rousmaniere, T., Berzins, S., Hoyt, W. T., Whipple, J. L., Miller, S. D., & Wampold, B. E. (2016). Creating a climate for therapist improvement: A case study of an agency focused on outcomes and deliberate practice. *Psychotherapy, 53*(3), 367–375.
<https://doi.org/10.1037/pst0000060>

Mark, T. L., Hinde, J. M., Barnosky, A., Joshi, V., Padwa, H., & Treiman, K. (2021). Is implementation of ASAM-based addiction treatment assessments associated with improved 30-day retention and substance use? *Drug and Alcohol Dependence, 226*, Article 108868.
<https://doi.org/10.1016/j.drugalcdep.2021.108868>

94 My hope is to have clear language about providing services concurrently. Especially with level 3.7. I believe there should be a synergy of 3.7 and 4500 (SACOT) to enable programing to meet both the cognitive and physiological needs of individuals.

95 None

96 The medication management piece may be an issue for insurance companies

97 More confusion in the assessing accurately in the LOC.

98 There are not enough IOP programs in the community, and IOP is a heavy time commitment for youth in school; having this as a recommendation is important, but not always an available or realistic option for our clients. Additionally, PHP is not feasible for youth. Summarily, some of the treatment recommendations may be accurate according to the ASAM criteria but they are not going to be available, or be utilized.

Furthermore, there could be more specific recommendations such as peer support, peer groups, etc. that could support long-term remission.

99 Will need to explicitly detail withdrawal management capabilities at each level of care so as to mitigate risk that ill-equipped and poorly prepared programs and providers accept patients for whom they are not able to appropriately treat.

Also would like writers of ASAM 4 to think about how management of co-occurring pain in persons with SUD can be integrated into the criteria. While some SUD treatment programs may be equipped to provide routine medical services, they may not be appropriately equipped to successfully manage co-occurring moderate to severe pain. Don't know if this requires a separate level of care or unique distinction within levels of care, but should be considered- maybe something along the lines of co-occurring capable as is planned for psychiatric disorders.

100 I perceive that the national nursing shortage and the impact this is having on agencies throughout the country will affect the enhancement of services ASAM is recommending for some areas of care.

101 Not sure at this point

102 Updating the continuum of care to reflect the evolving treatment system Expanding Levels of Care within Level 1

COMMENTARY: The proposed changes don't allow for delineation of Enhanced Outpatient Services as recognized in Colorado (5-8 hours) that are currently applied to justice populations. This narrows the scope that can be recognized in provision of services.

RESPONSE: They retain revisions incorporating Level 1.0 Long-Term Remission Monitoring as outlined. They change Level 1.5 to Level 1.1 - Traditional Outpatient Therapy and define as services up to 4 hours weekly. They redefine Level 1.5 - Enhanced Outpatient Therapy and define as services providing 5-8 hours weekly.

A significant area of concern is around how the licensing body (Office of Behavioral Health) will interpret the changes and then change state licensing rules.

Additionally, not all Substance Use Disorder (SUD) treatment facilities retain the services of a psychiatrist or medical doctor. Level 1 outpatient programs do not have the expectation to offer 24/7 access to services.

****Any changes must include adequate funding and/or increase in rates to support proposed changes. Otherwise, it is an unfunded mandate.

***Unfunded mandates in an already woefully underfunded system is unacceptable.

COMMENTARY: In the current version of ASAM, "BIO" services are an adjunctive that can be added at any level in the continuum. The new construct of having separate levels of services suggests that an entity would have to change licensure to align with this rather than retaining a previously established license with additional services incorporated. Thus, a program licensed as

Level 3.5 – Clinically Managed High-Intensity Residential would presumably have to be relicensed as Level 3.7 – Medically Monitored Intensive Residential Services.

RESPONSE: Create the new Level 1.7, 2.7, and 3.7 distinctions but provide a secondary option of Level 0.7 – Medically Monitored Adjunctive Services that could be added to any of the existing levels of care to support the use of MAT and Psychiatric based services in those levels. This would not add the burden of having to also incorporate Withdrawal Management services and instead afford existing programs to retain established MOUs and working relationships with programs specifically designed to provide withdrawal services.

Encourage improved continuity of care along the continuum

Eliminate steep drop-offs in the intensity of clinical services:

COMMENTARY – This is largely an unfunded mandate. Unless fee structures and reimbursement will be aligned with the additional clinical services being provided, this will require programs to increase contacts and costs to deliver the programming without corresponding fee increases to cover these expenses. Additionally, without clarification, this makes levels 3.5 and 3.1 largely indistinguishable. The likely response would be to further increase expectations for clinical services within 3.5 which are already ambiguous and open for interpretation. States have chosen to arbitrarily adopt a stance of 10 hours or more of clinical services per week which again came as an unfunded mandate with the most recent ASAM revisions.

RESPONSE – Clarify the expectations for all levels in writing with each explicitly listing the clinical hour requirements and ranges. Establish a baseline expectations and guidelines for funding that allows these programs to be maintained or provides the necessary information to appropriately inform funding decisions from states and third party reimbursement sources.

THESE CHANGES DO NOT ACCOUNT FOR JUSTICE INVOLVED INDIVIDUALS and NEEDS.

COMMENTARY – Colorado already aligns justice services with Enhanced Outpatient (Level 1.5*) but there isn't a corresponding ASAM level.

RESPONSE – See the feedback above related to the Level I services.

103 I like the proposed update to Level 3.7 to reflect care in residential settings. Renaming the level “Medically Monitored Intensive Residential Services,” can only help to qualitatively differentiate those Level 3.7 programs that do not offer the treatment or withdrawal management because of concerns regarding evacuation of those patients with unstable biomedical conditions or complicated withdrawal emergencies. I imagine they will update the set standards and admission criteria to better align with the potential needs of individuals receiving care at this level. This will be a helpful improvement in that identification of programs that provide BIO is currently difficult in part because they are not generally recognized as a distinct and more intensive level of care. Referring a member to a program without the ability to provide the appropriate services for an unstable biomedical problem puts the patient at risk.

104 Maybe some confusion to start with, but I don't really see any at this time.

105 Please diversify or relax the requirements for level I services - a ridge requirements for providing services under 'mental health' will hurt us as we have no resources under 'medical'.

Substance induced neurological disorders - depression, anxiety, and cognitive impairments - executive dysfunction, memory loss, attention deficits, lack of motivation, etc - separate them from those defined under DSM. For instance, we treat cognitive impairments with the symptom clusters like ADHD under DSM with CNS stimulants. The dose is much higher to achieve desired clinical results. Literature support is scarce and objections from pharmacies and colleagues are abundant mostly quoting psychiatry literatures.

Please add withdrawal management to level I. That is our daily routine. We are not a 'continuum' of 'detox' from other levels of care.

106 With there being so many levels, I think it would be very easy for large locations that may encompass many of the possible levels to either mark the wrong level or forget to mark a different level as the client moves from one to another throughout their treatment program.

I work at a smaller clinic where we have clients in two categories, MAT services or outpatient mental health. If I'm reading this correctly we would be utilizing level 1.7 for MAT and 1.5 for our mental health only clients. If having multiple levels in one building is an issue, then it's an issue. Another possible issue is making sure the right level is marked if someone moves from one program to the other such as when they miss too many days of MAT services so they have to wait to re-enter those services but have the ability to continue with mental health services until they re-enter MAT. The other concern is there is not much information on how the team plans to align the standards. While we only have 1.5, not 2.5, I don't know how these standards are going to be aligned or what this is going to look like.

107 I do believe the eliminating steep drop-offs in care, from 5 hours to 9 hours, could deter some people from completing inpatient treatment as they must begin to rehabilitate their lives, returning or seeking work, additional treatment requirements might not be realistic for most.

108 I would suggest you add a section on management of SUD and homelessness. This issue is unfortunately becoming more serious, particularly in large cities, with housing shortages, increases housing costs, etc. A recent study spoke about SUD and homelessness being bidirectional. This language and a greater understanding of this is important

109 I don't feel there will be potential unintended consequences of the proposed changes. I sit on ASAM's subcommittee for level of care. ASAM Criteria will be the standard guidelines that is needed.

110 We had issues with multiple levels of 3 and 2s, when a patient needed a place to go that was higher than 0, it made the assessment so overwhelming for many providers. Adding more, will not help.

111 While recognizing the changes are intended to enhance the ASAM model, there are areas that, without further definition, clarification, or input from frontline clinicians and people with lived experiences, may result in unintended consequences.

Expanding Level of Care within Level 1

Long term remission monitoring, Level 1.0, can occur at any care setting. Currently, it is placed in outpatient on the ASAM care continuum. ASAM's proposal to add more detailed standards in an ambulatory setting may be limiting.

Our recommendation is to add language regarding the use of lower levels of care (inclusive of harm reduction) as a means of motivational enhancement. In the current state, if a patient is not willing to engage in the level of care required, a gut reaction of the treatment center is to defer the patient until they are ready. The intent is to meet patients where they are at and provide professional resources that can help patients engage through the stages of change. ASAM can provide more explicit guidance that the onus is on the provider to connect the individual to resources for a level of care the patient is ready to engage in. Further, we recommend ASAM incorporate harm reduction into each level of care to engage patients where they are at regardless of care setting.

We find there may be unintended consequences in the linear nature in which the ASAM Criteria is visually depicted. The line imposes a rigid view of treatment levels rather than the flexibility treatment services may need to meet patients where they are. Recovery is not a linear process; it is dynamic and encompasses a continuum of behaviors from severe use to total abstinence, which can fluctuate throughout the patient's recovery. For this reason, we believe that the depiction of treatment levels in the ASAM Criteria should reflect such fluctuation. We also believe the pathway of starting at a higher level of care and then trending down should be an essential component of the visual representation of the ASAM criteria.

Level 3 – Eliminating steep drop-offs in the intensity of clinical care

As mentioned above we believe this is a beneficial edit to the ASAM Criteria, however there may be unintended financial consequences. The reimbursement rates may not be sustainable to

increase hours for particular services. Rates must be evaluated and updated accordingly for treatment center fiscal operations. A change without ample guidance may also lead to confusion regarding what constitutes a clinical service and who can provide them (e.g., in PA a broad range of people can provide services, whereas in WV a master's level degree is required for clinicians).

To provide more clarity while acknowledging the national variation of scope of practice, we recommend ASAM use examples of what the care/provider can look like (e.g., emphasize that ASAM does not require that groups be run by master's-level professionals to encourage states like WV to loosen their criteria).

Level 3 - Clarifying how recovery residences fit into the continuum of care

We greatly encourage the inclusion of recovery residences in the continuum of care and the alignment with Level 3.1. There may be a consequence of misuse of inclusion of recovery residence without explicit definition. There may also be confusion of the services provided in recovery residences and if they must only align with care furnished in 3.1.

We recommend recovery residence should be included at any non-residential level of care. We would also encourage ASAM to provide more clarity on the length of stay within all the various levels of care, including recovery residence.

Level 4 - Inpatient

To provide greater clarity as to what is referred to by "inpatient" (as opposed to "residential"), we recommend clarifying the language. For instance, adding "acute care" or reference to hospitals may help with clarification.

112 As the CONTINUUM software and alliance with CARF become more entrenched, JCAHO will be marginalized and agencies and providers that cannot afford the software will be displaced.

113 none

114 Sudden drop out of level 3 care to level two or one with no heads-up, no adequate housing

115 * You are still using the outmoded term "addiction."

* The language is, if anything, more opaque than in the 3rd edition.

* Levels of care are, if anything, described in narrower ways than before, while medical practice is focused more on broader definitions

(* minor note: for those who speak a little German, the acronym for National Association of Recovery Residences is distinctly unfortunate)

116 possible insurance difficulties because of potential ways for further dividing care

117 A standardized treatment planning template would be helpful

118 Potential unintended consequences include:

-The risk of payors avoiding coverage of effective treatment modalities due to insufficient, vague or confusing language in the levels of care.

-The risk of patients not receiving effective evidence-based mobile, telehealth and digital services because of lack of payment parity or inappropriate clinician use. I urge the editors to consult with experts in the field of technologic delivery of addiction treatment to create a 4th edition that will not only meet the current treatment landscape, but set a standard that will continue to be a reliable guide in the future and will anticipate a coming wave of technological innovation.

119 Change of level 3.7
Currently our agency has standalone acute inpatient withdrawal management level of care, as the prior ASAM 3.7 medically monitored intensive inpatient service and the updated 3.7 is considered residential there would be need to be more clarification on where the standalone acute inpatient withdrawal management would fit. We would need a description of services, programmatic needs, level of certification/degree/experience from a staff standpoint that will be needed.

P. 3 – Clarify how recovery residences fit into the continuum of care
How does ASAM incorporate Social Determinants of Health (SDOH) into the level of care recommendations? Housing, sober social supports, financial support, others are all critical elements for maximizing success in recovery.

Payers utilizing the ASAM level of care criteria for prior authorizations for residential and inpatient services often require ‘failed attempts’ at outpatient treatment prior to approving an authorization for residential or inpatient services. Does ASAM have a position on this?

P. 4 Facilitate transitions of care within programs

The standards for staffing and scope of practice requirements – would be helpful for ASAM to consider allowing flexibilities due to state licensing requirements, rural and frontier geographic locations as this criteria is used to determine authorizations and payment. If the standards for staffing and scope of practice are stringent, there may be an adverse impact to people being able to access care and providers to receive payment for services.

120 -potential for insurance companies to limit support to treatment plans specified in the guidelines

-potential to require certification in order to provide MAT/MAR (concerning lack of certification available for PAs and NPs)

121 The proposed changes look very good.

I want to see less waste, more efficiency, lower barriers for patients, and better outcomes.

I suggest that patients be directed to the lowest level of care for which they meet criteria. (I believe facilities now direct patients to the highest level of care for which they meet criteria.)

I suggest that patients be allowed to choose a lower level of care than criteria allow. For many patients, the extensive counseling required at their level prevents them from entering or staying in treatment.

We know that health plans are using ASAM Criteria to determine payment. You should embrace that and use that as a major guide in how the Criteria are written.

122 Given the direct attention to treatment needs of lesbian, gay, bisexual, and transgender individuals, I wonder if the proposed changes could also include greater attention to unique treatment of racial and ethnic minorities?

Given the increased attention to coordinating care for those with co-occurring mental health conditions, I also wonder if there can be an increase in attention to coordinating care with those with co-occurring medical conditions, that are in part due to hazardous substance, use at each level of care?

123 A lack of guidance for the utilization of Digital Health/PDTs contributes to confusion among provider and payer networks regarding their adoption, integration into care and effective use:

- Limited clinician awareness for the appropriate use, or inappropriate use, of PDTs in the context of the ASAM Levels of Care
- Underserved and rural populations impacted by health inequities may be especially impacted by a lack of guidance on the appropriate/inappropriate use of PDT treatments
- Lack of ASAM Levels of care guidance may be inappropriately applied by payors to avoid coverage of effective digital health and/or PDT treatments
- The overall evidence-based medicine paradigm is hampered by a lack of clear guidance for implementation and integration of PDTs in clinical practice, ultimately delaying additional care options for many patients

124 1 important unintended consequence of the proposed updates will lead to a missed opportunity for providers and patients to understand except and embrace the use of prescription digital therapeutics for folks with substance use disorder. PTTs are now FDA authorized and are evidence-based. They have PI information just like any other medication and can be used alone in many cases or along with buprenorphine to help patients remain in treatment. For those who his primary substance of abuse is not an opioid they also have been shown to help patients achieve recovery in a statistically significant fashion compared to those who are not using PTTs. Any new school that is introduced in our healthcare system in any discipline is slow to be accepted by providers were used to doing things a certain way. Insurance companies are slow to accept new modalities as well mainly because they do not understand them, do not understand their potential benefits, and failed to try to realize the cost savings they might provide.

If we do not include very specific guidance on the use of prescription digital therapeutics we will end up continuing this current state of limited clinician awareness for how to use them appropriately as well as an understanding of how they can be used inappropriately which is just as dangerous as inappropriate use of any prescription medication.

I am not including very specific guidance we also risk payers finding ways to avoid covering prescription digital therapeutics that have been demonstrated to be effective the FDA scrutiny. Tears do not avoid placing medications on their formulary that are FDA approved and although the tear for those drugs might be different they are covered in this case prescription digital therapeutics in the way I themselves victims of discrimination by health care system made up of pairs and providers that have failed to take the effort to fully understand them and how incorporation into patient's care can improve outcomes.

Insurance companies will likely look to the ACM criteria when making the determinations about coverage for digital therapeutic treatment modalities. Some tears are already excepting of PTTs but I believe the uptake for this has been slow I always believe there should be guidelines that are very specific and up-to-date regarding appropriate patient selection, appropriate implementation, appropriate monitoring, and equally important would be appropriate education for patients and families for what this new tool of digital therapeutics is all about.

125 While the changes to residential treatment continuum do seem necessary, there is such a need in most communities for increased access to any inpatient settings that it may deflect from the need to focus more on options for outpatient management even in patients who present with high levels of acuity
