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Supporting People, Health and Quality of Life

Comments on Draft Guidance for ICFs/MR for Conditions of Participation: Governing Body, Client Protections, Facility Staffing, Active Treatment, Client Behavior, Health Care Services, Physical Environment, and Dietetic Services

Dear Deputy Director Wilkerson,

The American Health Care Association (AHCA) and the National Center for Assisted Living (NCAL) represents ICFs/MR across the country; our member ICFs/MR serve over 7,500 individuals with developmental disabilities (DD) in their facilities. The California Association of Health Facilities (CAHF,) an AHCA affiliate, represents over 500 ICF/MR providers of services throughout California. AHCA/NCAL and CAHF appreciate the opportunity to comment on the draft revised interpretive guidance (IG) for the following Conditions of Participation for ICFs/MR: Governing Body, Client Protections, Facility Staffing, Active Treatment, Client Behavior, Health Care Services, Physical Environment, and Dietetic Services

We would like to acknowledge what we consider to be positive changes within the draft guidance, which include:

1. the outline for evidence-based assessment when addressing challenging behaviors;
2. the expansion of the discussion of active treatment, including the emphasis on linking skill acquisition to everyday living experiences and;
3. the focus on the importance of enhancing each client's communication abilities.

Given these positive changes, we are unsure why the IGs now have a significantly greater reliance on paper documentation as a key determinant in evaluating facility compliance. In our view, this represents a clear departure from the long-established outcome-focused survey process, and will likely cause facilities to spend more time and attention on administrative and paper processes, which do not necessarily equate to quality client care.
CMS has an opportunity to use the IGs as a "best practices" document by adding references to current literature or web-based resources that support evidence-based and promising practices in key areas such as active treatment, program implementation, and managing behavioral challenges. The resources and references provided in the Online

Supplemental Support Program would be a valuable addition to the IGs, and would mirror the CMS practice of including such information in guidance for other types of facilities that it certifies (Reference “Surveyor Guidance” for Skilled Nursing Facilities.)

Summary

Our comments and major concerns on the draft guidance focus on three areas, which are outlined below:

1) We are concerned that the draft guidance creates new rules for facilities that were never intended by the original duly promulgated regulations. Some examples include:

- Requiring facilities to seek legal representation for clients;
- Requiring an assessment to determine if the client’s family or guardian understands the client’s rights;
- Requiring that a female staff member be present if a male staff member is attending to a female client and;
- Requiring that facility policies and assessments contain specific elements.

As these and other items, which appear to be new requirements for ICFs/MR, were not included in the original regulations, they would essentially pass new rules if included in the final revised guidance without going through the formal rule making process. U.S. Code Chapter 5, § 553(b) provides that, as a general rule, “notice of proposed rulemaking is to be published in the Federal Register,” and subsection (c) requires that the agency promulgating the rule “give interested persons an opportunity to participate in the rule making process,” only after which the agency may incorporate the rule. Although federal agencies may publish interpretive guidelines or general statements of policy without going through the formal rule making process, it may not prescribe new requirements in this fashion. We therefore ask that you consider our requests, as outlined in the “Specific Comments” section below, to delete certain items from the draft guidance that exceed the scope of ICF/MR regulations.

2) Our second general comment is that, although person centered care is crucial in an ICF/MR, the rights of the majority of clients can sometimes only be protected and promoted by subordinating the choices of the individual, whether it means denying the individual free access to other persons’ belongings or asking the individual to participate in recreational activities that

are not always their first choice. While we appreciate CMS’ effort to focus on individual clients’ rights, we feel the draft guidance makes it difficult for facilities to teach clients the importance of compromise, in select situations, when residing in a communal living setting.

3) Finally, there are a number of typographical errors and/or unfinished sentences throughout the document, including but not limited to the following:

W266 First sentence
W268 Line 1
W269 First sentence
W289 First sentence
W309 Last sentence of first paragraph

Specific Comments:

Condition of Participation: Governing Body

W 112: The regulation states that the facility must keep confidential all information contained in clients' records, regardless of the form or storage method of the records. The draft guidance adds further prescriptive requirements beyond the regulation, including that the facility
"develop and follow procedures for maintaining confidentiality of client information during transport or during medical outings" and that "the facility must ensure that any client information provided to day services programs is maintained confidential."

- *We recommend that the guidance at W112 be modified to state that the items referenced above are examples for facilities to consider when establishing processes for record confidentiality. We additionally recommend that the requirement that facilities "ensure" confidentiality (as stated in the second paragraph of the draft guidance) be deleted as it would be impossible for facilities to meet this standard without being continuously present in all of the clients' care/activity settings. Instead, the guidance could suggest that as facilities evaluate their protocols to promote confidentiality of client records, that this process include consideration of other settings in which such information is maintained, such as day programs, schools and job sites.*

W113: The regulation requires the facility must develop and implement policies and procedures governing the release of any client information, including consents necessary from the client or parents (if the client is a minor) or legal guardian. The draft guidance exceeds the regulatory requirement by dictating what the "policies must address at a minimum."

- *We recommend that in the guidance at W113, the statement "These policies must address at a minimum:" be deleted and replaced with "Policy elements to consider include:"*

Condition of Participation: Client Protections:

W122: The regulation requires the facility to ensure the rights of all clients, but the guidance appears to require the facility to seek "legal representation" for the client and/or a guardian for clients without family even though there is no mention of the same in the regulation. Given an individual facility's resources and those of the community, obtaining these advocacy services may be difficult if not impossible. Again, the draft guidance appears to exceed the scope of the regulation.

- *We recommend that CMS delete from guidance at W122 that the facility secure "legal representation independent of the facility when an assessment identifies the need."*

W123: The regulation requires that clients and their legal representatives be informed of the client's rights and the rules of the facility. The draft guidance goes a step further and asks the facility to "make some assessment of whether the client, their family or guardian understood the rights presented and if not make addition [sic] efforts to communicate the rights." This requirement of an assessment of not only the client but the family is clearly beyond the scope of the regulation.

- *We recommend that CMS delete from guidance at W123 that the facility is obligated to "make some assessment of whether the client, their family or guardian understood the rights presented and if not make addition [sic] efforts to communicate the rights."*

<u>W125:</u> The regulation requires ICFs/MR to allow and encourage individual clients to exercise their rights as clients of the facility, and citizens of the United States, including the right to file complaints and the right to due process. In light of the regulation, we are confused as to what CMS means when it says "clients who need guardianship or advocacy, and do not have this need addressed, are not prepared to exercise their rights as citizens of the United States." Does this mean that CMS doesn't want clients to vote under those circumstances? Does this mean that the facility is obligated to hire attorneys or guardians for the client at its own expense? We believe that the above mentioned statement is beyond the scope of the regulation.

- *We recommend that CMS clarify the statement at W125, "clients who need guardianship or advocacy, and do not have this need addressed, are not prepared to exercise their rights as citizens of the United States" in the final guidance*.

<u>W127</u>: The regulation requires that clients not be subjected to any type of abuse. However, the guidance includes language that would leave surveyors "second guessing" any change in a client's status as a potential sign of abuse. We believe creates a bias that abuse is a prominent and frequent reason for changes in clients' status.

- *We recommend that CMS remove the draft guidance at W127 and, instead insert the direction in the Task 2 protocols of current ICF/MR guidance at W127, which states that client changes in status should be a consideration when assessing the facility's processes to identify possible abuse.*

<u>W129</u>: The regulation requires that facilities provide each client with the opportunity for personal privacy. Our concern with the draft guidance is that some smaller ICFs/MR do not have private bedrooms or any areas that are not common space. The draft guidance seems to require that there be physically separate private areas, whereas the regulation speaks to personal privacy only, which we have always interpreted to mean privacy during dressing, bathing, toileting, etc. which can be reasonably provided in existing settings with the use of privacy curtains. To comply with the requirements in the revised guidance, some facilities would need to make physical plant changes, which may be infeasible. Regardless of that complication, the apparent new requirement in the guidance exceeds the regulation and it should be removed.

- *We recommend that CMS revise the guidance at W129 to reflect that clients' privacy needs are met if, when a client/family desires privacy, that certain outdoor or indoor communal space can be utilized with consideration of the needs of other clients.*

<u>W130</u>: The regulation states that facilities must ensure privacy [for clients] during treatment and care of personal needs. The draft guidance states that female clients may not be attended by a male staff member without a female staff member in attendance. This violates the prohibitions against sex discrimination contained in Title VII of the Civil Rights Act of 1964 (42 U.S.C. §§2000e, *et seq.*) and should therefore not be included in the revised guidance.

- *We recommend that CMS delete from the guidance at W130 the following language: "the facility must ensure that female clients are attended in private situations by female staff members or by a male staff member with a female staff member in attendance."*

W 137: The regulation requires that clients have the right to retain and use appropriate personal possessions and clothing. The draft guidance states that "age appropriate" refers to anything that reinforces recognition for a client as a person of a certain chronological age. This creates an ambiguous standard that could result in surveyors questioning adults who choose to collect and display dolls, model cars or other items that could be considered "child-like."

- *We recommend that clarifying language be added to the guidance at W137 to assure that when clients choose to have dolls, model cars or other items traditionally used by children, that these can still be part of "age appropriate "activities.*

W144: The regulation requires the facility to answer communications from clients' families and friends promptly. The draft guidance says that the response should be within 48 hours. This, again, creates a rule where no rule existed before. Depending on the inquiry, it may or may not be reasonable for a facility to obtain an answer within 48 hours. In addition, the family or friend who contacted the facility may not be available for facility staff to speak with in the specified timeframe.

- *We recommend that CMS deleted the following language from the guidance at W144: "It is reasonable to expect that the facility will respond to inquiries from the client's families and friends within 48 hours."*

W154: The regulation at W154 requires that the facility have evidence that all alleged violations are thoroughly investigated. However, the draft guidance creates the expectation that surveyors will have access to all information that the facility gathered in conducting such an investigation. Although the regulation requires that a facility produce evidence of a thorough investigation, the draft guidance creates a standard that exceeds the regulatory requirement.

- *We recommend in the guidance at W154, the sentence "A thorough investigation includes at a minimum:" be deleted and replaced with the following sentence: "Examples of a thorough investigation include but are not limited to:" Additionally, the guidance should state that, beyond facilities demonstrating to surveyors that a thorough investigation has been completed, facilities are not required to produce for surveyors any related documents that are protected from disclosure by attorney-client privilege.*

W155: This regulation is not included in the draft guidance. If this was an error, please distribute the draft guidance to stakeholders and allow them to comment.

Condition of Participation: Facility Staffing

W 166: This regulation establishes that professional program staff must work directly with other professional, paraprofessional, nonprofessional staff who work with clients. The draft guidance now establishes new requirements that there be written documentation that the professional program staff trains other staff. Again, the draft guidance exceeds the regulation. Note: It is unclear if the draft guidance also requires that staff initial the program plan. The statement in the draft guidance "Documentation should provide evidence that the professional trains the paraprofessional and nonprofessional **initial** [emphasis supplied] on the program…." is unclear. Regardless, requiring initials on program plans would also exceed the regulation.

- *We recommend that CMS delete the third paragraph from guidance at W166. More appropriate language in the guidance would convey that, if there is a concern about the facility's compliance with this regulation, that surveyors interview professional staff to evaluate if needed training and monitoring of paraprofessional and nonprofessional staff is occurring.*

W186: The staffing regulation says that the facility should provide "sufficient direct care staff…. defined as the present on-duty staff calculated over all shifts in a 24 hour period for each defined residential living unit." The draft guidance states that supervisors may not be included in direct care staff ratios. However, in many facilities, supervisors will provide direct care to clients in addition to their other duties, and as such they should be included in the staffing ratio.

- *We recommend that CMS revise the second to last sentence of the guidance at W186 to state the following: "Direct care supervisors, if assigned to work directly with the clients providing support during activities of daily living and active treatment programs, may be included in direct care staff ratios."*

W187: This regulation governs the direct care ratios and is very specific. The draft guidance states if a facility is not certified under Chapter 32 or 33 of the life safety code (LSC,) when clients are present in the home there must be a minimum of two direct care staff on duty at all times. No Chapters in the LSC address the number or qualifications of staff, including Chapters 18 and 19, under which many ICFs/MR are certified. It is also our understanding that CMS plans to adopt the 2012 version of the LSC. It would behoove CMS to delay finalizing the guidance at W187 until the content of the new LSC is available for review.

- *We recommend that CMS delay finalizing the draft guidance at W187 until it is confirmed that the 2012 version of the LSC is being adopted. If Chapters 18 and 19 of the 2012 LSC also do not contain minimum staffing requirements, CMS should delete the last sentence in the draft guidance, which states "If a facility is not certified under Chapter 32 or 33 of the Life Safety Code, when clients are present in the home there must be at a minimum 2 direct care staff persons on duty at all times.*

Condition of Participation: Client Behavior

W270 and W271: The regulation at W270 requires that the facility specify the client conduct that is to be allowed or not allowed, but the draft guidance states that the house rules "must also include direction to staff about the intervention to be used if a house rule is broken," and further, that "episodes of house rules being broken should be reported to the QMRP for consideration of an individual program." This appears to be an additional requirement not intended in the regulation.

Similarly, the regulation at W271 calls for the "house rules" to be available to staff, clients, parents of minor children, and legal guardians, but the draft guidance says "policies and procedures for management of conduct between staff and clients [emphasis provided] should be provided to clients, parents of minor children, and legal guardians at admission and upon request." This additional requirement, not contemplated by the regulation, should be deleted from the guidance. This deletion is also appropriate as conduct between staff and clients is not the focus of the "house rules" described under W270.

- *We recommend that CMS remove the language in the draft guidance at W270 and W271 which requires that: 1) house rules and policies include staff direction on interventions, and 2) that these policies and procedures be provided upon admission.*

W 274: The regulation requires that the facility must develop and implement written policies and procedures that govern the management of inappropriate client behavior. The draft guidance clearly exceeds the regulatory requirement by mandating that policies and procedures include three specific elements, which are listed on the top of page 5 in the "Client Behavior" draft guidance."

- *We recommend that the language at the beginning of the draft guidance at W274 be revised as follows: "Examples of elements to consider in developing policies and procedures regarding the management of maladaptive behavior may include, but are not be limited to the following:"*

W278: This regulation requires that, for managing inappropriate client behavior, prior to the use of more restrictive techniques, the client's record must document that programs incorporating the use of less intrusive or more positive techniques have been tried systematically and demonstrated to be ineffective. The draft guidance now establishes a new requirement that a functional analysis of behavior must completed to demonstrate compliance with W278.

- *We recommend that the first sentence be modified to state, "Examples of policies and procedures that may be utilized by the facility when restrictive procedures are to be implemented may include, but not be limited to the following:"*

W 281: This regulation requires that (policies/procedures) be established for the use of drugs to manage inappropriate behavior. The draft guidance exceeds regulation by mandating specific elements in policies.

- We *recommend that the first statement in the guidance at W281 be revised as follows*: "*In developing such policies, examples of positive facility practices include addressing the following:"*

W315: This regulation requires a client's drug regimen review to be monitored for adverse consequences by facility staff, which is appropriate. However, the draft guidance states that "everyone who works with the individual "should be aware of the specific profile of side effects for a drug." We believe this language is inappropriate as it essentially requires that all staff have a nursing scope of practice, mostly likely beyond the skill set of their actual position, which may be as a habilitation aide, a dietary or activities worker, etc. Many of these employees would not even have access to the client's medical record and/or know what medications the client takes. It is reasonable to expect all staff to report what they anecdotally consider to be significant changes in client behavior, but requiring that staff know specific drug side effects exceeds the regulation.

- *We recommend that CMS remove the following language from the guidance at W315: "It is important that everyone who works with the individual be aware of the specific profile of side effects for a drug and report any of these side effects promptly."*

Condition of Participation: Health Care Services

W348: The regulation states that the facility must make arrangements for dental treatment. The draft guidance, however, exceeds the regulation by requiring "written arrangements" for emergency dental

services; the applicable language should therefore be removed from the guidance. The remaining language in the guidance adequately conveys that facilities are required to provide dental care to clients.

- *We recommend that CMS remove the following language from the guidance at W348: "In any event, the facility must have written arrangements in place to secure 24/7 emergency dental services for the clients."*

W351: The regulation requires a complete extraoral and intraoral examination, but the guidance, similar to W348, goes beyond the scope of the regulation by requiring an oral cancer screen to be a part of the routine dental exam. Since it is our understanding that such screening is not part of a typical extraoral and intraoral dental exam, the draft guidance creates a new rule not contemplated by the regulation.

- *We recommend that CMS remove the following language from the guidance at W351: "The intraoral examination should include not only the teeth and gums but also include an oral cancer screen."*

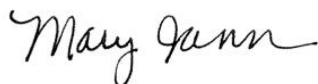
W362: The regulation requires that a pharmacist, with input from the interdisciplinary team, must review the drug regimen of each client at least quarterly. The existing ICF/MR guidance refers to Appendix N, which we recognize is no longer part of the ICF/MR survey manual. However, current guidance at W362 directs surveyors to confine reviews to the section of the Appendix entitled "Indicators for Surveyor Assessment of the Performance of Drug Regimen Reviews."

The draft guidance now includes a reference to the State Operations Manual, Appendix PP which is specific to skilled nursing facilities (SNFs,) but the language directing surveyors to confine reviews to the "Indicators for Surveyor Assessment of the Performance of Drug Regimen Reviews" is not in the draft guidance. This language should be added back in.

- *We recommend that the last sentence of the guidance at W362 be changed to "Refer to the 'Indicators for Surveyor Assessment of the Performance of Drug Regimen Reviews' in Appendix PP to the State Operations Manual (Pharmaceutical Service Requirements in Long Term Care Facilities.)"*

Please feel free to contact our organizations should you wish to further discuss our comments. We would enjoy providing further input during the revision process.

Sincerely,



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