March 4, 2020

Zane Garcia Ramadan
Interim Assistant Director
Division of Developmental Disabilities
Department of Economic Security
1789 W. Jefferson
Phoenix, AZ 85007

SUBJECT: Compliance Action – Notice to Cure

Dear Mr. Garcia Ramadan:

The Arizona Health Care Cost Containment System/Division of Health Care Management (AHCCCS/DHCM) has determined that the Department of Economic Security/Division of Developmental Disabilities (DES/DDD) is in violation of its Contract YH6-0014 Section D, Paragraph 14 Case Management and Paragraph 20 Grievance and Appeals System as well as Section F, Attachment F1, Member Grievance and Appeal System Standards. In addition, DES/DDD is in violation of Section D, Paragraph 9 Scope of Services, including but not limited to those provisions regarding coverage of services outlined in AHCCCS Medical Policy Manual (AMPM) 310-P and adherence to prior authorization requirements delineated in 42 CFR 438.210. Accordingly, AHCCCS is issuing this Notice to Cure in response to DES/DDD's failure to comply with federal and state coverage and authorization requirements specific to Augmentative and Alternative Communication (AAC) devices as well as DES/DDD's failure to comply with critical grievance and appeals system protections and requirements set forth in 42 CFR Part 438 Subpart F, AHCCCS Contract YH6-0014, and AHCCCS Contractor Operations Manual (ACOM) Policy 414. With respect to authorization requests for AAC devices, for an extended time period DES/DDD has failed to issue timely and accurate Notices of Adverse Benefit Determinations to members who have requested such devices and/or related services and supports, providing members with no reasonable or reliable mechanism to challenge DES/DDD's failure to act in accordance with state and federal requirements.

Background:

On both December 19, 2019 and January 9, 2020, AHCCCS was notified by external parties of a variety of concerns regarding DES/DDD's process for approving AAC devices for members, most of whom were children. In part, the communications expressed concerns regarding DES/DDD's refusal to process authorization requests for AAC devices, DES/DDD's development of coverage policies that appear to violate federal guidelines, extensive delays in the provision of AAC devices, and the increasing phone calls to advocates from families seeking assistance.

To provide DES/DDD an opportunity to address these allegations and to apprise AHCCCS of these matters, AHCCCS met with DES/DDD on January 14, 2020 regarding AAC devices and its handling of authorization requests. During the meeting, DES/DDD disclosed to AHCCCS, for the first time, that DES/DDD had implemented a process to "hold" all AAC decisions as of August 1, 2019, resulting in an estimated 300 requests where no determinations of coverage by DES/DDD had been issued. DES/DDD additionally disclosed that there was concern in the community regarding DES/DDD's failure to issue timely authorization determinations as well as DES/DDD's failure to inform members of their appeal rights regarding the outcome of their AAC requests. AHCCCS reiterated federal, state, contractual and policy requirements that decisions on all non-expedited requests for services/supports must be made no

later than 14 calendar days of receipt absent those requests which are subject to extension. DES/DDD assured AHCCCS that it was aware of the compliance implications and that a comprehensive plan was established to address all outstanding AAC device requests. DES/DDD stated that there would be an internal meeting to discuss risks and barriers at the end of the day on January 14, 2020 and that providers would receive an updated policy document for review and feedback no later than January 21, 2020.

On January 16, 2020, two days after the AHCCCS-DES meeting, both agencies received a joint letter from the Arizona Center for Law in the Public Interest (ACLPI) and the Arizona Center for Disability Law (ACDL) alleging that nearly 400 members have been improperly denied medically necessary AAC devices since early 2019. Among other concerns, the advocates contended that the DES/DDD policy for DME violates federal regulations for coverage of DME and is unduly restrictive. In response, Dr. Cara Christ, Interim DES Director and Jami Snyder, AHCCCS Director issued a joint communication to ACLPI and ACDL on January 24, 2020. This correspondence stated, in part, that DES/DDD has developed a thorough plan to address all pending requests for AAC devices to include an individual response notice to each affected member by the end of February and that DES/DDD is collaborating with providers and is conducting a comprehensive review of its AAC policies and procedures to ensure compliance with all federal and state laws, rules, and regulations.

Subsequently, on February 26, 2020, AHCCCS received a letter from ACLPI outlining several concerns regarding the disposition of AAC requests, including "boiler plate reasons for denials" (rather than individualized determinations) where numerous children and adults have allegedly received the same denial reasons for many different types of AAC devices, denials of AAC devices when the information requested by DES/DDD for review had been attached to the requests for the devices, and concern that possibly no or few AAC requests have been approved by DES/DDD. It was further alleged that DES/DDD has only offered one opportunity for providers to review DES/DDD prior authorization policies and that the policies maintain the same restrictions and concerns outlined in the January 16, 2020 letter from ACLPI and ACDL. Redacted samples of Notices of Adverse Benefit Determinations were submitted along with the ACLPI letter. ACLPI also stated its intention of pursuing litigation if DES/DDD failed to come into compliance with Medicaid requirements.

AHCCCS has also recently received complaints and concerns regarding DES/DDD's denials of AAC devices beyond those presented by advocates. As an example, at least one provider has alleged that member-identifying information was not shared in a denial notice to allow for the opportunity to provide more specific information regarding the request. AHCCCS also became aware of at least one member who received approval for an AAC device in excess of 17 months ago and has yet to receive the device.

Request for Data and Information:

AHCCCS is requiring DES/DDD to submit the following documentation to the Agency for review:

- Total number of AAC device requests received on or after August 1, 2019
- Total number of AAC device requests that have been reviewed on or after August 1, 2019
- Total number of AAC device request determinations issued on or after August 1, 2019 that were previously on hold or are currently on hold and where a determination has not been made within 14 calendar days from receipt of the request.
- Total number of AAC device decisions that have been issued on or after August 1, 2019, along with a breakdown of the timeliness of determinations (decision made within 0-14 calendar days, 15-30 calendar days, 31-60 calendar days, 61-90 calendar days, 91+ calendar days)
- Total number of AAC device approvals that have been issued on or after August 1, 2019

- Total number of AAC device request reviews since August 1, 2019 that have required follow-up prior to issuing a determination
- Total number of AAC device denials that have been issued on or after August 1, 2019
    - As a subset, the number of decisions that offered an alternative service/device in lieu of the requested device
- Total number of AAC device approvals that have been issued, regardless of date, where the device has not yet been received by the member
    - Include a detailed listing of these instances, including member first name, member last name, AHCCCS ID number, date of birth, device requested, date of device approval, date of anticipated receipt of device if known, and rationale for delay
- Documentation substantiating DES/DDD's "thorough plan to address all pending requests" as stated in the joint response letter to ACLPI and ACDL on January 24, 2020 as well as the current status of any action item outlined in the plan
- Documentation substantiating DES/DDD's commitment to provide an "individual response to each request by the end of February" as stated in the joint response letter to ACLPI and ACDL on January 24, 2020
- Documentation regarding DES/DDD's collaboration efforts with providers related to general AAC device requests and/or policy/FAQ concerns, specific device requests that require additional information from providers, and any other relevant provider engagement
- Documentation regarding DES/DDD's efforts to conduct a "comprehensive review of its policies/procedures to ensure compliance with all federal and state laws, rules, and regulations" as stated in the joint response letter to ACLPI and ACDL on January 24, 2020
- Professional credentials for any person(s) who has reviewed and/or issued a decision regarding an AAC device request on or after August 1, 2019
- A written summary outlining the steps of the AAC device request review process, including but not limited to intake, review, medical necessity criteria used to evaluate requests, provider and/or member engagement, requests for extension, issuance of determinations, and, in instances of device approval, the process by which DES/DDD ensures that approved devices are provided to the member in a timely manner
- The evidence based criteria currently in use at DES/DDD to review requests for AAC devices, as well as any future anticipated changes in the criteria applied
- The medical records currently requested to evaluate requests for AAC devices, and the process at DES/DDD to request additional medical records where these are required
- A description and review of the workflow for clinical review of these requests
- Confirmation that adverse determinations are evaluated by a licensed clinical professional
- Documentation of the process for providers to request peer-to-peer reviews
- Documentation of the process to deliver Notices of Adverse Benefit Decision to the member and provider requesting the service

All requested information in this section is due to AHCCCS by **close of business on Wednesday, March 18, 2020.**

Immediate Policy Modifications:

AHCCCS is requiring DES/DDD to immediately make modifications to section 1250-F of the DDD Medical Policy Manual while AHCCCS undertakes a comprehensive review of the policy's compliance with federal, state, and contractual requirements. Required policy modifications are outlined in Appendix A of this letter. Although AHCCCS does not formally approve Managed Care Organization (MCO) policies prior to their adoption, AHCCCS does review and provide feedback identifying required and/or recommended revision to MCO policies.

DES/DDD must confirm in writing, no later than **March 18, 2020**, that the identified provisions from Policy 1250-F have been rescinded or revised consistent with the above. DES/DDD must submit documentation, no later than **March 25, 2020**, that all staff responsible for the implementation of the policy has been retrained on the policy revisions. Additionally, DES/DDD must review all Notices of Adverse Benefit Determination that have been issued on or after August 1, 2019 which have denied AAC devices. If the Notice of Adverse Benefit Determination has denied an AAC device citing any of the above invalid reasons, DES/DDD must re-evaluate those denied requests no later than **April 10, 2020** to determine whether further action by DES/DDD is needed consistent with aforementioned requirements. DES/DDD must take such actions (e.g. approval of the device, consultation with the provider, and/or replacement of the device) within 14 calendar days of Adverse Benefit Determination review and no later than **April 24, 2020**.

Notice to Cure:

AHCCCS has identified serious and continuing deficiencies with respect to DES/DDD's review and approval processes regarding coverage and authorization of AAC devices, its compliance with fundamental grievance and appeals system protections and requirements, and its lack of timeliness and accessibility to covered services for vulnerable members as set forth in the preceding pages. DES/DDD shall come into compliance with all federal, state, contract, and policy requirements no later than **May 1, 2020**. DES/DDD shall immediately undertake all necessary actions to achieve compliance with federal and state provisions for providing timely and accurate member notifications that adhere to state and federal requirements for provision of services and for communication of adverse determinations. DES/DDD may request technical assistance from AHCCCS for any elements outlined in this Notice to Cure.

DES/DDD shall develop a comprehensive Action Plan that, at a minimum, identifies in detail all activities that will be instituted to successfully implement modifications to its Medical Policy Manual 1250-F Policy, AAC FAQs, and related request review processes as well as its Notice of Adverse Determination letter documentation process to comport with aforementioned federal and state requirements. Completion dates for each identified activity must be specified in the Action Plan. Upon approval of the Action Plan by AHCCCS, DES/DDD shall submit a written narrative as well as relevant data points on a weekly basis (each Monday by 10:00 AM, reflective of the previous work week), outlining AAC device request reviews, determinations, status of outstanding matters, and related processes. Additionally, DES/DDD will identify and designate a core team of staff knowledgeable about AAC requirements and involved in the corrective action efforts who will meet with AHCCCS every two weeks regarding these processes.

Upon completion of re-review of all previous AAC denials as outlined above, and no later than **April 17, 2020**, DES/DDD will submit a full accounting of all decisions made on or after August 1, 2019 to include member first name, member last name, AHCCCS ID number, date of birth, date of AAC request, date of determination, and determination status (approved, denied, pending additional information). AHCCCS will randomly select 30 members for an audit of the determinations. Upon completion of the audit, Subsequently, AHCCCS will determine next steps in regards to DES/DDD's ongoing documentation submission requirements specific to AAC device determinations.

DES/DDD shall submit the Action Plan and all other requested information and reporting to Ena Binns, Operations Compliance Officer, at Ena.Binns@azahcccs.gov. The summary of aforementioned data and information as well as the Action Plan shall be submitted by **close of business on Wednesday, March 18, 2020**.

Failure to address these deficiencies as delineated in this letter may result in additional compliance action in accordance with the Contract, Section D Paragraph 76, Arizona Administrative Rule R9-28-606, and ACOM Policy 408, including but not limited to, imposition of sanctions and/or required use of a third party to conduct reviews/determinations.

If you have any questions or concerns, please contact Jakenna Lebsock at (602) 417-4229 or via email at Jakenna.Lebsock@azahcccs.gov.

Sincerely,

Meggan LaPorte (Mar 4, 2020)

Meggan LaPorte
Chief Procurement Officer
AHCCCS

cc: Dr. Cara Christ, Interim Director, DES
Virginia Rountree, Interim Deputy Director, DES
Lynn Lingwall, Compliance Officer, DES/DDD
Dr. Timothy Peterson, Interim Chief Medical Officer, DES/DDD
Jami Snyder, Director, AHCCCS
Dr. Sara Salek, Chief Medical Officer, AHCCCS
Shelli Silver, Deputy Director, AHCCCS
Dr. Satya Sarma, Medical Director, AHCCCS
Christina Quast, Operations Administrator, AHCCCS
Ena Binns, Operations Compliance Officer, AHCCCS
Brandi Howard, Medical Management Manager, AHCCCS

Appendix A: Required Policy Modification for DES/DDD Policy 1250-F

1. Remove the language on page two that permits the Support Coordinator 15 working days to submit a packet of information requesting equipment to the Health Care Services Unit in the DES/DDD Central Office. Consistent with the federal regulation at 42 CFR 438.210(d), the Division's contract with AHCCCS requires that final determinations on standard service authorizations must be made within 14 calendar days of the request from the provider and expedited requests must be responded to within 72 hours of the request (unless an extension of no more than 14 calendar days is justified for the individual request).

2. Revise page two of the policy so that it clearly states that the mere failure to submit all of the listed items in the packet of information is not a basis for denial of the prior authorization request. The federal regulation at 42 CFR 440.70(b)(3)(v) requires that DES/DDD must use reasonable criteria to assess coverage of medical equipment. It is unreasonable to require production of every item listed on pages 2 and 3 as a precondition of approval. Consistent with 42 CFR 438.210, if the documentation supplied in support of the request is sufficient to establish medical necessity, the request should be approved even if not every item is provided. If additional information is needed, DES/DDD must consult with the requesting provider to obtain sufficient information but should not request information that it not necessary in the individual case to determine coverage.

3. Remove item L from the list of required documentation on page two of the policy. Information regarding the existence of third party liability is irrelevant to the determination of medical necessity. While, under 42 CFR 433.139(b), the probable existence of a liable third party may be a basis for rejecting a claim for payment, it is not an acceptable basis for an adverse benefit determination.

4. Revise the second paragraph on page three of the policy to remove the statement that the Home Health Services unit in the DES/DDD Central Office will either "refer for further evaluation or order the device, as appropriate [sic] within 15 working days of the receipt of the completed packet" and conform the language to 42 CFR 438.210(d). As noted above, final determinations for standard service authorizations must be made within 14 *calendar* days, not working days, of the request from the provider (and not from the receipt of the information packet from the Support Coordinator). Expedited requests must be responded to within 72 hours of the request unless an extension of no more than 14 calendar days is justified for the individual request.

5. Delete exclusions A, B, and E on page three of the policy. As mentioned above, the federal regulation at 42 CFR 440.70(b)(3)(v) requires that DES/DDD must use reasonable criteria to assess coverage of medical equipment. It is not reasonable to require that every individual have "a poor prognosis for the development of oral communication, have the ability to make independent choices, or does not have a history of destructive behavior" as a precondition for coverage. Coverage standards based on the presence or absence of these criteria are not consistent with the EPSDT standard articulated in 42 USC 1396d(r)(5) which contemplates individualized determinations of whether the item will "correct or ameliorate defects and physical and mental illnesses and conditions."

6. Delete exclusion C on page three of the policy. That the item will be used exclusively in an educational setting is not relevant to the coverage determination. Under regulations implementing the Individuals with Disabilities in Education Act, specifically 34 CFR 300.154(b)(1)(ii), the State Medicaid agency (and by extension its MCOs) "may not disqualify an eligible service for Medicaid reimbursement because that service is provided in a school context."

7. Delete exclusion F on page four of the policy. Under 42 CFR 440.70(b)(3)(v), it is not reasonable to require that the item is used in "all settings."

8. Delete Service Provision Guideline F.1. on page four of the policy. Under 42 CFR 440.70(b)(3)(v), it is not reasonable to refuse replacement based on the cause of the need for replacement. That the item was damaged as the result of carelessness does not lessen the need for the item to correct or ameliorate the individual's condition.

Furthermore, AHCCCS strongly recommends modification of the section on page one of the policy entitled "Adaptive Aids (Acute Care Services) to more clearly conform to 42 CFR 440.70(b)(3)(v). That regulation provides that the State (and by extension its MCOs) can have lists of preapproved medical equipment but may not have absolute exclusions and must have processes and criteria for requesting medical equipment not on the list. While item J on page one provides for coverage of any other items determined to be medically necessary, the introduction, which states that coverage is "limited to" the items in the list that follows, could be misinterpreted to conflict with the federal requirement.

In addition, AHCCCS is concerned that DES/DDD is using approval criteria that are not reflected in the current policy. Under 42 CFR 438.404(b)(2), adverse benefit determinations issued by DES/DDD must include the reasons for the adverse determination including the medical necessity criteria and any processes, strategies, or evidentiary standards used in setting coverage limits. AHCCCS is requiring DES/DDD to immediately cease using Medicare coverage standards to make service authorization determinations. While policy 1250-F does not explicitly reference Medicare standards, it has come to the attention of AHCCCS that DES/DDD has issued Notices of Adverse Benefit Determination that cite Medicare standards as the basis for the decision. Under 42 CFR 440.70(b)(3)(ii), DES/DDD may not rely on or cite Medicare standards as a basis for a service authorization decision respective to medical equipment. Similarly, DES/DDD must refrain from issuing denials based on the absence of an ICD-10 code if the individual's diagnosis is clear from the documentation provided. A denial based on the mere absence of an ICD-10 code is not a reasonable criterion under federal regulation. In general, notices should contain information that is specific to the unique circumstances of each request.