Hearing Report and Summary

Hearing Date: 5/29/2018 Today's Date: 6/8/2018

Agency: Ohio Department of Medicaid

Rule Number(s): 5160-10-09, 5160-10-11, 5160-10-13, 5160-10-19, 5160-10-22, 5160-10-23, 5160-10-24

If no comments at the hearing, please check the box. ☐

List organizations or individuals giving or submitting testimony before, during or after the public hearing and indicate the rule number(s) in question.

1. Kam Yuricich/OAMES, all rules except 5160-10-24
2. Beth Mulcahy, 5160-10-24
3. Kimberly Hale, 5160-10-24
4. Sherry Lanyi, 5160-10-24
5. Amy Miller Sonntog, 5160-10-24
6. Pat Schwinn, 5160-10-24
7. Abby Berlin, 5160-10-24
8. Dan Lipka, 5160-10-24
9. Lynn Dudek, 5160-10-24
10. Katie Boarman, 5160-10-24
11. Ane Marie Polovick, 5160-10-24
12. Katie Vargo, 5160-10-24
13. Rachel Dick, 5160-10-24
14. Ann Bohannon, 5160-10-24
15. Stephanie Goetz, 5160-10-24
16. Sandra M Grether, 5160-10-24; 17. Alicia Trax, 5160-10-24; 18. Lewis Golinker, 5160-10-24; 19. Forbes Rehab Services, 5160-10-24

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Consolidated Summary of Comments Received

Please review all comments received and complete a consolidated summary paragraph of the comments and indicate the rule number(s).

Testimony provided support for all rules except 5160-10-24. Many of the objections raised in testimony at the public hearing appear to be directed against an earlier version of the draft rule. Other objections are based on a misreading of the proposed rule.

Comments are addressed in the next section of this hearing report and summary.

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Incorporated Comments into Rule(s)

Indicate how comments received during the hearing process were incorporated into the rule(s). If no comments were incorporated, explain why not.

Rule 5160-10-24, along with rule 5160-10-02, sets forth coverage and payment policy for speech-generating devices (SGDs). Rule 5160-10-24 primarily affects enrolled Medicaid providers of durable medical equipment. The Ohio Department of Medicaid (ODM) met with various SGD providers and SLPs in the development of this rule. Our objective was to provide an acceptable rule that was beneficial to all parties involved, especially the Medicaid individuals who use these items.

Many of the objections raised in testimony at the public hearing appear to be directed against an earlier version of draft rule 5160-10-24. Other objections are based on a misreading of the proposed rule.

ODM has compiled all of the issues from both the written and oral testimonies and is providing a comprehensive response to stakeholders.

Trial Period

The section of the rule that referred to the trial period in the proposed version of rule 5160-10-24(A)(4) stated that payment would not be made until after a minimum four week trial was completed. There was some confusion that this section of the rule meant that authorization would not be made until after the trial period. However, the proposed rule actually stated that a claim for payment could be made after a successful trial period.

There was also some confusion that the trial period meant that the already lengthy evaluation process would be extended by a minimum of four weeks. However, the trial period coincides with the industry's standard 30 day return policy. The industry uses the 30 day return policy to see if the SGD is appropriate for the individual. Once the SGD is deemed appropriate, a claim for payment may be submitted. If the SGD is not appropriate, it is returned to the provider who may submit a request for payment of one month's rental.

Because the term 'trial period' caused so much confusion, it has been eliminated from the proposed rule. After delivery of a SGD, the vendor waits four weeks to see whether the prescribed device works appropriately for the individual. If it does, the provider requests full Medicaid payment. If it does not, the provider takes it back and may request a small Medicaid payment to defray costs.

ODM received testimony that most providers offer a free trial of the SGD device. It also recommended that the SLP should be able to institute a trial period at their discretion. This is not a trial period. It is the first 30 days the consumer receives their SGD. If it is not appropriate, it is returned, if it is found to be appropriate, the provider may bill. The most current language does not prevent ODM from paying the provider for a longer timeframe. It is at the providers' discretion when to bill after four weeks. The proposed rule simply puts a hold on payment to SGD providers until an individual has had a reasonable opportunity to use a device. The rule neither requires SLPs (as prescribers) to conduct a formal trial period, nor does it prevent them from doing so.

The trial period for a SGD is not a new concept. The current rule has a trial rental period. The proposed rule continues a modified version of a trial period, which includes the removal of the

term “trial.” As previously stated, a month was found by industry standards to be a proper minimum amount of time to determine if an SGD is appropriate for the consumer.
In a prior version of the rule, the trial provision added time to the evaluation timeframe. Paragraph (F) in 5160-10-24 was removed from this earlier draft version at the urging of the SLP workgroup that assisted in revising the new SGD rule. The workgroup shared that a trial period shouldn’t last more than a month. The group stated that a month was a sufficient amount of time to make an accurate determination as to whether the SGD was appropriate for the recipient. They informed ODM that, in most cases, an SLP will know by the end of the first month whether a device will be appropriate. The four-week period selected was not an arbitrary decision made by ODM. This change will also effectively end the open-ended trial period that is in the current rule.
The proposed rule does not require a separate prescription for the trial period. This provision existed in a previous draft version of the proposed rule. Again, due to working with the SLP workgroup, this provision was removed from the proposed rule.
In several testimonies, wheelchairs were compared to SGDs. This is an inaccurate and inappropriate comparison. Wheelchairs and SGDs, while they may sometimes serve in concert, address very distinct needs. They also have very different processes to determine an appropriate device that best serves the customer.
Tablets
Based on testimony, many SLPs believe that a tablet cannot perform as an SGD. While ODM agrees that in the majority of cases, a tablet would be inappropriate, ODM currently provides tablets, when medically necessary and prescribed by the practitioner. The current rule is stated in the negative, “a tablet is not covered unless.” The new proposed rule phrases coverage in the positive, “a tablet is covered if.” This rephrasing is not a change in policy, it is intended to clarify current policy.
Although much of the testimony against tablets as SGDs focused on a specific group of children, it was not fully recognized that older children and adults could successfully use a tablet. Normally-functioning adults who lose their ability to speak could easily use a tablet.
ODM believes that tablets do meet the requirements for DME as they generally last 3-5 years. CMS instituted a 3 year time frame for new DME items effective January 2012. As further support to ODMs belief that tablets can serve as SGD in appropriate situations, Tobii Dynavox as just introduced a speech case the transforms a tablet into a true augmentative and alternative communication (AAC) speech tablet.
Other testimonies stated that unlocked tablets are not appropriate for certain children as behavioral issues would arise from having full access to apps and games. Whether to "lock" a tablet (i.e., to restrict its use to a particular software application) is a matter to be decided by the user (or the user's parent) and the health care practitioner, not by the payer of health care claims.
Further along these lines, ODM does not have issue with a child acting as any other child by playing games on their tablet. As many schools provide tablets, this would have a normalizing effect. The child would not have the stigma of carrying around a “special” box. Multiple studies support this idea.
The risk of theft exists for most durable medical equipment. However, it is believed that if the

tablet was being used appropriately as an SGD, the risk of theft would be minimal.
Providing tablets is not a cost saving measure. The intent of the rule is to provide ease of access for the few individuals that qualify for tablets and prefer them over the traditional SGDs, not to replace traditional SGDs. The rule also is not designed to an avenue to substitute SGDs for tablets; this is clearly stated in the proposed rule.
Based on testimony, it appeared that a major point was overlooked. As SLPs are the individuals that prescribe SGDs, they would not have to prescribe a tablet as a SGD.
Evaluation
Testimony was provided that emotions shouldn't be included on the evaluation. The intent was to provide as much applicable information as necessary. In fact, many testimonies included anecdotal evidence of children having emotional and behavior issues that would make them poor candidates for tablets. It is this type of information that is needed. The intent of the rule was for the evaluator to provide the information when applicable. If behavior or emotions are not a factor in the evaluation, then it would need to be included. We have changed to wording to clarify this.
It is correct that trials must be completed on the same type of equipment recommended. It would be incorrect and inappropriate to trial an individual on an SGD that is not the same type of SGD that the individual would receive. This is why the rule stated, "Payment may be made only for the type of SGD used by an individual during a trial period. No item can be substituted for one that has been explicitly prescribed." Since the public hearing, the rule has been updated to state, "Payment may be made only for the type of SGD prescribed. Substitution (e.g., provision of a tablet instead of a standalone unit running proprietary software) requires the approval of the prescriber."
Rule Mechanics
The reconstruction of OAC 5160, Chapter 10 was completed to provide accurate, consistent information. The repetition of the same information in each rule is unnecessary. With the format to only include definitions in the -01 rule, only one rule would need to be changed instead of making changes to 20 plus rules. As the proposed rules are written, deviations from rule 5160-10-01 are called out in the specific rule.
Each specific rule includes specific information regarding said rule. It is unnecessary and redundant to spell out the same procedures in each individual rule. Specific prior authorization designations of items will be found on the supply list located on the ODM website.
The proposed rule does not state that someone needs to prove that an SGD is beyond repair. The proposed rule states that an upgrade, modification, or replacement will only be made if the current SGD no longer meets the individual's basic communication needs. It further states that useful life is the frequency limit (5 years). Replacement during the useful life is only considered when it is more cost effective than modifying the device, repair does not extend the useful life of the device.
Testimony stated that the rule only offers mounting equipment for wheelchairs. This is incorrect. The section of the rule immediately following the wheelchair reference covered all other applicable areas. However, for further clarity, we rewrote this language and removed the reference to wheelchairs.
Human Rights Violations/Free Speech/Disability Discrimination

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Several testimonies stated that the proposed rule violates human rights and free speech. These ideas were presented in a combination of disputing the 1/5 year frequency and the repair rule. ODM bases decisions on medical necessity and does not discriminate in the provision of services.

Multiple testimonies also stated that ODM is discriminating against the disabled, accusing ODM of disability discrimination. The question asked was in reference to the frequency limit of 1 every 5 years. ODM was asked if we ask "typical non-disabled individuals to wait 5 years and, now more, to have new phones, laptops, technology…" The answer to this is "no." ODM does not provide disability items to the able bodied. Non-disabled people do not qualify for items intended for the disabled. ODM follows the DME guidelines provided by CMS, one being that if the item is not useful in the absence of a medical condition or illness, it is not considered DME. Tablets are not for everyone. They may be appropriate for only a small percentage of individuals who lack vocal communication. But if a SLP determines that a tablet is appropriate for a particular individual (e.g., an adult who has had a laryngectomy), it would be inappropriate for Medicaid to force that individual to carry around a proprietary standalone SGD.

Family Reimbursement

The second concern that the rule does not provide a procedure for how a SLP requests a family to be reimbursed is unfounded. It is not the responsibility of an SLP to make sure a family gets reimbursed. More accurately, a family does not get reimbursed, the provider receives payment from ODM after the device is provided to the consumer. The decision for an AAC vendor to provide tablets or not is a business decision. There are providers who currently provide tablets. The current rule does not explain how a SLP requests a family to be reimbursed, nor does it provide instructions on where to go to obtain a SGD.

Analysis

An analysis was provided in testimony stating that providing tablets would be an increase in expenditure and that ODM was incorrect about the budget remaining neutral. However, as understood by ODM, the testimony presented used a hypothetical amount of approved tablets on top of the same approval amount of traditional SGDs to demonstrate how ODMs expenditure would increase with the addition of tablets. However, if ODM approved this hypothetical amount of SGDs, that would mean that the same number of traditional SGDs were not approved. This would result in a decrease in ODMs expenditure and would potentially save money as SGDs are much more costly than tablets.

We expect that few -- if any -- software applications running on a tablet or laptop computer will be prescribed during this biennium. Rule 5160-10-24, however, allows for the possibility. The goal of the rule is to expand access to advancing technology, not to save what amounts to a few pennies on a budgetary scale.

Conflicting Testimonies

Several testimonies were contrasting or conflicting. One issue was the limit frequency of a SGD. While the proposed rule has not changed the frequency limit, this was the subject of multiple testimonies. It was stated that the 1 in 5 years frequency limit was too long for SGDs. Testimony was provided to support this statement by sharing several instances that ODM provided new SGDs at 3 years instead of 5 years. However, other testimony state that tablets only last 3 years and couldn't meet the 5 year requirement.

Another issue was in regards to the durability of SGDs. It was shared that SGDs go through rigorous durability testing. Yet testimony against the repair rule stated that SGDs were fragile and needed repairs more than twice a year.
Testimony essentially stated that SGDs need a lower time limit frequency of 3 years and that tablets need to be held to a 5 year frequency limit.
Written testimony suggested that ODM pay for loaner SGDs. However, testimony against the misunderstood trial period stated that there were not enough loaner SGDs to make this feasible.
Removed items/Phrasing/Structure
There were requests to include rule language that was previously deleted from the current rule. ODM was requested to return the conflict of interest section. ODM does not believe that we need to include the language regarding conflict of interest. As we were reminded during testimony, SLPs are professionals. This provision is stated by their licensing board in rule 4753-9-01(A)(2)(e). ODM believes there is no practical reason to restate this.
Another request was to return the SGD definition to the proposed rule. ODM does not believe it is prudent to maintain the SGD definition. A definition is both inclusive and exclusive by nature. With evolving technological advances, ODM does not want to inadvertently exclude new items. Additionally, the industry definition is accepted as the standard.
ODM was also requested to include the DME definition in the proposed rule. As this definition is easily located on the CMS site and other places, it is somewhat redundant and ODM does not believe that it is necessary to include it in the proposed rule.
One testimony included the request include the term SGD instead of “item” in rule. The SGD rules only speaks to SGDs and rule 5160-10-01 includes any DME item. ODM believes the current wording is efficient and sufficient.
Included in this same testimony was the request to return the procedural instructions to the proposed rule along with listing, in rule, all of the changes that were made. ODM does not believe that this is appropriate. All of the common procedural instructions have been removed from all chapter 10 rules and consolidated into proposed rule 5160-10-01. Any specific procedural instructions would be found in the relevant rule. We follow specific guidelines to describe our rule changes. A description of rule changes can be found in ODM’s Medicaid Transmittal Letters (MTLs)
While ODM is attempting for provide clarity in the proposed rule, we are also attempting to keep the rule language simple and concise. It was found in testimony that the proposed rule states that ODM will no longer cover SGDs. ODM is unsure of how this is read into the proposed rule. If ODM was eliminating coverage of SGDs, we would not create a proposed rule for SGDs.
It was also requested that ODM return the statement that SGDs are reimbursed according to the appendix DD to rule 5101:3-1-60. This is not possible as ODM has removed all DME items from appendix DD to rule 5160-1-60 (formerly 5101: 3-1-60) and transferred all of these items to OAC rule 5160-10-24
Rule 5160-10-02 Repair vs Replacement
We received testimony that ODM would not pay for the same repair more than twice in the same year. The testimony was incorrect, ODM will not pay for repairs for a duplicate item.
The life expectancy of a proprietary standalone SGD is 3-5 years. The life expectancy of a tablet

running SG software is 3-5 years
Paragraph (B)(5)(b) of new rule 5160-10-02 concerns two separate items, not the same item: "No separate payment will be made for...[r]epair of an item if within the preceding twelve months the department has paid for the repair of a duplicate or conflicting item currently in the recipient's possession, regardless of payment or supply source."
We received testimony stating that batteries are a common repair item and would be replaced more than twice a year. Batteries are not repaired, they are replaced. Batteries would fall under supplies. This would not be a repair issue.
Rental/Loaner
ODM received a request to return long term rental to the proposed rule. ODM does not believe that long term rental serves a practical purpose. Purchase is made at 10 rental payments, at that point, the customer owns the SGD. If the person only requires an SGD for a few months, then a tablet could be appropriate.
ODM does not currently pay for loaner devices. This same principle is used for wheelchairs.
We appreciate your interest in this rule and hope the revisions we have made to the rule are helpful to address any remaining issues.