

<b>DMEPOS PROPOSED REGULATIONS: QUESTIONS</b>		<b>RESPONSES</b>
1.	<p>What is the timeline for these regulations to be implemented? When will the new fee schedule take effect? When will these changes be reviewed?</p>	<p>Regulatory packages go through a defined process. Information on the regulatory process may be found at:  <a href="http://www.law.alaska.gov/doclibrary/drafting_manual.html">http://www.law.alaska.gov/doclibrary/drafting_manual.html</a></p> <p>Once the public comment period closes, it could be estimated that the final effective date might be somewhere between 3 to 6 months from closing. This date range is dependent upon a number of factors.</p> <p>Written comments received during the public comment period are carefully considered, including comments on costs of compliance to private persons. Substantive changes may require an additional public comment period to ensure the public has an opportunity to review the changes. While this may extend the length of time to adoption, it is an important step in the process.</p> <p>The fee schedule is part of the regulatory package and will be adopted by reference when the final version of the proposed regulations is filed by the Lieutenant Governor.</p>
2.	<p>All base prostheses billing codes would require prior authorization.            What is the thought behind this change?            These codes are required for use with new amputees.</p>	<p>The intent of the regulatory change was not to expand P&amp;O service authorization requirements, only to maintain the service authorization requirement for Durable Medical Equipment (DME) over \$1,000 per item. Consideration will be given to exclude specific prostheses billing codes from service authorization in the final revision of the fee schedule; the proposed fee schedule will be updated to reflect such changes.</p>
3.	<p>L2820 and L2830 extend the life of an orthosis and avoid making a new one when all that is required is a new interface to protect the patient's skin. This does not exceed the price of a new orthosis but is a common need in our active and remote population.            Why are these codes excluded?</p>	<p>Medicare rules were consulted in the decision to propose exclusion of these replacement components. Based on comments received, consideration will be given to allow coverage in the event the component becomes worn. The proposed fee schedule would be updated accordingly to reflect the change.</p>

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4.	<p>Who will be communicating these decreased quantity limits to the recipients?</p> <p>Are they to purchase their additional quantity or will there be a DHSS process in place to submit a PA for additional quantity? What additional information would be required for what is now considered over-utilization?</p>	<p>Program changes are communicated to recipients through multiple means including public notice of regulations, communications to enrolled providers through remittance advice messages, provider billing manuals, other publications, and posting of program rules on the program’s site. The Department will utilize a communication plan to disseminate the information once final regulations are adopted.</p> <p>The Department has maintained an avenue for situations where clinical needs support medical necessity of utilization beyond the proposed limits. Under 7 AAC 120.210(b), a “service authorization is required for ... (2) medical supplies that exceed the maximum units or a 30-day limit set by the Department.” For example, T4528 ordered at 150 units per month or less will not require a service authorization, but T4528 ordered at 210 units per month would require a service authorization. Under current regulation, T4528 requires service authorization regardless of the amount ordered. The intent of this change is to decrease administrative burden on the provider. A CMN (Certificate of Medical Necessity) will continue to be required.</p>
5.	<p>Is DHSS going to modify the current incontinence CMN to include the additional requirements?</p>	<p>The Department will work to ensure that any necessary changes that are needed on associated forms are made to comply with adopted regulations. Revised forms will be made available on the Enterprise web portal for ease of access.</p>
6.	<p>If these regulations are adopted, the savings to the state, will be 300K per year. How did you arrive at this number?</p>	<p>The Department estimates the proposed changes will result in an increase of \$400,000 to the Medicaid DMEPOS budget. This increase is primarily attributed to an increase in the reimbursement rates for Prosthetic and Orthotic codes of approximately 20% above current reimbursement rates. DME and Medical Supply code reimbursement may see an increase of up to 10% on some codes but smaller increases on other codes. The estimated increase to the budget was based on an evaluation of historical billing patterns against the proposed reimbursement rates.</p>
7.	<p>Was there any consideration given to the limited access that may not be available for certain lines of DME such as hospital beds, sleep equipment, wheelchairs and custom mobility if these regulations are implemented? Where will the custom mobility recipients obtain service if we are unable to support these regulations?</p>	<p>The Department attempts to balance patient access with fiduciary responsibility when proposing regulatory changes and is open to comments and suggestions on areas where access may be impacted in the proposed regulations. Providers are encouraged to provide specific comments during the public comment period to further inform regulation development.</p>

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8.	Why are chairs that are upfront purchase with Medicare not the same with Medicaid? What happens with rentals for patients who lose their Medicaid coverage during the rental period?	The Department will give consideration to alignment with Medicare's Purchase Option of Capped Rental Items guidance, including Complex Rehabilitative Power Wheelchairs and Standard Power Wheelchairs. Providers are encouraged to provide specific comments with regards to the proposed capped rental regulations during the public comment process to further inform regulation development.
9.	What methodologies were used to arrive at the new volume levels?	The Department used multiple tools to arrive at the new volume levels, including NCCI MUE (National Correct Coding Initiative Medically Unlikely Edits) rules, review of other state quantity limits, historical claims review, and scoping meetings where information and suggestions were offered by providers.
10.	Why has there been a requirement added that only new equipment can be rented out to Medicaid recipients? This is not in line with Medicare's requirement of new or like new equipment, which can be provided as long as it has an RUL of 5 years.	The proposed changes to the regulations adds the clarifier to the existing regulation that the provider need not replace the item with a new item if a used or refurbished item was used in compliance with 7 AAC 120.299.  The proposed regulations state in 7 AAC 120.215(c): “(2) replaces the item with a new item if it was previously used by a person other than the recipient before it was rented to the recipient , <b>unless the item is used or refurbished equipment, as defined in 7 AAC 120.299, and is billed to the department as such in compliance with this section.</b> “
11.	How did you arrive at the cost plus percentages that are in these regulations for codes not priced?	The Department worked with the Office of Rate Review to align reimbursement with national pricing while providing a sustainable reimbursement structure. Providers are encouraged to consult the Medicare Pricing, Data Analysis and Coding site (PDAC) and the corresponding DMEPOS Product Classification List to ensure the appropriate HCPCS code is being used when billing for a specific product.
12.	What is the plan for pediatric patients under 3 that are needing specialized formulas? What about the current recipients receiving them?  Can patients over the age of 18 receive pediatric formulas if medically necessary?	The Department did not intend for an age restriction for medically necessary specialized “formulas” and it is not included in regulation text. The proposed fee schedule will be updated to clarify.  The service authorization process will be available to evaluate situations where medical necessity is demonstrated by the prescriber.
13.	For incontinence products, specific products have an age limitation which seems arbitrary since fit is more closely aligned with weight. What about the exceptions to the age limitation for these products?	Under the proposed regulations, the Department is not requiring service authorization for incontinence products that conform to the criteria posted in regulation and the corresponding fee schedule. For exceptions to the criteria for incontinence products, the service authorization process will be available to evaluate situations where medical necessity is demonstrated by the prescriber.

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14.	Was the state aware that eliminating higher allowables for T and B codes, would eliminate providers' ability to supply them? Are you eliminating cost plus 40% for these products?	<p>In reviewing historical claims submittals for B and T codes, it was observed that a significant amount of time was required by providers to submit additional paperwork to justify higher allowable requests within this category. Therefore, the Department is proposing a reimbursement rate structure that takes into account the higher acquisition costs of products within these categories that would allow claims to process and pay at the time the claim is submitted. The result minimizes manual intervention, thus increasing claims processing efficiency, decreasing time to reimbursement, and decreasing the administrative burden on the provider.</p> <p>Providers are encouraged to provide comments on specific products of concern, including proposed reimbursement of those products, during the public comment process to further inform regulation development.</p>
15.	Are providers limited to supply only the brand name products listed in the enteral fee schedule?	<p>Enteral products are not restricted to the listed products. Enteral products supplied must be billed with the appropriate HCPCS code. A provider may bill B4161 with the "CG" modifier if the product dispensed is listed on that line of the fee schedule. For example, Elecare® may be billed as B4161 CG.</p> <p>The Product code/NDC is required on all enteral claims which allows the system to calculate the appropriate pricing at the time of claim submittal.</p>
16.	<p>HCPCS code B4104 shows "EF additive, fiber" will not be covered. What does this mean?</p> <p>Will Medicaid coverage for the Promote with Fiber product be stopped? If so, what is the rationale for the change?</p>	<p>The products under HCPCS code B4104, which are items that might be added to a complete enteral formula (e.g., extra fiber), would not be covered under the proposed regulations.</p> <p>The Department will continue to cover commercially available products that include fiber in their formulations, such as Promote with Fiber which is billed under B4150.</p>
17.	With the proposed movement to A6250 and A4335 by NDC unit, is pricing set by NADAC? What is the pricing proposed for these items? Is it now billing by the ounce or bottle? How do I determine the reimbursement for A6250 products?	<p>The per-NDC units rate for items covered under A6250 is based on WAC unit pricing effective on the date of the fee schedule. For creams, ointments, pastes, and powders, the NDC unit is grams; for solutions, sprays, gels, cleansers, and lotions, the NDC unit is milliliters (mL). Providers must submit both the HCPCS units dispensed and the correct NDC units on the claim. Correctly submitted claims will not require manual pricing, thus making the claims processing for these items more timely and efficient.</p> <p>Items covered under A4335 require manual pricing.</p>

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18.	There are codes that are currently being used that right now have no price listed. What does that mean (e.g., A4466, A4435)?	In the transition to the new fee schedule structure, the Department utilized "\$0.00" in the reimbursement field to represent what is currently understood as "By Report". Further information on how reimbursement will be determined may be found in the proposed regulations under 7 AAC 145.420(c).
19.	There are no maximum units listed for gloves on the fee schedule, is this correct?  Can gloves be dispensed to individuals residing in Assisted Living Facilities?	Thank you for bringing this oversight to our attention. The Department will consider appropriate utilization measures on this product.  As per guidance distributed on March 10, 2016, the cost of gloves used by employees of an assisted living home in the provision of care for a Medicaid-eligible resident are the responsibility of the employer and are not separately reimbursable to the durable medical equipment (DME)/medical supplies provider by the Alaska Medicaid program. <a href="http://manuals.medicaidalaska.com/docs/dnld/Update_Policy_Clarification_Gloves.pdf">http://manuals.medicaidalaska.com/docs/dnld/Update_Policy_Clarification_Gloves.pdf</a>
20.	Can a patient pay cash if they want to replace or repair an item more frequently than what is allowed by Medicaid?	The Department does not currently have specific regulations restricting a patient from paying cash for replacement items; however, a provider may not influence a patient to pay cash for items. If the patient is a dual eligible recipient, it is expected that the provider would ensure compliance with Medicare rules. Providers are encouraged to refer to 7 AAC 105.400 for additional information.
21.	Why doesn't E0241 say "installed"?	The Department has maintained the formal HCPCS long description for E0241 as "Bath tub wall rail, each" on the fee schedule for consistency. No change to the expectations for this HCPCS has been proposed with the regulations.
22.	Why are some of the wheelchair codes listed as replacement only when CMS allows on initial set up?  Why are some of the wheelchair codes listed with only one unit max allowable (e.g., arm rests)?	Medicare rules were consulted in the decision to reduce the possibility of unbundling of these replacement components. Based on comments received, consideration will be given to allow coverage of these items at the initial set up. The proposed fee schedule would be updated accordingly to reflect the change.  Thank you for bringing this example to our attention. The Department will review the variations and consider modifications to the proposed fee schedule. The fee schedule would be updated accordingly to reflect the changes.
23.	Why are some of the OTS (off-the-shelf) orthotics that should be allowed to be dispensed by DME providers not listed on the proposed fee schedule?	Thank you for outlining this concern. The Department will review the variations between current allowances and proposed allowances that have been identified and consider modifications for these products. The proposed fee schedule would be updated accordingly to reflect any change.

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24.	Is an Incontinence CMN (certificate of medical necessity) still required to be completed even if the incontinence supply doesn't require an SA (service authorization)?	Yes, an incontinence CMN would still be required to be completed by the Medicaid enrolled ordering prescriber. The CMN is to be kept on file by the Medicaid enrolled Medical Supply company providing the incontinence supplies to the recipient.
25.	What does it mean by replacement standard for used DME?	<p>The proposed regulation change is intended to align with the federal definition of "reasonable useful lifetime" (RUL) for DME outlined in 42 CFR 414.210(e)(4) and 42 CFR 414.210(f)(1). While Medicare historically considered the reasonable useful lifetime of DME to be no less than 5 years, with the updated definition of DME in 42 CFR 414.202, the Department took into consideration the environment within which the equipment is being used and has proposed a 3 year reasonable useful lifetime in lieu of the historically stricter 5 year RUL.</p> <p>42 CFR 414.202 – Definitions  <i>"Durable medical equipment"</i> means equipment, furnished by a supplier or a home health agency that meets the following conditions:  (1) Can withstand repeated use.  (2) Effective with respect to items classified as DME after January 1, 2012, has an expected life of at least 3 years.  (3) Is primarily and customarily used to serve a medical purpose.  (4) Generally is not useful to an individual in the absence of an illness or injury.  (5) Is appropriate for use in the home."</p>

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<p>26. Could AK Medicaid have a voucher program, for incontinence supplies, so that consumers could get their incontinence supplies from a store, as they need them, instead of a full month's supply all at one time?</p>	<p>The Department appreciates suggestions for innovative methods for providing services and continues to research multiple avenues. Under current and proposed program rules and regulations, members are not required to take receipt of a full month's quantity of incontinence supplies when the recipient has a portion of the previous month remaining. Dispensing a full month quantity of incontinence supplies, when the recipient has a significant amount of supplies left, might place an undue burden on the member.</p> <p>Current regulations state under 7 AAC 120.200(l)(1) that a provider must document the recipient's request for a 30-day refill, but if the recipient has stock on-hand, the quantity requested by the recipient and supplied by the provider does not need to equal a 30-day quantity. For example, if the recipient has been authorized 5 briefs per day and has 50 briefs on-hand (equating to 10 days), the 30-day refill request may be for a quantity of 100 briefs (20 days). This quantity request would mean that the recipient would have 30 days of stock on-hand and not need a refill again for 30 days, thus satisfying current regulation.</p> <p>Under proposed regulations, the Department is using the opportunity to clarify this point by encouraging providers and members to communicate about the needs of the patient, including communicating the amount of stock on-hand. Members may continue to request only the supplies that are needed for that month, within the approved 30 day quantity limits noted on the fee schedule or authorized via a service authorization, under the new regulations.</p>
<p>27. In section 7AAC 120.200 (w), you state that the prescriber's wet or authenticated digital signature can not be a copy or a signature stamp or it will not be accepted; however, we receive most of our referrals by fax. Will a faxed referral be accepted?</p>	<p>A faxed signature of the recipient's prescriber is acceptable as long as it is derived from the original signature and not a stamp or copy. The prescriber must maintain a copy of the signed incontinence prescription in the recipient's health record, per regulation 7 AAC 120.200(q).</p>
<p>28. In proposed section 7 AAC 120.210(b)(3), it states that a service authorization must be made for customized durable medical equipment. Are prosthetics and orthotics included in this umbrella of DME in this context?</p>	<p>The referenced proposed regulation, 7 AAC 120.210(b)(3), is outlined under current regulation in 7 AAC 120.210(b)(4). No change to the interpretation of this item is implied with the renumbering. Prosthetics and orthotics are not considered DME in this context. Please refer to the proposed fee schedules for additional information on items requiring service authorization as well as referencing question #2 above.</p>

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<p>29. Orthotics and prosthetics are not refillable items. We are curious as to why the following regulation is included in this section as it is not something that is provided by prosthetics and orthotics. Why is the following regulation included in this section?</p> <p><i>7 AAC 120.200 Section (l)(1): “document and maintain record of recipients request for a [30-DAY] refill”</i></p>	<p>Thank you for your question. The section referenced (7 AAC 120.200(l)) exists in current regulation to outline general provisions under the Durable Medical Equipment and Medical Supplies; Related Services category.</p> <p>The proposed regulation under 7 AAC 120.200(l)(1) removes the term “30-day” from the regulation. Since refills are not standard to orthoses and prostheses, the impact of this change to prosthetic and orthotic providers would be minimal.</p>
<p>30. One of the proposed changes states:</p> <p><i>7AAC120.200 Section (r): “A provider enrolled under this section may not make unsolicited contact with the recipient of medical assistance under 7AAC 100 for the purpose of marketing the providers products or services.”</i></p> <p>Does this include follow up calls?</p>	<p>The Department encourages providers to follow up with the recipients to ensure that the items the provider has dispensed are functioning in a manner that meets the prescribed need(s) and/or specifications. Such activities are considered part of the provision of care for recipients. For the purpose of this regulation change, follow up phone calls on services being actively provided are not considered to be unsolicited contact with the recipients.</p>
<p>31. The proposed regulations in 7 AAC 120.200(s)(4) state that the order must contain the directions or instructions for use including frequency. What is the purpose of having the prescribing physician state these directions and is it really necessary on the prescribing order?</p>	<p>The Department agrees that while there are specific orders that necessitate a frequency to be included by the prescriber (e.g., medical supplies such as diabetic test strips, wound care, incontinence products, etc.); there are situations where a frequency may not be specifically relevant to the order. The Department will consider this in final revisions.</p>
<p>32. The proposed regulations state that the CMN may not be prepared by a supplier of durable medical equipment for the prescriber. How does the Department intend for that to work?</p>	<p>The intent of the proposed regulations is to align regulatory language with the current CMN process which designates which fields can be processed by which professionals. The prescriber is responsible for the content of the CMN as attested by his or her signature which includes authorizing a specific treatment plan which may be contributed to by an authorized professional.</p>

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33.	<p>The proposed regulations remove therapists as prescribers. How will this affect me? Will I no longer be able to provide splints to recipients?</p> <p>Is the physician or other prescriber supposed to orient and train patients on items I supply under their order?</p>	<p>Thank you for the thoughtful questions regarding the proposed regulations to remove language that references physical therapists, occupational therapists and speech language pathologist as prescribers. This proposed update to the regulations is to align the language in the DMEPOS regulations with therapists' scope of practice and other regulations referencing therapists under Medicaid (e.g., for Occupational Therapy refer to 7 AAC 115.110(a)). Since therapists don't prescribe but rather provide services to recipients under order of a prescriber (physician, PA-C, ANP), this proposed change is introduced to reconcile this discrepancy.</p> <p>As the provider of the service, it is appropriate for the therapist to provide the orientation and training versus the prescriber.</p>
34.	<p>What is the WAC unit pricing and where can I find that information?</p>	<p>WAC stands for Wholesale Acquisition Cost. The WAC, similar to AWP (Average Wholesale Price), is set by the manufacturers and reported to databanks such as First Data Bank and Medispan. The WAC is generally the average cost of the product to wholesalers. Currently, DME items that are covered under HCPCS A6250 and A4335 are reimbursed based on AWP (Average Wholesale Price).</p>
35.	<p>In the SFY2017 DMEPOS Fee Schedule I do not see the incontinence supplies listed (such as T4528=adult brief). Where can I find the new pricing for these items?</p>	<p>The Department has divided the fee schedules into 4 separate documents based on category. The categories are as follows:</p> <ul style="list-style-type: none"> <li>Table I-5 = DME and Med Supplies</li> <li>Table I-6 = Prosthetics and Orthotics</li> <li>Table I-7 = Incontinence</li> <li>Table I-8 = Enteral</li> </ul> <p>The adult briefs (T4528) may be found on Table I-7.</p>