10-144 C.M.R. Chapter 101, MaineCare Benefits Manual
Chapter II, Section 60, Medical Supplies and Durable Medical Equipment

Summary of Public Comments and the Department's Responses
And List of Changes Made to the Final Rule

The Department of Health and Human Services (Department) held a public hearing on August 2, 2023. Written and verbal comments were accepted through August 12, 2023. Comments were received from the following people:

Table of Commenters

1. Catherine Hamilton, President & CEO, Home Medical Equipment and Services Association of New England (HOMES), Orono, ME
2. Diane Racicot, MBA, RD, Vice President, Payer Relations North Division, National Seating & Mobility, Chattanooga, TN
3. Kelly Hassett, Vice President, Operations, MedCOR Professionals, Scarborough, ME
4. Marc DeMarie, Senior Manager, Payor Strategy & Contracting, Bedard Pharmacy &Medical Supplies, Auburn, ME
5. Tawney Clark, Senior Corporate Account Manager, Health Plans Solutions, Medtronic, Northridge, CA

Summary of Comments and Responses

1. **Comment:** Commenter 1 commented that the definition of "Medical Supplies" in Section 60.01-6 should refer to a more commonly supplied item, such as incontinence supplies, including catheters or absorbent products, because it would make the definition clearer.

   Response: The Department thanks the commenter for the comment. The examples in the definition are of items that are not "Medical Supplies," so it would be inappropriate to add the suggested examples. No changes to the final rule were made because of this comment.

2. **Comment:** Commenter 1 commented that the Department should add a definition for "complex rehabilitation technology."

   Response: The Department thanks the commenter for the comment. The term "complex rehabilitation technology" does not appear in the rule, and, thus, does not need a definition. No changes to the final rule were made because of this comment.

3. **Comment:** Commenter 1 expressed concern that the Department, in Section 60.04(4), added an exception to allow the Department to waive the storefront requirement at its discretion for the benefit of the program. The commenter noted if the intent is to sole source a product, the Department should include stakeholders in discussion. The commenter also relayed that there are many MaineCare members who are particular about who they receive products and/or services from, which should be considered before any changes to product categories. The commenter also commented that they would like the Department to make them aware when provider adequacy is a concern for products for members.

   Response: The Department thanks the commenter for the comment. This change will expand members' access to medical supplies and durable medical equipment (DME) that are not

available through in-state providers. The Department frequently consults with in-state, enrolled MaineCare providers to connect members with medical supplies and DME and to determine what medical supplies and DME are available in-state. No changes were made to the rule because of this comment.

4. **Comment:** Commenter 1 commented that, in regard to Section 60.04(5), that "concern exists with this section as relates to specialty modified low protein foods and formulas for the purpose of billing the Department as the supplier of prescription metabolic foods."

   Response: The Department thanks the commenter for the comment. The content in the new Section 60.04(5) provision previously existed in Section 60.01-12. The Department created the new provision for clarity, and there is no substantive change. Since the commenter did not include specific concerns, no changes were made to the rule because of this comment.

5. **Comment:** Commenter 1 expressed concern about the requirement, in Section 60.06-2(J), which requires the prescribing provider to maintain documentation that includes a statement verifying the date of the face-to-face encounter. The commenter noted the Section 60 provider has no control over the face-to-face encounter and that the requirement seems better placed in a section of policy that relates to physicians and other prescribers.

   Response: The Department thanks the commenter for the comment. The Department made minor edits for clarity in this provision but did not make substantive changes to the requirement. In addition, the provision only requires Section 60 providers to maintain documentation that includes a statement verifying the date of the face-to-face encounter and the name of the qualified provider who conducted it, both of which are within Section 60 providers' ability to do. No changes were made to the rule because of this comment.

6. **Comment:** Commenter 1 asked, regarding Section 60.06-3(F), "if the provider must retain documentation of equipment being able to pass freely through all entryways or that modification is complete prior to authorization, wouldn't it be preferred to state that all equipment, as applicable, needs to freely pass through all entryways?" In addition, the commenter expressed concern that a member may need to remain without equipment and/or remain in inpatient or residential care if repairs and/or modifications are unable to be completed on time. The commenter also expressed concern about the limited availability of contractors throughout the state.

   Response: The Department thanks the commenter for the comment. The only substantive change in Section 60.06-3(F) is to require providers to retain, rather than submit, documentation. The Department will not remove the unchanged documentation requirement and the new requirement to retain the documentation. These requirements also align with Medicare requirements, which the Department regularly considers and adopts for consistency and ease of provider processes and member access. No changes were made to the rule because of this comment.

7. **Comment:** Commenter 1 asked for clarification on the intent to rent and purchase DME consistent with Medicare practices in Section 60.06-4. The commenter agreed with the provision in theory but asked the Department to modify the language to ensure that accessories billed separately for complex wheelchairs be purchased items, along with the base chairs. The commenter noted these are customized products, so it is not practical to provide the same product to another individual as a rental, nor is it practical to retrieve provider-owned accessories from a member-owned wheelchair.

Response: The Department thanks the commenter for the comment. The Department, in alignment with Medicare, will make accessories and options for complex rehabilitative wheelchairs available for purchase. The Department will not add more specific language because the current language is sufficient and Medicare rental and purchase practices may change in the future. No changes were made to the rule because of this comment.

8. **Comment:** Commenter 1 asked whether there will be any changes to the current 13-month capped rental process and/or payment rates.

   Response: The Department thanks the commenter for the comment. The Department is not contemplating any process changes at this time and will reimburse providers using rates set by the reimbursement methodology in Section 60.10. No changes were made to the rule because of this comment.

9. **Comment:** Commenter 1 commented that MaineCare currently makes code E0730 available for purchase, and providers may choose to no longer provide this device for non-narcotic pain management for MaineCare members, creating a gap in a service currently providing positive results.

   Response: The Department thanks the commenter for the comment. In alignment with Medicare, the Department makes code E0730 available for purchase. No changes were made to the rule because of this comment.

10. **Comment:** Commenter 1 commented that they appreciate the replacement DME policy in Section 60.06-7 but requested that the Department allow providers to deliver medically necessary equipment at the expense of the member in recognition of Medicaid being the payer of last resort.

    Response: The Department thanks the commenter for the comment. Providers may charge MaineCare members for non-covered services in accordance with Chapter I, Section 1.06-4. No changes were made to the rule because of this comment.

11. **Comment:** Commenter 1 suggested the Department adds a caveat to Section 60.06-7 to allow the Department to reimburse for new equipment that would improve a member's condition but was not available at the time the original equipment was delivered.

    Response: The Department thanks the commenter for the comment. Providers may submit a prior authorization for new equipment that would improve a member's condition, even if the member has functional equipment that serves the same purpose. The outcome of the prior authorization review will depend on the specific equipment and needs of the member. No changes were made to the rule because of this comment.

12. **Comment:** Commenter 1 recommended the Department implement "opportunities to maintain a complex wheelchair in functional order at the end of a 5-year RUL, with reimbursement for repairs, if needed, as well as allowing a new complex chair to be provided at the same time." The commenter relayed that this is advisable because of the delays in obtaining repair parts due to supply chain issues and costs. The commenter also noted that other states in New England are discussing or implementing a similar program.

    Response: The Department thanks the commenter for the comment. This comment is outside the scope of this rulemaking. No changes were made to the final rule because of this comment.

13. **Comment:** Commenter 1 asked if MaineCare would approve a new wheelchair with an appropriate accessory if a member needs an accessory to a wheelchair that is now obsolete.

    Response: The Department thanks the commenter for the comment. This comment is outside the scope of this rulemaking. No changes were made to the rule because of this comment.

14. **Comment:** Commenter 1 commented that subsequent pages following Section 60.07 have "60.06…..(cont.)" in the header.

    Response: The Department thanks the commenter for the comment. The Department corrected these incorrect headers.

15. **Comment:** Commenter 1 commented that they are concerned Section 60.08-8 is duplicative of Section 60.06-3(F). The commenter asked the Department to clarify if Section 60.06-3(F) pertains to all other DME, such as semi-electric beds, and, if so, clarify if the equipment must clear doorways while fully assembled. The commenter also asked the Department to clarify why an exemption for home modification exists for wheelchairs in winter months but not for other DME.

    Response: The Department thanks the commenter for the comment. The two Sections are not duplicative. Currently, power mobility devices and manual wheelchairs are the only equipment that must freely pass through all entryways, which is why Section 60.08-8, Power Mobility Devices, Power Operated Vehicles, and Manual Wheelchairs, contains the exemption. No changes were made to the rule because of this comment.

16. **Comment:** Commenter 1 asked the Department to clarify if Section 60.08-8 includes complex rehabilitation technology because they are typically differentiated by Medicare and other payers. The commenter requested that the Department include "complex rehabilitation technology" in Section 60.08-8 if the Section is supposed to be all inclusive.

    Response: The Department thanks the commenter for the comment. Section 60.08-8 contains requirements that pertain to all power mobility devices, which includes complex rehabilitative power wheelchairs. Since Section 60.08-8 does not contain specific requirements for complex rehabilitative power wheelchairs, there is not a need to call out that specific category of wheelchair. No changes were made to the rule because of this comment.

17. **Comment:** Commenter 1 commented, "For POV upgrading to Power Wheelchair – Should the member have documented awareness of three years without an upgrade to Power Wheelchair and the physician documented that no significant deterioration of condition is anticipated, yet the deterioration occurs, is there a mechanism for exemption to the upgrade to Power Wheelchair?"

    Response: The Department thanks the commenter for the comment. This comment is outside the scope of this rulemaking. No changes were made to the rule because of this comment.

18. **Comment:** Commenter 1 observed that the trial requirement that was in Section 60.06-8(D) is now in Section 60.08-11 and asked if the Department only made the change to house the requirement in the new location.

    Response: The Department thanks the commenter for the comment. Yes, the purpose was to move the requirement to a more appropriate Section. No changes were made to the rule because of this comment.

19. **Comment:** Commenter 1 recommended that the Department add breast milk storage bags and CPAP and Bi-PAP supplies to the list of items that can be dispensed in 90-day supplies in Section 60.08-13.

    Response: The Department thanks the commenter for the comment. The Department added breast milk storage bags and CPAP and Bi-PAP supplies to the list of items that can be dispensed in 90-day supplies.

20. **Comment:** Commenter 1, regarding Section 60.10-3(B), asked the Department to "clarify if a MaineCare provider is required to remit payment to a manufacturer with a contract to be a supplier, a provider cannot bill MaineCare until the invoice is paid. If this is the case, HOMES is concerned that this will provide an undue burden to providers to integrate holds pending receipt of invoices from the supplier/manufacturer."

    Response: The Department thanks the commenter for the comment. This comment is beyond the scope of this rulemaking. No changes were made to the rule because of this comment.

21. **Comment:** Commenter 1 expressed concern that the cost plus 15% methodology for specialty modified low protein food may not be sufficient for providers and added that there are significant costs associated with preparing prior authorizations, billing, applying payment, delivery and/or shipping, labor, overhead, and software costs.

    Response: The Department thanks the commenter for the comment. This comment is outside the scope of this rulemaking. No changes were made to the rule because of this comment.

22. **Comment:** Commenter 1 expressed concern that there may be challenges for crossover claims for oxygen contents.

    Response: The Department thanks the commenter for the comment. No changes were made to the rule because of this comment.

23. **Comment:** Commenter 1 commented that Section 60.10-10 and 60.11-1(A) appear contradictory and recommended clarifying the two Sections.

    Response: The Department thanks the commenter for the comment. The Department added language that clarifies members are responsible for paying required co-payments in Section 60.10-10.

24. **Comment:** Commenter 1 commented that transitioning policy, reimbursement, and/or prior authorization detail in Section 60.12 to the MaineCare HealthPAS Portal is concerning because it is not uncommon for providers without usernames and passwords to needs access to those details.

    Response: The Department thanks the commenter for the comment. Section 60 providers have always needed a Trading Partner Agreement (TPA) and account on the HealthPAS Portal to access required prior authorization sheets. The Department is not transitioning any policy or reimbursement details to the HealthPAS Portal. No changes were made to the rule because of this comment.

25. **Comment:** Commenter 2 commented that they theoretically agree with the Department's intent to rent and purchase DME in alignment with Medicare but asked the Department to clarify that

providers may purchase accessories, as well as the base chairs, for complex wheelchairs that are billed separately. The commenter noted these are customized products, and it is not practical to provide the same product to another individual as a rental, nor is it practical to retrieve provider-owned accessories from a member-owned wheelchair. The commenter referred the Department to relevant policy from the Centers for Medicare & Medicaid Services (CMS).

Response: The Department thanks the commenter for the comment. The Department is making the referenced DME available for purchase in alignment with Medicare, and the Department believes it is sufficient to say that it will align rental and purchase options with Medicare. The Department declines to add specificity in the rule because CMS's rental and purchase policy regarding particular DME may change in the future. No changes were made to the rule because of this comment.

26. **Comment:** Commenter 2 asked if there will be adjustments to the current 13-month capped rental process and/or payment rates.

    Response: Please see the response to comment 8.

27. **Comment:** Commenter 2 requested that the Department add language to Section 60.06-7 that allows for providers to deliver medically necessary equipment at the expense of the member in recognition of Medicaid being the payer of last resort.

    Response: Please see the response to comment 10.

28. **Comment:** Commenter 2 asked the Department to cover equipment when technological advances can improve the member's condition beyond what was available at the time the current equipment was provided.

    Response: Please see the response to comment 11

29. **Comment:** Commenter 2 commented that they are working with the national Coalition for Rehab Technology in other states to implement opportunities to maintain a complex wheelchair in functional order at the end of a 5-year regular useful lifetime with reimbursement for repairs while allowing providers to deliver a new complex chair at the same time. The commenter relayed the older chair will be a backup chair for the member in the event of a breakdown, which is necessary due to continued delays in obtaining repair parts due to supply chain issues and costs. In addition, the commenter noted there are no loaner chairs that are individually configured and appropriate to provide members, and this is particularly challenging for members with Group 3 chairs with specialized seating. The commenter commented that CMS currently only approves a manual wheelchair as a back up to power wheelchair users but that this not helpful to members in Group 3 chairs. The commenter mentioned that other New England states are discussing this and Massachusetts already implemented a similar program.

    Response: Please see the response to comment 12.

30. **Comment:** Commenter 2 asked the Department to clarify if Section 60.08-8 includes complex rehabilitation technology because they are typically differentiated by Medicare and other payers. The commenter requested that the Department include "complex rehabilitation technology" in Section 60.08-8 if the Section is supposed to be all inclusive.

    Response: Please see the response to comment 16.

31. **Comment:** Commenter 2 commented, "For POV upgrading to Power Wheelchair – Should the member have documented awareness of three years without an upgrade to Power Wheelchair and the physician documented that no significant deterioration of condition is anticipated, yet the deterioration occurs, is there a mechanism for exemption to the upgrade to Power Wheelchair?"

    Response: Please see the response to comment 17.

32. **Comment:** Commenter 2 asked if MaineCare would approve a new wheelchair with an appropriate accessory if a member needs an accessory to a wheelchair that is now obsolete.

    Response: Please see the response to comment 13.

33. **Comment:** Commenter 3 explained that code E0730 represents a Transcutaneous Electrical Nerve Stimulation (TENS) unit, which is a non-narcotic pain management option that they service to MaineCare members. The commenter said that TENS units are one of few non-narcotic options providers have to manage patient pain, and the commenter provided a brief overview of their TENS-related program.

    The commenter noted that if this rulemaking passes and aligns with Medicare's rental and purchase options, they will no longer be able to continue to deliver TENS units and offer their program.

    The commenter relayed that they confirmed with the Department that TENS units would continue to only have a purchase and hoped that MaineCare will consider keeping it this way.

    Response: The Department thanks the commenter for the comment. In alignment with Medicare, the Department will continue to only offer a purchase option for TENS units. No changes were made to the rule because of this comment.

34. **Comment:** Commenter 4 requested the Department remove certain PA criteria for continuous glucose monitors (CGMs) in the Appendix and to align CGM criteria with Medicare. The commenter noted Type 1 and Type 2 diabetes is increasingly managed by family practice, internal medicine, and other qualified providers and aligning with Medicare would increase near-term accessibility of CGM monitoring and patient compliance with blood glucose control for better long-term A1C management.

    Response: The Department thanks the commenter for the comment. The Department is removing the entirety of the Appendix. Following rule adoption, the Department will align its CGM PA criteria with Medicare's criteria. No changes were made to the rule because of this comment.

35. **Comment:** Commenter 4 commented that patient access has decreased for many mobility products because of national companies acquiring Maine-based DME providers and a constant consolidation of services. The commenter explained that patients who live in regions that are no longer covered by DME providers that offer mobility devices can end up paying out of pocket for the equipment or utilize inferior alternatives because they are unaware of the items that can be covered.

    To address the decrease in access to mobility devices, the commenter requested the Department to consider a one-time delivery fee when MaineCare members live outside the normal delivery zone of 30 miles. The commenter suggested the Department could do this by covering code

A9901 with a $75 rate for DME delivery. The commenter said they were open to discussing the applicable limits to prevent abuse and to ensure it is used to increase access.

Response: The Department thanks the commenter for the comment. The Medicare rates CMS sets for DME are inclusive of delivery, and since the Department is increasing the reimbursement for DME from 85% of 2011 to 100% of current Medicare fee schedule rates, the Department declines to reimburse for delivery costs. No changes were made to the rule because of this comment.

36. **Comment:** Commenter 5 expressed concern about MaineCare members' ability to obtain diabetes technology to optimize their diabetes care. The commenter noted that the MaineCare endocrinologist requirements are restrictive because there are few endocrinologists in Maine. The commenter mentioned that no other neighboring states have the same requirement and asked the Department to consider allowing an enrolled Medicaid provider with experience in diabetes treatment to fulfill the role of the endocrinologist. The commenter concluded this change would greatly benefit MaineCare members.

    Response: The Department thanks the commenter for the comment. Please see the response to comment 34. Following rule adoption, the Department will implement Medicare's criteria for CGMs, which will remove the endocrinologist requirements. No changes were made to the rule because of this comment.

List of Changes Made to Final Rule
Based on Comments Received and OAG Legal Review

1. In response to a comment, the Department added language that clarifies members are responsible for paying required co-payments in Section 60.10-10

2. In response to a comment, the Department corrected incorrect headers that appeared after Section 60.07.

3. In response to a comment, the Department added breast milk storage bags and CPAP and Bi-PAP supplies to the list of items that can be dispensed in 90-day supplies in Section 60.08-13.

4. As a result of final rule review, the Department removed "Power Operated Vehicles" from the title of Section 60.08-8 because "Power Mobility Devices" is inclusive of power operated vehicles.

5. Pursuant to P.L. 2023, ch. 216, as codified in 22 MRS 3174-KKK, the Department specified in Section 60.08-16 that electric breast pumps and supplies are covered under MaineCare without prior authorization or limitation when they are prescribed by a Qualified Provider. This provision in policy will be effective on October 25, 2023, the date the law becomes effective. Note that the Department already covers electric breast pumps and supplies without prior authorization or limitation.

6. As a result of final rule review, the Department removed "The Department shall submit to CMS and anticipates approval for a State Plan Amendment related to these provisions" from Section 60.10 because the Centers for Medicare & Medicaid Services (CMS) approved the relevant state plan amendment.