DHS Responses to Public Comments Regarding Continuous Glucose Monitors and Diabetic Supplies (Second Notice of Rulemaking)

Chad Moreau, MBA

Comment: My name is Chad Moreau and I am a resident of Cabot. I am submitting public comment on behalf of numerous Arkansans, including myself, who are deeply concerned about the imminent changes to how Continuous Glucose Monitoring (CGM) supplies are provided.

Because of your interpretation of Act 393 of 2023 I will not be able to get CGM supplies from my durable medical equipment (DME) provider and will have to get them from a pharmacy, who I'm not sure will be providing CGMs.

While this may seem like a mere administrative change, it poses a significant inconvenience for us. Previously, we had the benefit of having our essential CGM supplies delivered directly to our homes by local durable medical equipment providers. With the upcoming changes, we will now be required to travel, in many cases, many miles to acquire these necessary supplies from a providing pharmacy. I have reached out to my local pharmacy and they will NOT deliver these products.

For many individuals, this change poses more than just a mere inconvenience. There are numerous home-bound patients, elderly residents, and individuals without regular access to transportation for whom this shift could result in a dangerous interruption in their diabetes management. For some, this change may even deter them from obtaining their supplies altogether, risking severe health complications.

Diabetes is relentless. Our management tools should not be further than a doorstep away, especially in these trying economic times. I understand that changes in health policy often seek to streamline services and reduce costs. However, this alteration seems to disproportionately affect a vulnerable portion of our state's population, putting their health, and in some cases, their lives, at risk.

I urge you to please allow CGMs to be available both as a medical benefit and a pharmacy benefit.

Thank you for your time and consideration. I trust in your dedication to the well-being of all Arkansans to ensure continuous and accessible diabetes care for everyone.

Response: Thank you for communicating your concerns regarding this policy. We have considered all comments received and will allow CGMs and diabetic supplies to be provided by both DME providers and pharmacies beginning 5/1/2024.

James R. McCoy, MD

Comment: My name is James R. McCoy and I am a resident of Searcy, AR. I am submitting public comment on behalf of numerous Arkansans who are deeply concerned about the imminent changes to how Continuous Glucose Monitoring (CGM) supplies are provided.

Because of your interpretation of Act 393 of 2023 many patients will not be able to get CGM supplies from their local Arkansas durable medical equipment (DME) providers and will have to get them from a pharmacy, who I'm not sure will be providing CGMs.

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Diabetes is relentless. CGM products and other management tools should not be further than a doorstep away, especially in these trying economic times. I understand that changes in health policy often seek to streamline services and reduce costs. However, this alteration seems to disproportionately affect a vulnerable portion of our state's population, putting their health, and in some cases, their lives, at risk.

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Response: Thank you for communicating your concerns regarding this policy. We have considered all comments received and will allow CGMs and diabetic supplies to be provided by both DME providers and pharmacies beginning 5/1/2024.

Shelley Roach, resident of Morrilton, AR

Comment: My name is Shelley Roach and I am a resident of Morrilton, Arkansas.

I am submitting public comment on behalf of numerous Arkansans, including myself, who are deeply concerned about the imminent changes to how Continuous Glucose Monitoring (CGM) supplies are provided. Because of your interpretation of Act 393 of 2023 I will not be able to get CGM supplies from my durable medical equipment (DME) provider and will have to get them from a pharmacy, who I'm not sure will be providing CGMs.

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Response: Thank you for communicating your concerns regarding this policy. We have considered all comments received and will allow CGMs and diabetic supplies to be provided by both DME providers and pharmacies beginning 5/1/2024.

John Heflin, resident of Cabot, AR

Comment: My name is John Heflin, and I am a resident of Cabot. I am submitting public comment on behalf of numerous Arkansans who are deeply concerned about the imminent changes to how Continuous Glucose Monitoring (CGM) supplies are provided.

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Response: Thank you for communicating your concerns regarding this policy. We have considered all comments received and will allow CGMs and diabetic supplies to be provided by both DME providers and pharmacies beginning 5/1/2024.

Timothy Peoples (letter submitted by Brad White)

Comment: My name is Timothy Peoples, and I am a resident of Morrilton Arkansas. I am submitting public comment on behalf of numerous Arkansans, including myself, who are deeply concerned about the imminent changes to how Continuous Glucose Monitoring (CGM) supplies are provided.

Because of your interpretation of Act 393 of 2023 I will not be able to get CGM supplies from my durable medical equipment (DME) provider and will have to get them from a pharmacy, who I'm not sure will be providing CGMs.

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Response: Thank you for communicating your concerns regarding this policy. We have considered all comments received and will allow CGMs and diabetic supplies to be provided by both DME providers and pharmacies beginning 5/1/2024.

Phillip Stewart (letter submitted by Brad White)

Comment: My name is Phillip Stewart, and I am a resident of Morrilton Arkansas. I am submitting public comment on behalf of numerous Arkansans, including myself, who are deeply concerned about the imminent changes to how Continuous Glucose Monitoring (CGM) supplies are provided.

Because of your interpretation of Act 393 of 2023 I will not be able to get CGM supplies from my durable medical equipment (DME) provider and will have to get them from a pharmacy, who I'm not sure will be providing CGMs.

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Response: Thank you for communicating your concerns regarding this policy. We have considered all comments received and will allow CGMs and diabetic supplies to be provided by both DME providers and pharmacies beginning 5/1/2024.

Michael Worsham

Comment: My name is Michael A Worsham and I am a resident of Little Rock, AR. I am submitting public comment on behalf of numerous Arkansans, including myself, who are deeply concerned about the imminent changes to how Continuous Glucose Monitoring (CGM) supplies are provided.

Because of your interpretation of Act 393 of 2023 I will not be able to get CGM supplies from my durable medical equipment (DME) provider and will have to get them from a pharmacy, who I'm not sure will be providing CGMs.

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Response: Thank you for communicating your concerns regarding this policy. We have considered all comments received and will allow CGMs and diabetic supplies to be provided by both DME providers and pharmacies beginning 5/1/2024.

Cole McCoy

Comment: My name is Cole McCoy, and I am a resident of Bentonville. I am submitting public comment on behalf of numerous Arkansans who are deeply concerned about the imminent changes to how Continuous Glucose Monitoring (CGM) supplies are provided.

Because of your interpretation of Act 393 of 2023 many patients will not be able to get CGM supplies from their local Arkansas durable medical equipment (DME) providers and will have to get them from a pharmacy, who I'm not sure will be providing CGMs.

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Response: Thank you for communicating your concerns regarding this policy. We have considered all comments received and will allow CGMs and diabetic supplies to be provided by both DME providers and pharmacies beginning 5/1/2024.

Humza Hashmi

Comment: My name is Humza and I am a resident of Little Rock. I am submitting public comment on behalf of numerous Arkansans who are deeply concerned about the imminent changes to how Continuous Glucose Monitoring (CGM) supplies are provided.

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I urge you to please allow CGMs to be available both as a medical benefit and a pharmacy benefit. Thank you for your time and consideration. I trust in your dedication to the well-being of all Arkansans to ensure continuous and accessible diabetes care for everyone.

Response: Thank you for communicating your concerns regarding this policy. We have considered all comments received and will allow CGMs and diabetic supplies to be provided by both DME providers and pharmacies beginning 5/1/2024.

Alicia McCoy

Comment: My name is Alicia McCoy and I am a resident of Little Rock, AR. I am submitting public comment on behalf of numerous Arkansans who are deeply concerned about the imminent changes to how Continuous Glucose Monitoring (CGM) supplies are provided.

Because of your interpretation of Act 393 of 2023 many patients will not be able to get CGM supplies from their local Arkansas durable medical equipment (DME) providers and will have to get them from a pharmacy, who I'm not sure will be providing CGMs.

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Thank you for your time and consideration. I trust in your dedication to the well-being of all Arkansans to ensure continuous and accessible diabetes care for everyone.

Response: Thank you for communicating your concerns regarding this policy. We have considered all comments received and will allow CGMs and diabetic supplies to be provided by both DME providers and pharmacies beginning 5/1/2024.

Missy Cole

Comment: My name is Missy Cole and I am a resident of Fayetteville, AR. I am submitting public comment on behalf of numerous Arkansans who are deeply concerned about the imminent changes to how Continuous Glucose Monitoring (CGM) supplies are provided.

Because of your interpretation of Act 393 of 2023 many patients will not be able to get CGM supplies from their local Arkansas durable medical equipment (DME) providers and will have to get them from a pharmacy, who I'm not sure will be providing CGMs.

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Response: Thank you for communicating your concerns regarding this policy. We have considered all comments received and will allow CGMs and diabetic supplies to be provided by both DME providers and pharmacies beginning 5/1/2024.

Lawson Gunn

Comment: My name is Lawson Gunn and I am a resident of Fayetteville. I am submitting public comment on behalf of numerous Arkansans who are deeply concerned about the imminent changes to how Continuous Glucose Monitoring (CGM) supplies are provided.

Because of your interpretation of Act 393 of 2023 many patients will not be able to get CGM supplies from their local Arkansas durable medical equipment (DME) providers and will have to get them from a pharmacy, who I'm not sure will be providing CGMs.

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Response: Thank you for communicating your concerns regarding this policy. We have considered all comments received and will allow CGMs and diabetic supplies to be provided by both DME providers and pharmacies beginning 5/1/2024.

Brad White, C.Ped, CFo
President
Morrilton Respiratory Care Inc. DBA Petit Jean Medical Supply

Comment: I am highly concerned about the future accessibility of CGMs to Arkansas's Medicaid population. Not only does Arkansas need to further expand access of CGMs for Medicaid Diabetic patients, but full compliance and patient lifestyle integration of new CGM technology requires robust case management and frequent patient contact that is only possible through Arkansas's Medical Equipment Providers (DMEPOS). Restricting or limiting patient access to just the few pharmacies that are properly licensed to distribute medical devices would negatively impact Arkansas's ability to attack diabetes and improve Arkansan's lives.

I urge DHS to continue to cover CGMs as a Durable Medical Equipment benefit and to allow this benefit to be paid through the long established traditional Medical Equipment claim processing venues.

Response: Thank you for communicating your concerns regarding this policy. We have considered all comments received and will allow CGMs and diabetic supplies to be provided by both DME providers and pharmacies beginning 5/1/2024. Traditional insulin pumps and tubing will remain as a DME benefit only. To accommodate coordination between medical and pharmacy, Medicaid processes and rules will be administered through the Magellan portal, and a new rate will be calculated. Rates for items, regardless of supplier, will be Wholesale Acquisition Cost. Additionally, providers will have the option of claiming the professional dispensing fee.

Training for the Magellan portal will be available and the DME fee schedule will be updated for 5/1/2024.

Beather Peterson

Comment: I wish to continue to get my diabetes supplies from Total Medical Suppy company. They have been doing a great job sending my diabetes supplies out to me every month and I wish to continue to do business with them.

Response: Thank you for communicating your concerns regarding this policy. We have considered all comments received and will allow CGMs and diabetic supplies to be provided by both DME providers and pharmacies beginning 5/1/2024.

Angela Brown

Comment: Hello, my name is Angela D Brown. I'm writing on behalf of getting my diabetes Monitor Supplies. They really helps out. Keep me from those painful sticks. Sometimes the pain hurts me bad. I'm grateful for my Diabetes Monitor Supplies. Please don't change things for me and others that have to check our blood sugar...

Response: Thank you for communicating your concerns regarding this policy. We have considered all comments received and will allow CGMs and diabetic supplies to be provided by both DME providers and pharmacies beginning 5/1/2024.

Angela Brown

Comment: Hello, my name is Angela D Brown. I've been having diabetes since late 1989. Using my Diabetes Monitor, I don't have to go through those painful sticks. I take 4 Insulin Shots a day. My blood sugar runs low at times. Having the Blood Sugar Monitor comes in handy for me. So, please don't take that away from us. We can't afford to pay for them. So, for me and the others please don't take that away from us...

Response: Thank you for communicating your concerns regarding this policy. We have considered all comments received and will allow CGMs and diabetic supplies to be provided by both DME providers and pharmacies beginning 5/1/2024.

Cole Riddell
General Counsel
Total Medical Supply

Comment: I write again today on behalf of Total Medical Supply, Inc., a family-owned durable medical equipment ("DME") company located in the great twin city of Texarkana. We specialize in delivering necessary diabetic supplies, such as continuous glucose monitors ("CGM"), to our patients' homes on a monthly basis. We are proud to supply diabetic supplies to thousands of patients across the State of Arkansas. For the second time, because of your interpretation of Act 393 of 2023, thousands of patients will no longer be allowed to receive CGMs and other diabetic supplies from DME providers. As such, I

urge you to allow Arkansas Medicaid to continue to cover CGMs under the DME benefit and pay based on the HCPCS codes and the corresponding Medicare fee schedule amounts, consistent with other DME products covered by Arkansas Medicaid.

Response: Thank you for communicating your concerns regarding this policy. We have considered all comments received and will allow CGMs and diabetic supplies to be provided by both DME providers and pharmacies beginning 5/1/2024.

A new rate methodology and claiming process for medical coverage of CGMs and other diabetic supplies is necessary to align the reimbursement of products which are the same regardless of benefit plan. While Act 393 of 2023 does not require collection of rebate on medical DME supplies, the state must consider and utilize all reasonable opportunities to maximize savings. Because wholesale acquisition cost (WAC) is the pricing methodology required to collect rebates on medically necessary products used to assist diabetics, the state determined the best option going forward is to make this change.

Respectfully, your proposed rule is contrary to state and federal law. Federal regulations require state Medicaid programs to cover CGMs under the DME benefit as they fall under the federal Medicaid Mandatory Medicaid home health benefit. In its 2016 final regulation, "Medicaid Program; Face-to-Face Requirements for Home Health Services; Policy Changes and Clarifications Related to Home Health," (81 Fed. Reg. 5530, February 2, 2016), the Centers for Medicare and Medicaid Services ("CMS") clarified the definition of medical supplies, equipment, and appliances. See 42 C.F.R. §440.70(b)(3). In that rule, CMS explained that supplies, equipment, and appliances that meet the mandatory Medicaid Home Health benefit definition must be covered under the Medicaid Home Health benefit. CMS further explained in that its clarification of the scope of coverage under the Medicaid home health medical supplies benefit was designed so that it would more closely align with the Medicare definition of durable medical equipment ("DME") at 42 C.F.R. 414.402 (with important differences for the Medicaid population; 81 Fed. Reg. at 5532). The Medicare Program recognizes CGMs as a covered DME benefit (see DME MAC LCD L33822). Therefore, the state must provide coverage of CGMs through the mandatory Medicaid home health benefit.

Response: Medicaid coverage of CGMs and diabetic supplies remains under the Home Health benefit as a medical benefit and is in compliance with 42 C.F.R. §440.70(b)(3).

As confirmed by Arkansas Attorney General's Opinion 2023-099, A.C.A 20-77-148(c) (aka Act 393 of 2023) only requires Arkansas Medicaid to allow eligible beneficiaries to obtain their CGMs through a pharmacy—it does NOT prevent Medicaid from also covering the monitors as a medical (DME) benefit, as required by federal law. In your memorandum to DME providers dated February 28, 2024, you stated, "DME providers will need to bill through the new Magellan web-based portal system. This change is required for the state to collect rebate, as required by Act 393 of 2023." (emphasis added). That is incorrect. Act 393 of 2023 does NOT require the state to collect a rebate for CGMs covered under a DME benefit—only a pharmacy benefit. A.C.A 20-77-148(c) clearly and unambiguously states "Coverage for a continuous glucose monitor under the Arkansas Medicaid Program shall allow the beneficiary to obtain a continuous glucose monitor through a prescription at a pharmacy and be eligible for rebates as a pharmacy benefit." Nothing in this Section requires the state to collect rebates for CGMs covered as a medical (DME) benefit.

Response: While Act 393 of 2023 does not require collection of rebate on medical DME supplies, the state must consider and utilize all reasonable opportunities to maximize savings and create administrative efficiencies. The rate methodology, fee schedules, and claim type submissions are being amended to ensure it is fully adapting coordination between medical and pharmacy processes to achieve economy, efficiency, and quality of care. Based on this, DHS has determined a need to change DME provider billing for CGMs and diabetic supplies to align reimbursement and collect available rebates across multiple provider types for the same products.

As we have repeatedly stated, Total Medical Suply (and other DME providers) has no issue with pharmacies providing CGMs to eligible beneficiaries as a pharmacy benefit. However, your proposed rule is contrary to state and federal law as it eliminates the ability for DME providers to bill for CGMs purchased and provided to Medicaid recipients in Arkansas. Specifically, your second notice of the proposed rule indicates DME providers would need to utilize the pharmacy point of sale portal to submit claims. But pharmacy portals require NDC codes to submit claims—DME products do not have NDCs listed on all CGM products. Further, you have indicated that DME providers would be reimbursed based on wholesale acquisition cost ("WAC"). But DME providers are different than pharmacies and have different cost structures. WAC reimbursement with dispensing fees is not sustainable for DME companies and will restrict, if not eliminate, access for Medicaid recipients. Indeed, in the 48 states that Total Medical Supply provides CGMs to diabetic patients, no state has ever required us to follow the WAC reimbursement system for CGMs. DME providers specialize in diabetes care and are not typically retail businesses. Instead, we provide patients with the value add of home delivery services, specialized diabetes education, and follow-up services to encourage compliance. DME providers should continue to be paid based on the CGM HCPCS codes and the corresponding Medicare fee schedule amount, as outlined in the Arkansas Medicaid state plan for DME products and services. Treating DME companies as pharmacies will force DME companies out of business and eliminate access to thousands of diabetics across the State of Arkansas. What potential "cost saving" or "rebate" is more important than the health of diabetics Arkansas?

Response: DHS has confirmed with CGM manufacturers that the three major wholesalers do have NDC specific inventory. DME providers will not be required to enroll as pharmacies to obtain and utilize NDC billing nor will they be required to network with a PBM. To accommodate coordination between medical and pharmacy, Medicaid processes and rules will be administered through the Magellan portal, and a new rate will be calculated. Rates for items, regardless of supplier, will be Wholesale Acquisition Cost. Additionally, providers will have the option of claiming the professional dispensing fee.

Training for the Magellan portal will be available and the DME fee schedule will be updated for 5/1/2024.

Wholesale acquisition cost (WAC) is a pricing methodology needed to collect rebates on medically necessary products used to assist diabetics with control and maintenance of their condition. DHS seeks to ensure the highest level of quality available for all Medicaid beneficiaries requiring healthcare within the state's limited resources. The state must consider every avenue of reimbursement available for the purchase of products. Based on this, DHS has determined a need to change DME provider billing for CGMs and diabetic supplies to align reimbursement across multiple provider types.

Total Medical Supply, along with DME companies across the State, are more than willing to help DHS find a solution that works best for the great State of Arkansas, pharmacies, DME companies, and most importantly, the thousands of diabetics across the State. But the proposed rule, as written, is not the solution as it is contrary to law, and it will restrict access to necessary medical supplies for thousands of diabetics across Arkansas. We strongly request you reconsider and continue to cover CGMs under the DME (medical) benefit and pay based on the HCPCS codes and the corresponding Medicare fee schedule amounts, consistent with other DME covered by Arkansas Medicaid.

Response: The purpose of this rule is not only to address ACT 393, but more broadly to assess the needs of Medicaid beneficiaries and to balance their increasing requirements for higher quality methods of monitoring and maintaining their conditions against the ever increasing costs of doing so. Medicaid coverage of CGMs and diabetic supplies remains under the Home Health benefit as a medical benefit and is in compliance with 42 C.F.R. §440.70(b)(3). Coverage will continue and be reported to CMS as such. The changes in rate and reimbursement processes were determined necessary to achieve a fiscally sound budget, create administrative efficiencies, and create a consistent quality of care for beneficiaries who are served in multiple areas of Medicaid benefit programs.

Dee Ann Stahly
Director, State Government Relations & Policy
Dexcom

Comment: First, we would like to thank Arkansas Department of Human Services, Division of Medical Services for its consideration, analysis, and the opportunity to provide comments on the Proposed Rules Revisions to Continuous Glucose Monitoring (CGM) and Diabetic Supplies Coverage. Founded in 1999, Dexcom, Inc. is the market leader in transforming diabetes care and management by providing superior continuous glucose monitoring (CGM) technology to help patients and healthcare professionals better manage diabetes. Since our inception, we have focused on better outcomes for patients, caregivers, and clinicians by delivering solutions that are best in class—while empowering our community to take control of diabetes. We believe that this policy will provide tremendous benefit to patients with diabetes and their caregivers in Arkansas.

We would like to thank and recognize DHS for their willingness to make changes to the draft CGM coverage policy to ensure the policy now reflects the practice of diabetes treatment in Arkansas. The Center for Medicare and Medicaid Services (CMS) recently updated its Medicare coverage policy for CGM and the draft coverage policy for CGM policy reflects those changes. We are supportive of these changes and would encourage DHS to adopt these revisions to CGM coverage policy.

We would also like to thank and support DHS in its decision to process CGM claims as a pharmacy claim submitted by pharmacies or DME providers. The quickest and most cost-effective channel for Medicaid patients to receive a CGM is through the pharmacy. Currently, 29 state Medicaid programs manage CGM through the pharmacy channel with more agencies moving to this model in 2024. Additionally, most commercial plans also offer CGM through the pharmacy. This is the most convenient way for patients to access their CGM, as they can pick up their supplies while also picking up their insulin. We are supportive of these changes and encourage DHS to adopt these revisions to the CGM coverage policy.

We applaud the Department's commitment to Medicaid patients with this proposed rule, and we urge you to adopt these revisions. Patients with better management of their diabetes have better health outcomes, a higher quality of life, and cost significantly less to the state. We look forward to working with you to help ensure that the most vulnerable populations have access to the technologies they need to successfully manage their diabetes while reducing costs for the state.

Please contact me if you have any questions or need more information. We appreciate the opportunity to submit our comments for your consideration.

Response: Thank you for your response to the upcoming changes outlined in the rule.

Craig Douglas
Vice President of Payer & Member Relations
VGM & Associates

Comment: The following comments are being submitted on behalf of VGM & Associates, the nation's largest and most comprehensive member service organization for post-acute healthcare products and services, including Durable Medical Equipment (DME), Orthotics & Prosthetics, Respiratory, Sleep, Wound Care, Complex Rehab, Women's Health, and Home/Vehicle Modifications. Over 2500 post-acute providers with nearly 7000 locations nationwide rely on VGM to connect them to valuable resources every single day. CGMs have proven their ability to improve patient care and reduce costs. See the attached document for detailed information.

1) Under the current proposal, we feel that Arkansas Medicaid, whether intentionally or unintentionally, will ultimately be removing coverage of CGMs offered through DME providers. VGM strongly opposes the removal of coverage of CGMs and diabetic supplies under the DME benefit. We recommend that Arkansas Medicaid continue to cover CGMs under the DME benefit while expanding coverage and making these products available under the pharmacy benefit. Offering coverage of CGMs through both the DME and pharmacy channels promotes better access to care, patient choice, therapy adherence, and reduces healthcare costs.

Response: Thank you for communicating your concerns. We have considered all comments received and will allow CGMs and diabetic supplies to be provided by both DME providers and pharmacies beginning 5/1/2024.

2) From a Medicare standpoint, CGMs meet the definition of DME, and are therefore available to Medicare beneficiaries as a covered DME benefit as part of the Home Health benefit. They do not meet the definitions required to be covered under the prescription drug benefit. Medicare beneficiaries who have Arkansas Medicaid as secondary coverage will need to get their supplies from a DME provider. The DME provider will need to submit claims to Medicare using the HCPCS codes established for CGMs. When those claims cross over to Arkansas Medicaid for the secondary portion of the claim to be processed, Arkansas Medicaid will need to be able to recognize, process, and pay the claims using those HCPCS codes.

Response: Medicare crossover claims reimbursement processes will remain the same as they are now.

Our current understanding is that Arkansas Medicaid intends to require DME providers to utilize the pharmacy point of sale portal to submit claims. This action would require DME providers to submit NDC codes on their claims, which aren't available for all CGM products. This requirement would eliminate the DME providers' ability to submit claims to Arkansas Medicaid for CGM products.

Response: DHS has confirmed with CGM manufacturers that the three major wholesalers do have NDC specific inventory. DME providers will not be required to enroll as pharmacies to obtain and utilize NDC billing nor will they be required to network with a PBM to use the pharmacy point of sale portal. Training on the use of the pharmacy portal will be announced soon.

3) We also understand that under the current proposal, DME providers would be reimbursed based on wholesale acquisition cost ("WAC") plus a nominal dispensing fee. Under this proposal, patient access to certain CGM products would be eliminated. Services that help drive optimal therapy compliance, such as home delivery services, specialized diabetes education, and follow-up services would also be eliminated.

Response: DHS has found no evidence that patient access will be diminished, and the dispensing fee for the CGM and other products was designed to assist with the ever-changing costs of services other than the actual product.

4) The state of Arkansas currently requires suppliers who provide DME to acquire and maintain a DME license. We don't believe that very many pharmacies currently hold a DME license and may be unwilling to obtain such license.

Response: The products for diabetic supplies can be dispensed in retail pharmacy without a DME license. These providers will bill *National Council for Prescription Drug Programs* (NCPDP) just as they do for beneficiaries of commercial plans now. The purpose of ACT 393 of 2023 is to allow dispensing of these products through both the pharmacy benefit and the home health benefit. Just as pharmacies will not be required to obtain a DME license to dispense and claim reimbursement for these products through the pharmacy portal, DME providers will not be required to enroll as pharmacies to obtain and utilize NDC billing nor will they be required to network with a PBM to use the pharmacy portal for billing claims. Training on the new claims processes will be announced soon.

5) We are also unclear as to whether or not pharmacies who have not historically carried and offered CGM products will start carrying them simply because they are covered under the pharmacy benefit going forward. Not maintaining a good mix of both pharmacies and DME companies that carry CGMs on hand will result in delays in care, access to care issues, and even preventable hospitalizations. For the reasons outlined above, we recommend and ask that Arkansas Medicaid continue to cover CGMs and related supplies as DME under the Home Health benefit, allowing DME suppliers to submit claims using established HCPCS codes for these products. We appreciate your consideration of our comments**.** Please contact me with any questions or requests for additional information.

Response: The purpose of this rule not only addresses ACT 393, but more broadly assesses the needs of Medicaid beneficiaries to balance their increasing requirements for higher quality methods of monitoring and maintaining their conditions against ever increasing costs of doing so. Medicaid coverage of CGMs and diabetic supplies remains under the Home Health benefit as a medical benefit and is in compliance with 42 C.F.R. §440.70(b)(3). Coverage will continue and be reported to CMS as

such. The changes in rate and reimbursement processes were determined necessary to achieve a fiscally sound budget and coordinate a consistent quality of care for beneficiaries who are served in multiple areas of Medicaid benefit programs.

David Chandler
Senior Director of Payer Relations
American Association for Homecare

Comment: Thank you for the opportunity to provide written comments regarding the second notice of the proposed rule that would eliminate coverage of continuous glucose monitors and diabetic supplies under the Durable Medical Equipment (DME) benefit. AAHomecare is the national association representing DME providers, manufacturers, and other stakeholders in the homecare community. Our membership services patients living with diabetes and provides medical equipment such as continuous glucose monitors ("CGMs") across the nation. CGMs provided by DME suppliers improve patient care and reduce costs. See the attached document for detailed information.

The American Association for Homecare (AAHomecare) strongly opposes removal of coverage of CGMs and diabetic supplies under the DME benefit. We recommend that Arkansas Medicaid continue to cover CGMs under the DME benefit in addition to expanding coverage under the pharmacy benefit. CGMs supplied by DME providers promote patient access, patient choice, therapy adherence, and reduced healthcare costs. In addition, federal regulations state that state Medicaid programs must cover CGMs under the Mandatory Medicaid home health benefit.

Response: We have considered all comments received and will allow CGMs and diabetic supplies to be provided by both DME providers and pharmacies beginning 5/1/2024.

This rule does not remove coverage of CGMs and other diabetic supplies from the Home Health benefit plan. Medicaid coverage of CGMs and diabetic supplies remains under the Home Health benefit as a medical benefit and is in compliance with 42 C.F.R. §440.70(b)(3). This coverage will continue and be reported to CMS as such. The changes in rate and reimbursement processes were determined necessary to achieve a fiscally sound budget and coordinate a consistent quality of care for beneficiaries who are served in multiple areas of Medicaid benefit programs.

The second notice of the proposed rule indicates DME providers would need to utilize the pharmacy point of sale portal to submit claims. Typically, pharmacy portals require NDC codes to submit claims. DME products do not have NDCs listed on all CGM products. This practice would eliminate the ability for DME providers to bill for CGMs purchased and provided to Medicaid recipients in Arkansas.

Response: DHS has confirmed with CGM manufacturers that the three major wholesalers do have NDC specific inventory. DME providers will not be required to enroll as pharmacies to obtain and utilize NDC billing nor will they be required to network with a PBM to use the pharmacy point of sale portal. To accommodate coordination between medical and pharmacy, Medicaid processes and rules will be administered through the Magellan portal, and a new rate will be calculated. Rates for items, regardless of supplier, will be Wholesale Acquisition Cost. Additionally, providers will have the option of claiming the professional dispensing fee.

Training for the Magellan portal will be available and the DME fee schedule will be updated for 5/1/2024.

The second notice of the proposed rule also indicates DME providers would be reimbursed based on wholesale acquisition cost ("WAC"). DME providers are different than pharmacies and have different cost structures. WAC reimbursement with dispensing fees is not sustainable and may narrow access for Medicaid recipients. DME providers that specialize in diabetes care are not typically retail businesses and instead provide patients with the value add of home delivery services, specialized diabetes education, and follow-up services to encourage compliance. DME providers should be paid based on the CGM HCPCS codes and the corresponding Medicare fee schedule amount, as outlined in the Arkansas Medicaid state plan for DME products and services.

Response: Wholesale acquisition cost (WAC) is a pricing methodology needed to collect rebates on medically necessary products used to assist diabetics with control and maintenance of their condition. DHS seeks to ensure the highest level of quality available for all Medicaid beneficiaries requiring healthcare within the state's limited resources. The state must consider every avenue of reimbursement available for the purchase of products. Based on these considerations, DHS has determined a need to change DME provider billing for CGMs and diabetic supplies to align reimbursement across multiple provider types.

Importantly, federal regulations require state Medicaid programs to cover CGMs under the DME benefit as they fall under the federal Medicaid Mandatory Medicaid home health benefit. In its 2016 final regulation, "Medicaid Program; Face-to-Face Requirements for Home Health Services; Policy Changes and Clarifications Related to Home Health," (81 Fed. Reg. 5530, February 2, 2016), the Centers for Medicare and Medicaid Services ("CMS") clarified the definition of medical supplies, equipment, and appliances. See 42 C.F.R. §440.70(b)(3). In that rule, CMS explained that supplies, equipment, and appliances that meet the mandatory Medicaid Home Health benefit definition must be covered under the Medicaid Home Health benefit.

CMS explained in the 2016 regulation that its clarification of the scope of coverage under the Medicaid home health medical supplies benefit was designed so that it would more closely align with the Medicare definition of durable medical equipment ("DME") at 42 C.F.R. 414.402 (with important differences for the Medicaid population; 81 Fed. Reg. at 5532). The Medicare Program recognizes CGMs as a covered DME benefit (see DME MAC LCD L33822). Therefore, the state must provide coverage of CGMs through the mandatory Medicaid home health benefit.

Response: Medicaid coverage of CGMs and diabetic supplies remains under the Home Health benefit as a medical benefit and is in compliance with 42 C.F.R. §440.70(b)(3). The state is required to follow an approved rate methodology for the benefit. The rate and process for Medicaid crossover claims will remain in alignment with Medicare. The state has requested to amend its rate methodology for CGMs and diabetic supplies for Medicaid only coverage to align and coordinate a reasonable rate for the same product across various benefit plans. The processes are being amended to ensure DHS is complying with principles of economy, efficiency, and quality of care which includes accommodating coordination between medical and pharmacy policy. Based on this, DHS has determined a need to change DME provider billing for CGMs and diabetic supplies to align reimbursement across multiple provider types for the same products.

ASK: AAHomecare recommends that Arkansas Medicaid continue to cover continuous glucose monitors (CGMs) under the durable medical equipment (DME) benefit and pay based on the HCPCS codes and the corresponding Medicare fee schedule amounts, consistent with other DME covered by Arkansas Medicaid.

Response: Medicaid coverage of CGMs and diabetic supplies remains under the Home Health benefit as a medical benefit and is in compliance with 42 C.F.R. §440.70(b)(3). The state is required to follow an approved rate methodology for the benefit. The rate and process for Medicaid crossover claims will remain in alignment with Medicare. The state has requested to amend its rate methodology for CGMs and diabetic supplies for Medicaid only coverage to align and coordinate a reasonable rate for the same product across various benefit plans. The processes are being amended to ensure DHS is complying with principles of economy, efficiency, and quality of care which includes accommodating coordination between medical and pharmacy policy. Based on this, DHS has determined a need to change DME provider billing for CGMs and diabetic supplies to align reimbursement across multiple provider types for the same products.

We appreciate your consideration of our comments.

AAHOMECARE
American Association for Homecare

CGMs Provided by DME Suppliers Improves Patient Care and Reduces Costs
January 2024

About American Association for Homecare (AAHomecare)

AAHomecare is the national association representing durable medical equipment (DME) suppliers, manufacturers, and other stakeholders in the homecare community. Our membership services patients living with diabetes and provides medical equipment such as continuous glucose monitors (CGMs) across the nation.

About Continuous Glucose Monitors (CGMs) Medicaid Coverage

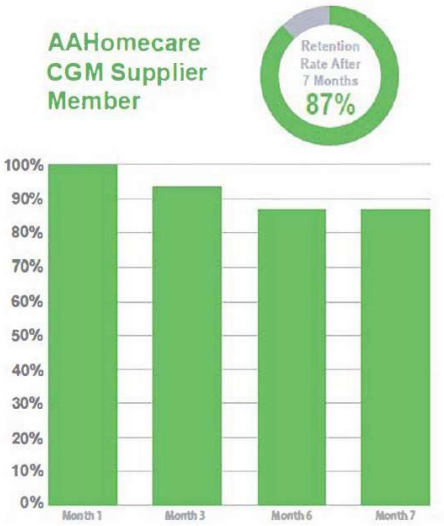
CGM is an innovative diabetes monitoring technology that measures blood glucose levels continuously in real- time. In 2017, Medicaid programs expanded coverage to include CGMs, either covering under the Durable Medical Equipment channel and/or the Pharmacy channel. Based on feedback from DME suppliers, manufacturers, patients, and other stakeholders, DME suppliers are better suited to provide a more comprehensive service to CGMs patients. DME suppliers promote reduction in healthcare costs, and improve health equity, patient care, patient choice and access.

DME Suppliers Aid in the Reduction of Healthcare Costs

HIGH RETENTION UNDER DME CHANNEL– DME suppliers have a CGM patient retention rate of approximately 87%, which is 20-30% higher than under the pharmacy benefit.[i]

- Retention under the DME channel is better due to suppliers being in regular contact with beneficiaries and checking-in with patients on their adherence to the therapy.
- Proper adherence to prescribed diabetes therapy leads to improved glycemic control and as a result reduced worsening of the condition and additional healthcare costs.

- Without proper management, diabetes patients have a higher risk of serious health complications and increased health care costs.
- Diabetes patients that do not have control over their diabetes and have chronic complications can expect to pay additional healthcare costs ranging from $648-$937 a year.[ii]



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CGM USE REDUCES DIABETES-RELATED HOSPITALIZATIONS AND COSTS—Studies have shown that CGM utilization reduced hospitalizations caused by acute diabetes complications by approximately 50%.[iii]

- A study has shown substantial cost savings by pregnant women with Type 1 diabetes primarily through reduced admission and duration of stay in neonatal intensive care unit.[iv]
- Another study showed the use of CGMs reduced diabetes-related events and hospitalization for people living with Type 2 diabetes irrespective of age and gender.[v]

DME Suppliers Advance Health Equity for Diabetes Patient Population

DME SUPPLIERS ARE BETTER SUITED TO SUPPLY CGMS TO THE GROWING POPULATION OF PEOPLE LIVING WITH DIABETES[vi]—DME suppliers employ diabetes management staff to ensure patients on CGMs have a resource to answer any issues or questions with their CGMs, this is especially important considering the prevalence of diabetes diagnosis in recent years.

- 11% of the American population live with diabetes, it is projected 21% will be diagnosed with diabetes by 2050.vii,viii
- Approximately 14% of Medicaid recipients under the age of 64 live with diabetes.[ix]
- Low-income individuals are disproportionately more likely to be diagnosed with diabetes and have co- morbidities, which makes accessing and maintaining prescribed therapy crucial.[x]

DME SUPPLIERS PROVIDE ADDITIONAL NEEDED SUPPORT FOR PEDIATRIC DIABETES PATIENTS—Children living with Type 1 diabetes and their parents need a network to support the child's diabetes management.[xi]

- 283,000 children and young adults under the age of 20 are estimated to have diabetes.[xii]

- DME suppliers provide educational resources in diabetes management and are available to answer issues and questions with therapy management provided to the child to the entire family with a focus on developmentally appropriate care.[xiii]

DME Suppliers Improve Patient Care

DME SUPPLIERS HAVE CGM PRODUCT EXPERTISE – DME suppliers are specialized and have trained agents who can provide CGM guidance and product assistance to diabetes patients.

- Diabetes is a complicated medical diagnosis that requires individualized care. While pharmacies carry and sell CGM devices and supplies, DME suppliers provide patient-centered services.
- Suppliers are more engaged with manufacturers and are knowledgeable of the newest technology that is in the best interest of diabetes patients.

DME SUPPLIERS PROVIDE CGM PATIENT RESOURCES – In addition to product expertise, DME suppliers provide educational resources, onboarding services, and follow-ups for CGM patients.

- Due to the ongoing care provided by DME companies, suppliers build relationships with their patients.

DME SUPPLIERS SUPPORT CONTINUITY OF CARE – DME suppliers are proactive about ensuring patients do not have an interruption in receiving critical therapy and supplies.

- In 2019, diabetes was a top 10 leading cause of death in the country—282,801 death certificates mentioned diabetes as a cause of death.[xiv]
- DME suppliers are more involved in-patient care, checking in with patients, communicating with their insurances, and assisting patients through benefit changes.

DME SUPPLIERS ARE KNOWLEDGEABLE OF DOCUMENTATION AND COVERAGE REQUIREMENTS – DME suppliers have strong relationships with payers and prescribers and are experienced in the documentation and coverage requirements for different payers.

- Prior authorization is owned by the DME supplier under the DME channel, and it is owned by the prescriber under the pharmacy benefit. Typically, prescribers are not aware of the restrictions of the drug formulary, which can add complications to the ordering process.

DME Suppliers Promote Patient Choice and Access

DME SUPPLIERS PROVIDES PATIENT CONVENIENCE – DME suppliers maintain a broad inventory and can deliver devices and supplies directly to a patient's home or office.

- Due to fast-paced product evolution, there is pressure placed on store inventories. These frequent changes in technology and product advancements can result in difficulties stocking the newest products.
- DME suppliers' operations allow for the newest technology to be available to patients.
- When CGM supplies are provided by DME suppliers, it alleviates transportation issues: this is especially helpful for Medicaid programs that reimburse transportation costs.

PATIENTS REPORTS HIGHER SATISFACTION WITH DME SUPPLIERS—Patients that have switched from the pharmacy channel to the DME channel have voiced greater satisfaction with service under the DME channel.[xv]

- DME suppliers are especially sensitive to providing timely services to patients to prevent delays in needed therapy.
- CGM patients have shared strong satisfaction receiving services from DME suppliers:

- *"I've been a type 1 Diabetic for 21 years. My son (9) has been a type 1 for 2 years. Hands down the worst part about this disease is insurance/pharmacy. But [DME supplier] has made getting my supplies the easiest it has ever been for me! Thank you!"*
- *"The customer service staff are very friendly and know the product well. They got the intake info and product correct the first time. They also did a follow up call to keep me up to date on the process. I am so happy I called [DME supplier]. The reprocess from start to product deliver at my home was less than 10 days, whereas the big box pharmacy was over 3 months of phone calls and going in person only to find some problem…"*

COVERAGE ALIGNMENT FOR DUAL ELIGIBLES — Coverage and payment is an issue for dual eligibles when Medicaid programs do not cover CGMs under the DME channel.

- Under Medicare, CGMs fall under the DMEPOS benefit.
- Medicaid programs that cover CGMs under the pharmacy channel typically automatically deny payment when Medicare is the primary payer due to the misalignment of the CGM benefit category between Medicare and Medicaid. The initial denial of payment by Medicaid requires DME suppliers to file an appeal, causing additional costs for both the supplier and Medicaid.
- CGM and insulin pump together are one therapy system, when both products are covered under the DME channel, it promotes simplicity and better patient experience.

FORMULARY RESTRICTIONS UNDER PHARMACY— Medicaid only allows for certain drugs to be provided under the pharmacy channel, limiting patient access.

- CGM and external insulin infusion pump are two products that are used as one therapy system.
- Because external insulin infusion pump is covered under the DME channel, it would be beneficial for beneficiaries to have channel alignment for CGMs and pumps.
- External insulin infusion pumps used with CGMs are not interchangeable, there are specific pumps that only work with specific CGMs. When CGM is covered under the pharmacy channel, it creates an access barrier for beneficiaries who may not get the appropriate set of CGM and pumps.

ASK: AAHomecare recommends that all state Medicaid programs cover continuous glucose monitors (CGMs) under the durable medical equipment (DME) channel. CGMs supplied by DME suppliers promotes patient access, patient choice, therapy adherence, and reduced healthcare costs.

REFERENCES:

[i] Based on information shared by Diabetes Council CGM supplier members.
[ii] https://www.goodrx.com/conditions/diabetes-type-2/annual-cost-of-managing-diabetes-and-treating-uncontrolled- diabetes
[iii] https://pubmed.ncbi.nlm.nih.gov/33879536/
[iv] https://pubmed.ncbi.nlm.nih.gov/31162713/
[v] https://pubmed.ncbi.nlm.nih.gov/33644623/
[vi] https://www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/Data-Snapshots-Diabetes.pdf
[vii] https://diabetes.org/about-us/statistics/about-diabetes
[viii] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7171935/

[ix]https://www.cdc.gov/pcd/issues/2018/18_0148.htm#:~:text=Medicaid%20is%20especially%20important%20for,%2C%20had%20diabetes%20(4).
[x] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4902718/
[xi] https://diabetesjournals.org/care/article/28/1/186/25819/Care-of-Children-and-Adolescents-With-Type-1
[xii] https://www.cdc.gov/diabetes/data/statistics-report/diagnosed-diabetes.html
[xiii] https://diabetesjournals.org/care/article/28/1/186/25819/Care-of-Children-and-Adolescents-With-Type-1
[xiv] https://diabetes.org/about-us/statistics/about-diabetes
[xv] Patient experience shared by AAH CGM suppliers.

Response: DHS appreciates the exceptional efforts of DME providers to ensure the best quality of care and outcomes for this population of Medicaid beneficiaries. DHS has considered your comments and those of others in its efforts to achieve balance across the broad array of treatments, services, and products required to provide quality healthcare to Medicaid beneficiaries. Not only is the number of beneficiaries requiring care continuing to increase, so is the cost of the services, while DHS has been charged with limiting budget growth. Medicaid coverage of CGMs and diabetic supplies remains under the Home Health benefit as a medical benefit and is in compliance with 42 C.F.R. §440.70(b)(3). This coverage will continue and be reported to CMS as such. The changes in rate and reimbursement processes were determined necessary to achieve a fiscally sound budget, create administrative efficiencies, and achieve a consistent quality of care for beneficiaries who are served in multiple areas of Medicaid benefit programs.

Carson Moore
Director
Aeroflow Diabetes

Comment: Aeroflow, Inc. dba Aeroflow Health (Aeroflow) is a provider of Durable Medical Equipment (DME), and currently has a division that focuses exclusively on continuous glucose monitors (CGM) and related supplies to ensure the wellbeing individuals affected by diabetes. Aeroflow appreciates the opportunity to respond to your Request for public comment published February 2, 2024, regarding the Continuous Glucose Monitors and Diabetic Supplies as a Pharmacy Benefit. Specifically, Aeroflow wants to highlight that the proposed billing guidelines and reimbursement would logistically and financially be prohibitive for DME suppliers and would thus decrease critical access to patients.

Pharmacies Limit Access to Essential Supplies for Patients

Getting continuous glucose monitoring (CGM) supplies through a pharmacy rather than a durable medical equipment (DME) provider could significantly limit access to these essential supplies for patients managing diabetes.

Response: Medicaid coverage of CGMs and diabetic supplies remains under the Home Health benefit as a medical benefit. Access to these benefits in a pharmacy is being added to increase choice and access for beneficiaries in compliance with ACT 393 of 2023.

Limited Pharmacy Availability: Not all pharmacies stock CGM supplies, especially in rural or underserved areas where access to healthcare resources is already limited. Patients in these regions may face challenges finding a pharmacy that carries the specific CGM supplies they need, leading to delays or interruptions in their diabetes management.

Response: Beneficiaries will still have the choice of providers (DME or pharmacy) which best fit their needs. Nothing in the rule requires the beneficiary to use a pharmacy instead of a DME provider for these products. The pharmacy has the option of modifying business practices to include patient value adds such as ordering and shipping the product to the patient or delivering products to ensure patient safety and education for the CGM and supplies ordered by the beneficiary's physician.

Pharmacy Inventory Management: Pharmacies may not always have an adequate supply of CGM supplies on hand due to variations in demand and inventory management practices. Patients relying on pharmacies for CGM supplies may encounter difficulties obtaining their supplies in a timely manner, particularly if there are shortages or backorders.

Response: Pharmacies who choose to serve Medicaid beneficiaries with CGMs and other diabetic supplies are bound by the same provider responsibilities and accountability under the Medicaid provider contract. They must be trained and competent in the compatibility and specific technology required to ensure beneficiaries receive the correct diabetes products for their diabetes management plan. All Medicaid providers are accountable for knowing the specific ongoing needs for the diagnosed condition of the beneficiary receiving services and for ensuring product availability in a timely and efficient manner.

Compatibility Concerns: There are several CGM manufacturers on the market and the particular manufacturer supplied at a pharmacy may not be compatible with the CGM base reader used by the patient causing additional concerns with access to care. As well, CGM systems often integrate with insulin pumps and other diabetes management devices to provide comprehensive monitoring and treatment solutions. These integrations are brand and product specific to the patient's corresponding insulin pump and other management devices. When obtaining CGM supplies through a pharmacy, patients may face challenges ensuring compatibility between their preferred CGM system and other devices, such as insulin pumps. This could be detrimental to the effectiveness of their treatment and level of care.

Response: It is incumbent upon all parties and provider types to educate patients and ensure compatibility of technology when dispensing supplies to the patient requiring them. It would be irresponsible for any provider to be unaware of the care, usage, and compatibility of the products it dispenses. DHS has no evidence this will be the case.

Specialized Education and Support: DME providers often offer specialized education and support services to patients using CGM technology. At Aeroflow we participate in dedicated training sessions from the manufacturers specific to the challenges that patients face throughout their CGM usage. This may include training on device use, troubleshooting assistance, and ongoing support from specialized staff. Aeroflow's sole focus is patients with diabetes and the supplies critical to their care, unlike a pharmacy who manage multiple aspects of all disease states. Accessing CGM supplies through a pharmacy may not provide the same level of personalized support, leaving patients without the resources they need to effectively manage their diabetes.

Response: Dedicated training sessions from the manufacturers specific to the challenges that patients face throughout their CGM usage should be available to providers regardless of whether they are dispensing as a pharmacy or a DME provider. Providers who contract to be reimbursed by Medicaid are bound to the same requirements for ensuring patients have the resources and assistance necessary to understand and use the equipment and supplies critical to their care.

Patient Convenience and Compliance: Obtaining CGM supplies through a DME provider often offers greater convenience for patients, as they can typically receive all their diabetes management supplies from a single source. This streamlined approach can improve patient compliance with recommended monitoring protocols and enhance overall health outcomes.

Response: DHS appreciates and commends DME providers for their efforts to improve patient safety, compliance, and overall health outcomes. It is expected that pharmacies will fill gaps in patient access by rising to the challenge of meeting the same high standards for Medicaid beneficiaries and other Arkansans who must rely on their services.

Obtaining CGM supplies through a pharmacy instead of a DME provider could significantly limit access to these critical resources for patients managing diabetes.

Response: Medicaid beneficiaries will still have a choice of the providers (DME or pharmacy) who supply equipment to meet their diabetic needs.

DME Cannot Bill with NDC as some CGM products do not have NDC

Dexcom's Continuous Glucose Monitoring (CGM) system poses a unique challenge for Durable Medical Equipment (DME) suppliers when it comes to billing, primarily due to the absence of National Drug Codes (NDCs) associated with the SKUs distributed through the DME channel.
Separate SKUs for DME and Pharmacy Channels: Dexcom maintains distinct SKUs for products distributed through the DME channel and those available through pharmacies. However, the SKUs designated for DME distribution SKUs do not bear NDCs on the packaging or labeling, making it impossible for DME suppliers to utilize NDC-based billing methods.

Billing Integrity and Compliance: Billing for Dexcom CGM components using NDCs when they are not associated with the SKUs provided by DME suppliers would compromise billing integrity and could lead to regulatory non-compliance. DME suppliers are obligated to bill accurately for the products and services they dispense, and using NDCs not associated with the provided SKUs would inaccurately represent the products dispensed to patients. DME suppliers are licensed by and accredited as DME suppliers, not pharmacy. This may create additional burden on the DME suppliers to obtain appropriate license and accreditation in order to bill as a pharmacy.

Patient Safety and Transparency: Accurate billing practices are essential not only for regulatory compliance but also for patient safety and transparency. Patients rely on DME suppliers to provide them with the correct products and services for their healthcare needs. Billing with NDCs not associated with the provided Dexcom CGM SKUs could lead to confusion and potential errors in patient records, jeopardizing patient safety and undermining trust in the healthcare system.

The absence of NDCs associated with Dexcom CGM components distributed through the DME channel presents a significant obstacle to billing for DME suppliers. Billing with NDCs not associated with the provided SKUs would be inaccurate and could compromise billing integrity, patient safety, and regulatory compliance.

Response: DHS has confirmed with CGM manufacturers that the three major wholesalers do have NDC specific inventory. DME providers will not be required to enroll as pharmacies to obtain and utilize NDC billing nor will they be required to network with a PBM to use the pharmacy point of sale portal. To accommodate coordination between medical and pharmacy, Medicaid processes and rules will be administered through the Magellan portal, and a new rate will be calculated. Rates for items, regardless of supplier, will be Wholesale Acquisition Cost. Additionally, providers will have the option of claiming the professional dispensing fee.

Training for the Magellan portal will be available and the DME fee schedule will be updated for 5/1/2024.

Wholesale Acquisition Cost (WAC) will not cover the costs associated with supplying CGMs

Reimbursing CGM systems at WAC presents significant challenges for DME suppliers, as it does not adequately cover the costs associated with providing CGM systems to patients.

Cost of Goods: While WAC represents the price at which manufacturers sell products to wholesalers, it does not encompass all the expenses incurred by DME suppliers in acquiring CGM systems. DME suppliers must cover various costs, including procurement, storage, inventory management, and transportation of CGM systems. Many pharmacies have mentioned to Aeroflow the same reimbursement challenges exist in the pharmacy space. These costs can significantly exceed the cost of goods and thus eliminate entire product and brand categories. For example, published WAC rates would eliminate Aeroflow's ability to provide any Abbott Freestyle Libre 2 or Libre 3 sensor.

Educational and Support Services: As referenced in the section above, providing CGM systems involves more than just dispensing the product; it also requires comprehensive educational and support services to ensure patients can effectively use the technology. This includes training patients on device usage, troubleshooting issues, and providing ongoing support and assistance. These educational and support services represent additional costs for DME suppliers that are not adequately accounted for in WAC reimbursement rates.

Shipping and Logistics: Delivering CGM systems to patients' homes involves logistical challenges and expenses. DME suppliers must coordinate shipping, handle logistics, and ensure timely delivery of CGM systems to patients' residences. Shipping costs, packaging materials, and transportation expenses add up and are not fully covered by WAC reimbursement rates, including the dispensing fee.

Claim Submission: Maintaining a separate manual billing system solely to accommodate claim submission through the Magellan portal would impose significant logistical and financial burdens on healthcare providers. Firstly, implementing and managing a separate billing system requires additional resources, including personnel, software modifications, and infrastructure, which translates to increased operational costs for DME suppliers. This includes hiring and training staff proficient in navigating the manual billing process and managing the associated paperwork. This seems to be a step backwards in the progress made towards eliminating the operational burdens in healthcare and increasing cost in

healthcare. Moreover, manual billing is inherently prone to errors, leading to delays in claim processing, reimbursement denials, and potential compliance issues. These errors necessitate extensive resources for error detection, correction, and reconciliation, further adding to the administrative workload and costs. Additionally, managing multiple billing systems increases complexity and introduces inefficiencies in workflow processes, hindering overall operational efficiency and potentially impacting patient care.

Compliance and Regulatory Requirements: DME suppliers are subject to regulatory requirements and compliance standards governing the provision of medical devices and services. Meeting these standards involves administrative costs, quality assurance measures, and adherence to regulatory guidelines, all of which contribute to the overall cost of providing CGM systems. WAC reimbursement rates may not fully account for these compliance-related expenses.

Impact on Service Quality and Patient Outcomes: Inadequate reimbursement at WAC rates can compromise the quality of services provided by DME suppliers and ultimately impact patient outcomes. Insufficient reimbursement may force DME suppliers to cut corners, reduce service levels, or limit patient access to essential educational and support services, resulting in suboptimal diabetes management and poorer health outcomes for patients.

Long-Term Viability of DME Providers: Sustaining a business in the DME industry requires sufficient reimbursement to cover operating costs, maintain quality standards, and ensure financial viability. Inadequate reimbursement at WAC rates may undermine the long-term sustainability of DME suppliers, leading to service disruptions, reduced access to care, and consolidation within the industry.

Reimbursing CGM systems at WAC will not adequately cover the costs incurred by DME suppliers in providing these essential medical devices.

Response: DHS has considered your concerns pertaining to the use of wholesale acquisition cost plus dispensing fee to reimburse providers for CGMs and diabetic supplies. DHS must identify ways to achieve balance across the broad array of treatments, services, and products required to provide quality healthcare to beneficiaries. Not only is the number of beneficiaries requiring care continuing to increase, so is the cost of the service, all while DHS is being charged with slowing the growth of Medicaid spend. The changes in rate and reimbursement processes were determined necessary to achieve a fiscally sound budget, create administrative efficiencies, and achieve a consistent quality of care for beneficiaries who are served in multiple areas of Medicaid benefit programs.

Conclusion

In conclusion, the proposed changes present a multifaceted challenge for DME providers. Not only do these alterations introduce significant administrative burdens and increase operational costs, but they also disrupt billing processes, leading to potential errors and delays in reimbursement. Moreover, the financial strain imposed by these changes would eliminate DME providers' ability to supply CGM systems to patients, thereby limiting access to essential supplies for managing patient's diabetes treatment. It is essential for policymakers and stakeholders to thoroughly assess the implications of these proposed changes and seek alternative strategies that prioritize affordability, efficiency, and equitable patient access to CGM technology. Failing to address these concerns risks compromising patient care and exacerbating disparities in healthcare access among individuals with diabetes.

Response: Thank you for responding to DHS's request for public comments pertaining to the rule proposing addition of the pharmacy for dispensing CGMs and other diabetic supplies. DHS recognizes your concern for the multifaceted challenge faced by DME and other providers, manufacturers, suppliers, and payors. DHS has thoroughly assessed the comments presented in the public comment period and is making every effort to achieve balance across the broad array of treatments, services, and products required to provide quality healthcare to its beneficiaries while controlling growth of the Medicaid budget.

Additionally, Medicaid is working to develop point of sale authorization solutions to decrease the administrative burden for obtaining prior authorizations and other such billing mechanisms so providers can continue to focus on value adds for their patients. Training on the use of the pharmacy portal is being developed and will be announced soon. Alternative strategies that prioritize affordability, efficiency, and equitable patient access to CGM technology is ongoing beyond implementation of this rule and cooperation with stakeholders, policymakers and beneficiaries is an important part of assuring the highest level of quality achievable.

Monty Baugh, Attorney

Comment: I submit the following comments pursuant to the Arkansas Administrative Procedures Act and the Notice of Rule Making issued by DHS on February 2, 2024. My comment specifically addresses proposed Rule 216.101, the relevant portions of which provide (1) that effective April 1, 2024, continuous glucose monitors (CGMs) are processed as a pharmacy claim submission by pharmacies or DME providers, and (2) procedure codes and rates of reimbursement for CGMs are to be changed from fee schedule rates based on Medicare non-rural rates for the State of Arkansas to wholesale acquisition cost plus applicable professional dispensing fee. I oppose the proposed rule for the reasons explained herein.

The proposed rule exceeds DHS's statutory authority under Act 393 or 2023. Section 2 of Act 393 provides that coverage for a CGM under the Arkansas Medicaid Program shall allow the beneficiary to obtain a continuous glucose monitor through a prescription at a pharmacy and be eligible for rebates as a pharmacy benefit. The language in the statute is permissive, not restrictive, and is directed toward the availability of CGMs by Medicaid beneficiaries.

In response to Act 393 DHS originally promulgated a proposed rule 221.100, which was to take effect on January 1, 2024. That rule required that Medicaid beneficiaries obtain CGMs only from pharmacies and not from DME providers. DHS retracted the rule after receiving a multitude of comments in opposition to the rule. Additionally, the Arkansas Attorney General, in response to a request by Rep. Matthew Brown of Conway, opined that Act 393 did not limit CGMS as a pharmacy-only benefit under Arkansas Medicaid, and that there was no law or rule specifically prohibiting Medicaid from covering CGMs as both a pharmacy benefit and a medical benefit. See Op. Ark. Att'y Gen. 99 (2023). DHS responded by promulgating new rules that allow for Medicaid beneficiaries to obtain CGMs from pharmacies or from DME providers but changed the reimbursement procedure for DMEs to require that DMEs submit claims for reimbursement for CGMs as a pharmacy benefit claim rather than a medical benefit claim. That scheme is likely

unworkable because DME providers in Arkansas are not set up to submit claims for covered products as pharmacy benefit claims rather than medical benefit claims. For a DME provider to submit a claim for reimbursement for a CGM as a pharmacy benefit, it would need a National Drug Code for that CGM to submit to a pharmacy portal. A careful search of the National Drug Code Directory (available at https://www.fda.gov/drugs/drugapprovals-and-databases/national-drug-code-directory) did not reveal an NDC for any of the commonly available CGMs (i.e. "Dexcom, Freestyle, Libre, CGM, continuous glucose monitor, etc.").

Response: As noted, DHS revised its original rule to ensure Medicaid coverage of CGMs and diabetic supplies remains under the Home Health benefit as a medical benefit and is in compliance with 42 C.F.R. §440.70(b)(3). This coverage will continue and be reported to CMS as such. The changes in rate and reimbursement processes were determined necessary to achieve a fiscally sound budget, administrative efficiencies, and a consistent quality of care for beneficiaries who are served in multiple areas of Medicaid benefit programs.

DHS has confirmed with CGM manufacturers that the three major wholesalers do have NDC specific inventory. DME providers will not be required to enroll as pharmacies to obtain NDC labeled product and utilize NDC billing nor will they be required to network with a PBM to use the pharmacy point of sale portal. The pharmacy portal is being modified to accommodate claims processing for DME providers and is available at no cost. Training on the use of the pharmacy portal will be announced soon.

DHS has thoroughly assessed the concerns presented in the public comment period and is making every effort to achieve balance across the broad array of treatments, services, and products required to provide quality healthcare to its beneficiaries within a very finite budget. Medicaid is working to develop point of sale authorization solutions to decrease the administrative burden for obtaining prior authorizations and other such billing mechanisms so providers can continue to focus on value adds for their patients. Alternative strategies that prioritize affordability, efficiency, and equitable patient access to CGM technology is ongoing beyond implementation of this rule and cooperation with stakeholders, policymakers and beneficiaries is an important part of assuring the highest level of quality achievable.

The proposed rule provides that pharmacies and DME providers alike are to be reimbursed "at the Wholesale Acquisition Cost (WAC) plus the applicable professional dispensing fee." Proposed Rule 216.101(A). That reimbursement model fits with reimbursement for CGMs as a pharmacy benefit, but it fails to recognize and reimburse DME providers for their value-added services they provide to Medicaid beneficiaries in addition to supplying CGMs. Those value-add services include patient education, home delivery of products, follow-up services, and local inventory of monitors and supplies. Pharmacies presently provide none of these value-add services to users of CGMs. The result of the proposed rule will be that DME providers will be disincentivized to continue as a provider of CGMs to Medicaid beneficiaries. This will result in the rule's unintended effect of reducing in availability of CGMs to Medicaid beneficiaries rather than increasing availability, as DHS should purpose to do. This unintended effect is compounded by the announcements by Walgreens, CVS, and Rite Aid of their intent to close more than 1,500 stores, with minority and low-income communities being disproportionately affected. See "Drugstore closures are leaving millions without easy

access to a pharmacy," Washington Post, October 22, 2023 (available at https://www.washingtonpost.com/business/2023/10/22/drugstore-close-pharmacydeserts/).

Finally, the proposed changes to the Medicaid State Plan for coverage for CGMs are arbitrary and capricious. The requirement that DMEs submit for reimbursement as a pharmacy claim is proposed without identification of a single benefit to either state government or to Medicaid beneficiaries. Indeed, the notice of rule making states that the projected annual cost of this change for state fiscal year 2024 is $300,047.00. Traditional insulin pumps will remain available from DME providers and processed as a medical benefit. Beneficiaries with Medicare Part B benefits will continue to be serviced under the DME program. The proposed rule simply singles out CGM devices that are presently available to Medicaid beneficiaries from DME providers and disrupts both the beneficiaries' present supply chain and numerous Arkansas-based local businesses without any identified benefit.

For these reasons I oppose the adoption of the proposed Rule 216.101. Thank you for your courteous attention to this matter.

Response: DHS has considered your comments pertaining to the use of wholesale acquisition cost plus dispensing fee to reimburse providers for CGMs and diabetic supplies. DHS is making every effort to achieve balance across the broad array of treatments, services, and products required to provide quality healthcare to its beneficiaries. Not only is the number of beneficiaries requiring care continuing to increase, so is the cost of the services that must be reimbursed, all while DHS is being asked to control budget growth. The changes in rate and reimbursement processes were determined necessary to achieve a fiscally sound budget and still coordinate a consistent quality of care for beneficiaries who are served in a multiple of areas within Medicaid benefit programs. Dedicated training sessions from the manufacturers specific to the challenges that patients face throughout their CGM usage should be available to providers regardless of whether they are dispensing through pharmacy or home health benefit. Providers who contract to be reimbursed by Medicaid are bound to the same requirements for ensuring patients have the resources and assistance necessary to understand and use the equipment and supplies critical to their care. Additionally, Medicaid is working to develop point of sale authorization solutions to decrease the administrative burden for obtaining prior authorizations and other such streamlined billing mechanisms so providers can continue to focus on value adds for their patients. Beneficiaries still retain the option to use the provider of their choice (DME or pharmacy) and pharmacies are expected to rise to the challenge of meeting the same high standards for Medicaid beneficiaries and other Arkansans who must rely on their services.

Simay Okyay
Health Policy Manager
Applied Policy

Comment: CCS Medical (CCS) is submitting this letter in response to the Continuous Glucose Monitors And Diabetic Supplies As A Pharmacy Benefit – Second Notice Of Rule Making ("Second Notice") on moving diabetes supplies from the durable medical equipment (DME) benefit to the pharmacy benefit for Arkansas Medicaid enrollees.1 CCS appreciates the opportunity to comment on this rule.

CCS is the largest distributor of insulin pump and associated supplies, as well as one of the largest providers of continuous glucose monitor (CGM) equipment and supplies, for Medicare and Medicaid beneficiaries in the United States. CCS services more than 145,000 Medicare beneficiaries with diabetes through traditional fee-for-service and Medicare Advantage plans. Many of the beneficiaries we serve are dual-eligible and covered by state Medicaid programs. We serve more than 2,400 Arkansas Medicare and Medicaid enrollees. Our experience and size make us well-versed in the products and services requested by Medicare and Medicaid beneficiaries, and prescribed by their health care practitioners, to treat their diabetes. We work with beneficiaries daily to help them overcome real life situations that create barriers to access products and services they have been prescribed.

We thank Division of Medical Services (DMS) for clarifying that beneficiaries with Medicare Part B benefit can continue to be serviced under the DME program. We appreciate Arkansas Medicaid's recognition of the importance of maintaining access to diabetes supplies through the DME benefit for cross over claims, when servicing dually eligible Arkansans. We ask that DMS additionally clarify that dually eligible Medicaid enrollees may have traditional Medicare fee-for-service or Medicare Advantage as their primary payer in order to cross over with Arkansas Medicaid through the DME benefit.

Response: Medicare crossover claims reimbursement processes will remain the same as they are now.

Furthermore, we appreciate Arkansas Medicaid's announcement that CGMs will continue to be covered under the DME benefit in addition to being covered under the pharmacy benefit. However, we believe that the processes outlined in the Second Notice are not appropriate for items serviced under the DME benefit.

Concerns Regarding Claim Submission Process on the Magellan Portal

The Memorandum issued with the Second Notice states that "Medicaid beneficiaries are eligible for diabetic and blood sugar testing supplies processed as a pharmacy claim submission by pharmacies or DME providers." To our knowledge, DME providers must enroll with a pharmacy benefit manager (PBM) to be a part of its network. We understand that Magellan will allow DME providers to submit claims through a new portal2, for which DME providers enrolled in Arkansas Medicaid will need to register. All DME providers have operating systems to manage patient accounts, ship and deliver DME products, and automatically create and submit the 837 medical claims form that is used to submit medical claims with HCPCS codes. We are concerned that the PBM portal submission process will require us to manually enter all claims, creating unnecessary labor costs for suppliers to submit claims through the portal. We ask that Arkansas Medicaid please ensure DME providers can continue to submit CGM claims with the 837 form under the DME benefit, using the existing automated system and HCPCS codes.

We are also concerned that the requirement to utilize the pharmacy point of sale portal to submit claims means that we will be required to submit National Drug Code (NDC) for CGMs, rather than the HCPCS codes we currently utilize under the DME benefit. DME products, by nature, do not have NDCs. While CGM manufacturers do have NDCs for their retail pharmacy class of products, they do not have NDCs for their government class of products, which is the class of trade DME providers use.

For example, some CGM manufacturers sell their products by class of trade based on the payor who pays the claim. These classes of trade are pharmacy through a pharmacy benefit manager, commercial medical claims (DME), and government (Medicare, Medicaid, Medicare Advantage, Medicaid MCO)

medical claims (DME). Our contracts with the manufacturers follow this logic. The government class of trade is only permitted to be used for Medicare and Medicaid beneficiaries under the medical benefit. The manufacturers did not assign an NDC to these products since medical claims do not require this information for payment.

If Arkansas Medicaid requires DME providers to use NDCs instead of HCPCS codes in claim submissions, due to utilizing a pharmacy point of sale portal, this would eliminate the ability for DME suppliers to bill for CGMs purchased for and provided to Medicaid enrollees utilizing the government class of trade the manufacturers have established. Therefore, we ask that DMS maintain billing HCPCS codes for CGMs serviced under the DME benefit.

Response: DHS has confirmed with CGM manufacturers that the three major wholesalers do have NDC specific inventory which can be purchased by DME providers. DME providers will not be required to enroll as pharmacies to obtain this product and utilize NDC billing nor will they be required to network with a PBM to use the pharmacy point of sale portal. The pharmacy portal is being modified to accommodate claims processing for DME providers and is available at no cost. For example, Medicaid is working to develop point of sale authorization solutions to decrease the administrative burden for obtaining prior authorizations and other such billing mechanisms so providers can continue to focus on value adds for their patients. Training on the use of the pharmacy portal will be announced soon.

WAC is Not the Appropriate Cost Structure for DME Items

The pharmacy channel payment structure is set up for beneficiaries picking up drugs at their local retail pharmacies, and not for the DME home delivery system. The Second Notice indicates DME providers would be reimbursed based on wholesale acquisition cost (WAC) plus a professional dispensing fee payment rate of $10.50 per claim. This payment structure would not cover the cost of shipping and home delivery, and associated labor, to process the claim.

For example, the WAC is usually the acquisition cost of the product across the market for the Abbott Freestyle Libre CGMs. The additional $10.50 dispensing fee will not cover the local shipping costs, leaving DME suppliers without a margin to cover the labor costs associated with processing order, submitting claims, and talking to customers. The pharmacy WAC reimbursement structure is not a sustainable way to pay for DME supplies and it will limit enrollee access to the DME channel for this CGM brand. We ask that Arkansas Medicaid continues to pay DME providers for CGM claims based on HCPCS codes and the corresponding Medicare fee schedule amounts.

Response: The state has requested to amend its rate methodology for CGMs and diabetic supplies to align and coordinate a reasonable rate for the same product across various benefit plans. The processes are being amended to ensure DHS is complying with principles of economy, efficiency, and quality of care which includes accommodating coordination between medical and pharmacy policy. Based on this, DHS has determined a need to change DME provider billing for CGMs and diabetic supplies to align reimbursement across multiple provider types for the same products. Medicaid is working to develop point of sale authorization solutions to decrease the administrative burden for obtaining prior authorizations and other such streamlined billing mechanisms so providers can continue to focus on value adds for their patients.

DME Providers Improve Patient Care and Access for People with Diabetes

Diabetes is a complicated medical diagnosis that requires individualized care. While pharmacies carry and sell CGM devices and supplies, DME suppliers like CCS provide patient-centered care. DME suppliers are more engaged with manufactures and are more knowledgeable about the technologies that are in the best interest of patients with diabetes. There is no cure for beneficiaries with type 1 diabetes (T1D), and beneficiaries with type 2 diabetes (T2D) who are insulin treated are also unlikely to see changes in their condition within a short period of time. DME suppliers support continuity of care for patients with diabetes, which is necessary to prevent interruptions in adherence to therapy.

DME providers often specialize in treating certain conditions and often have field representatives working with prescribers to help facilitate the start of new equipment. We stay attuned to the rapid advances in CGM technology so that we can answer questions about product selection, setup, proper use of the CGM as well as provide ongoing support. In addition, DME providers often coordinate all diabetes supplies when the patient is also using an insulin pump system which integrates with their CGM. This level of experience and constant communication with patients about their diabetes supply needs or concerns allows for timely intervention to prevent complications.

Arkansas Medicaid enrollees who get their CGM supplies from a DME provider today should be able to continue to work with their DME providers, if they choose to do so. If DMS changes the DME reimbursement to a pharmacy point of sale model, we will not have the ability to continue to serve all CGM products or provide the training and support services we offer today. We ask DMS not to create barriers for DME providers to serve these patients by changing the billing and payment structure for CGMs provided under the DME benefit.

In order to prevent disruptions in patient access and care, we urge DMS to allow billing for CGMs under the DME benefit using HCPCS codes and the DME fee schedule amounts, consistent with other DME covered by Arkansas Medicaid.

CCS appreciates the opportunity to comment on this notice. Please contact Linda Langiotti at linda.langiotti@ccsmed.com should you have any questions.

1 https://humanservices.arkansas.gov/wp-content/uploads/Continuous-Glucose-Monitors-and-Diabetic-Supplies-Coverage-r.-2-2-24.pdf
2 Based on information in the email communication received from DMS Division of Medical Services Assistant Director, Cynthia Neuhofel Cynthia.Neuhofel@dhs.arkansas.gov on 2/23/2024.

Response: Thank you for communicating your concerns regarding this policy. We have considered all comments received. CGMs and diabetic supplies will continue to be provided under the Home Health benefit and reported to CMS as such. Pharmacies will be able to dispense CGMs and diabetic supplies beginning 5/1/2024.

The state is bound to fiduciary and budget concerns in administering a full array of Medicaid programs in a perpetually changing economy. The Medicaid program must responsibly balance concerns for quality of patient care against ever-increasing funding concerns in a state that requires a balanced budget.

Medicaid understands concerns regarding the change in processes and will provide training and assistance to DME providers for the Magellan portal. The portal is currently being modified to accommodate claims billing for CGMs and diabetic supplies under this rule.

As technology rapidly continues to change, Medicaid is amenable to working with its partners and stakeholders to explore better options for expanding claims processing opportunities.

NOTE TO ALL PROVIDERS: Medicaid is developing a FAQ to assist providers with the upcoming transition and problem-solving for preventing disruption in service to our mutual beneficiaries requiring these supplies.