Continuous Glucose Monitors and Diabetic Supplies as a Pharmacy Benefit – Zoom Public Hearing Transcript 10/25/23 @ 9:00 CST

Mac Golden: Good morning, everyone. Welcome to a public hearing on a rule regarding continuous glucose monitors and diabetic supplies as a pharmacy benefit. Anita Castleberry, the Division of Medical Services Business Operations Manager will be announcing the Notice of Rule Making. We will then open the floor for public comments. Please utilize the raise hand feature in zoom if you would like to make a comment. You will be recognized to give a public comment on the record. All official responses to public comments will appear on the DHS proposed rules website after the public comment period concludes. Ms. Castleberry will now read the notice of rulemaking.

Anita Castleberry: Thank you, Mac. Notice of Rule Making.

The Department of Human Services announces for a public comment period of thirty (30) calendar days a notice of rulemaking for the following proposed rule under one or more of the following chapters, subchapters, or sections of the Arkansas Code: §§ 25-10-129, 20-76-201, and 20-77-107.

The Director of the Division of Medical Services (DMS) amends the Arkansas Medicaid State Plan and corresponding provider manuals to implement Act 393 of 2023 of the 94th General Assembly. The Act requires Medicaid to cover continuous glucose monitors (CGMs) as a pharmacy benefit and mandates pharmacy coverage of CGMs for certain individuals with diabetes or hypoglycemia. Impacted beneficiaries include those with Type 1 diabetes or any other type of diabetes with either insulin use or evidence of level 2 or level 3 hypoglycemia, or beneficiaries diagnosed with glycogen storage disease type 1a. DMS also added blood glucose monitors (BGMs) and other diabetic supplies to the rule to benefit from additional state supplemental rebates and streamline access to care for beneficiaries.

Medicaid payments for the CGMs and related supplies are calculated using already established rate methodology for pharmacy with rebates being applied. The projected annual cost of this change for state fiscal year (SFY) 2024 is \$600,094.00 (of which \$432,067.00 is federal funds) and for SFY 2025 is \$213,589.00 (of which \$153,784.00 is federal funds).

Pursuant to the Governor's Executive Order 23-02, DHS repeals the following two rules as part of this promulgation: (1) DDS Policy 3018 – Reporting of Denial of Access to Services, and (2) DDS Policy 3018 – Mortality Review of Deaths of Persons Receiving Alternative Community Services Waiver Services.

The proposed rule is available for review at the Department of Human Services (DHS) Office of Rules Promulgation, 2nd floor Donaghey Plaza South Building, 7th and Main Streets, P. O. Box 1437, Slot S295, Little Rock, Arkansas 72203-1437. You may also access and download the proposed rule at ar.gov/dhs-proposed-rules. This notice also shall be posted at the local office of the Division of County Operations (DCO) of DHS in every county in the state.

Public comments must be submitted in writing at the above address or at the following email address: ORP@dhs.arkansas.gov. All public comments must be received by DHS no later than November 12th, 2023. Please note that public comments submitted in response to this notice are considered public documents. A public comment, including the commenter's name and any personal information contained within the public comment, will be made publicly available and may be seen by various people.

If you need this material in a different format, such as large print, contact the Office of Rules Promulgation at (501) 320-6428.

The Arkansas Department of Human Services is in compliance with Titles VI and VII of the Civil Rights Act and is operated, managed and delivers services without regard to religion, disability, political affiliation, veteran status, age, race, color or national origin.

Mac Golden: Thank you, Miss Castleberry. Please let the record reflect we have twenty-nine (29) attendees for today's public hearing. If an attendee would like to make a public comment at this time, please utilize the raise hand feature. It appears we have several people wanting to make comments. Barry I just want to start at the top with Mister David Chandler. Mr. Chandler you are recognized to give your comment on the record.

Mr. Chandler: Thank you. My name is David Chandler and I represent the American Association for HomeCare. AAHomecare is the National Association representing durable medical equipment, suppliers, manufacturers, and other stakeholders in the home care community. Our membership services patients living with diabetes and provides medical equipment, such as continuous glucose monitors or CGMs across the nation. AAHomeCare and the DME community understand the critical need for monitoring and controlling diabetes to improve the health and outcomes of these beneficiaries. We believe that it's critical to ensure that these beneficiaries receive the care they need in their home, and in a manner that makes it easy to access these items, and to ensure this access we're requesting that coverage through the durable medical equipment channel continues to be available to Arkansas Medicaid recipients to ensure continuity of care. Based on feedback from DME suppliers, manufacturers, patients, and other stakeholders, DMEs are better suited to provide a more comprehensive service to CGM patients. DME suppliers promote reduction in health care costs, improve health equity, patient care, patient choice and access. DME suppliers aid in the reduction of health care costs. A higher retention is achieved under the DME channel. DME suppliers have a CGM patient retention rate of approximately 87% which is 20 to 30% higher than under the pharmacy benefit. CGM use reduces diabetes related hospitalizations and costs. Studies have shown that CGM utilization reduced hospitalizations caused by acute diabetes complications by approximately 50%. Therefore, higher retention rates equal exponentially higher healthcare savings. DME suppliers advance health equity for diabetes patient populations. DME suppliers are better suited to supply CGMs to the growing population of people living with diabetes. 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 in recent years. DME suppliers provide additional needed support for pediatric diabetes patients. Children living with type one diabetes, and their parents need a network to support the child's diabetes management. DME suppliers improve patient care. DME suppliers are specialized and have trained agents who can provide CGM guidance and product assistance to diabetes patients. In addition, to product expertise, DME suppliers provide educational resources, onboarding services and follow-ups for CGM 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. DME suppliers are knowledgeable of documentation and coverage requirements. DME suppliers promote patient choice and access. DME suppliers promote patient convenience and maintain a broad inventory and can deliver devices and supplies directly to a patient's home or office. Patients report higher satisfaction with DME suppliers. Patients that have switched from the pharmacy to the DME have voiced greater satisfaction with service under the DME channel. So, in closing AA Homecare recommends that Arkansas Medicaid continues to cover continuous glucose monitors or CGM under the durable medical equipment benefit in addition to the pharmacy channel. CGM supplied by DME suppliers promote patient access, patient choice, therapy adherence and results in reduced healthcare costs. Thank you for your time.

Mac: Thank you for your comment. DHS will reply at the end of the comment period on the proposed rule website. Barry, you want to proceed to the next person wanting to make a comment. Geoffrey Yamauchi, you are recognized for your comment on the record.

Geoffrey Yamauchi: Thank you kindly. My name is Geoffrey Yamauchi. I represent Habibi's Durable Medical and as the previous David Chandler spoke, we are set up to do this business. With all the patients that pharmacies currently have, can they possibly keep up with this? What we have seen in the past is every time that either Medicare, Medicaid for whatever states they may be in, whether it MediCal or other states we have seen outcomes worsening in patients. Now a number was thrown around that this might save between 1.2 and 1.5 million dollars for the State. But being a rural state like we are, if patients are unable to get their sensors or have to go pick them up, how many will be unable to monitor their conditions as well? Many communities in this state don't have pharmacies within their borders, and they have to travel some cases 20, 30, 40 miles. In these cases, how is their diabetes being managed as well? We would like you to stay and continue to provide these services through DME or through the pharmacy as well. We are set up for this. We do have the necessary infrastructure to call and remind and deliver to our patients. So, I just hope that you will continue to allow us to provide, so that the outcomes of the patients, the Medicaid patients, don't worsen. My question is, how much does a foot amputation cost the state versus allowing the DME to continue providing these? And that is all I had to say. I appreciate you guys time very much and I hope we can get more people to comment through writing. Thank you.

Mac: Thank you, Geoffrey. Your comment will be taken into consideration and DHS will follow with a response.

Let the record reflect that since we began the public comments, we've picked up a few attendees. We now have thirty-two (32) attendees. We will proceed to the next person to make a comment, Misty Rae Drain.

Misty Rae Drain: My name is Misty Rae Drain and I represent myself and my son. His name is Jacob (inaudible). He is a type one diabetic. We have lived with this disease for nine years. Jacob also has autism, and it makes his type one diabetes care all the more critical because his CGM system is his voice. Critically we use this system 50 to 115 times a day. We were, in fact, homebound, and during COVID I had to home school him because there was no other options. He is now currently a senior at Lincoln High School. Because of Finnigan's consistent delivery through the DME Channel, I am a huge fan of having the option for pharmacy coverage, but can I speak to the practicality? I can tell you the good, bad and ugly that comes with the entire supply chain of all diabetes supplies in great detail. We have struggled every single month to get his basic supplies, and I am blessed to actually have a good care coordinator who does have my son's back. Not everyone does. Even with her regular help, with dozens of calls a month we scramble every single month just to get basics like insulin, ketone strips and blood strips from our local pharmacies here currently right now. I have had to coordinate with her out of state to get our blood strips because there are no local pharmacies willing to take us as a client right now with the current reimbursement rate. With the ration, they have in fact, rationed our supplies including insulin and ketone strips, and we have had to seek elsewhere. Our only consistent supply has been our DME supplier. Medicaid reimbursement rates are flat out denying service to those who are in rural communities, have multiple service issues and we can't guarantee that our local pharmacy as much as we love having that option, they'll be able to actually deliver CGM management supplies. Right now, I have called the local twenty pharmacies around my area. None of them have supplies. They can't get them until February. I have all of my ducks in a row. My son has seen an endocrinologist, a pediatric person. He's gone to Arkansas Children's and I have every single PA required. I can't get supplies right now. The only thing I have coming on a consistent basis to my door are these DME supplies. I should be able to go where the customer service consistently supplied supplies have been. With the shortage right now, a wait list to even see an Endocrinologists and a backlog, a January rollout doesn't make sense. So, either we need to include DMEs with pharmacy coverage, or there will be no continuity of care. You will have many people ending up in the ER. My son, one of them. This year alone we have avoided 15 ER visits. Why? Because if I were to follow Arkansas Children's protocol, that is what I would have had to do had I not had this service. It is \$5,000 to walk in that door sir. If I follow what they want to do, that is \$5,000 taxpayer dollars every single time to follow that versus having home delivery. It does not make sense. Even if you don't

like me, my son or anyone else that does not make good business sense. The rollout language needs updated to allow current customers to continue to receive these lifesaving supplies while local pharmacies can build up stock or at a minimum needs delayed as to its full effect. So, all stakeholders in the community are afforded the opportunity to be made aware, due to the magnitude of this change. A single zoom, (inaudible). I'm trembling as I speak as their advocate. The one consistent of supplies we have had have been our local DMEs. They're employed by local type ones. That has been whose answered my call. You're taking that supply away of support and advocacy and education. And no, it's okay. This is how you do this at 3 o'clock in the morning. I cannot speak to the importance of not having pharmacy coverage. We want that. But we just don't want to lose what we currently have in order to gain further options. It doesn't make sense. Please don't take away such a critical supply artery in my son's care. (inaudible) The reality is, those with diabetes that are home bound, have covid exposure, live in a rural area, or have any other disease that makes diabetes difficult don't need more hoops to jump through when we could have direct delivery to our doors. What we need are more options for preventive care, not less by not enacting these changes without a game plan. People who can't even be seen, you know, just can't even get these systems. Please help us to have both. We shouldn't have to suffer a continuity of care. Thank you. Have a blessed day.

Mac: Thank you, Miss Drain. Your comments will be taken and given serious consideration by DHS. Barry we can proceed to the next person. Sarah Wimberly you're recognized to give your comment.

Sarah Wimberly: Good morning, all. Thank you for the opportunity to speak today. I am writing and speaking today regarding the proposed change of CGMs from a DME benefit to a pharmacy benefit. I am a mother to a type one diabetic child. My son, Landon has been on the Dexcom G6 continuous glucose monitor since 2016. He has had great success with it, and we credit a lot of his success to the fact that his supplies arrive on time every month and directly to our home, with no interruption and service from Finnegan health services. They have been an amazing advocate for my son and for his supplies over the years. With the DME company there is no pre-ordering involved, no having to drive to his pharmacy, wait in lines and zero possibility that the item might be out of stock. Our local DME provider has made sure that we never miss a beat when it comes to his CGM supplies. We have never missed a month. We have never had to go without. I have a feeling that if this were to go to a pharmacy benefit, that would not be the case, because there have been several months that we have had to ration insulin because our local pharmacies did not have it. It has been mentioned by Dexcom that pharmacy distribution allows for a more seamless experience for physicians and patients. While this might be the case for physicians, this is not true for many patients. There are those patients who do not have access to transportation to get to their local pharmacy, those who live in rural areas that are miles and miles away from a local pharmacy and those that are high risk pregnancies or handicapped or disabled, that rely solely on delivery to get their much needed medical devices, such as their CGMs. Making this item a pharmacy only benefit shows complete disregard, in my opinion, towards these patients and their needs. The pharmacies in Arkansas, I do not believe, are equipped to handle the surge and CGM patients. Most pharmacies I've spoken to, including mine and my sons, regarding this change are not optimistic and or will not carry the supplies. For our local DME company it's as simple as having the item drop shipped from their distributor and shipped directly to our home in two to three business days. What happens if I go to my pharmacy to pick up my son's CGM and be told it's out of stock. This would not be an option for us, as we are not allowed to have testing supplies and CGM in the same month. So we technically don't even have testing supplies on hand if we were to need backup. I just don't believe this is having the patient's best interest in healthcare in mind. If a patient does not access to their CGM. They will have no choice but to do finger sticks which is another burden most diabetics are reluctant to go back to or don't have the supplies to do it. A lot of patients are also on insulin pumps, including my son, and have their CGM linked to the pump. This will cause another issue when they are out of supplies, and they must manually input their BG values into the pump. I do not think that this is the right option for the State of Arkansas at this point. I think it should be a dual benefit. Currently, there are approximately 363,781 people in Arkansas, 14.8% of the adult population living with diabetes. This number does not include children, and the many more diagnosed

each day. Here in Arkansas our pharmacies are already short-staffed, and ill-equipped to deal with this ever-increasing number. Please reconsider this change to a dual benefit, giving families the option that best suits them. Thank you for your consideration.

Mac: Thank you for your comment as well. We will proceed to the next person. Let's recognize S. McCoy. Can you please state your full name for the record and proceed with your comment.

Sean McCoy: My name is Sean McCoy. I'm the president for Eclipse Medical. I don't want to rehash some of the great comments that have already been made. I think David Chandler from AAHomecare and his comments, I think he covered a number of kind of key topics and points that we want to bring to the table today. I think I most want to recognize both of these mothers. These are mothers of type one diabetics, and they are a very vulnerable population here in the State of Arkansas. We all know how rural the state is. It's comprised of small towns from corner to corner. My wife is from one of these small towns, Carthage, Arkansas. A small town that I wasn't even familiar with as a native Arkansan until I met her. But these are towns of 300 people, 500 people, less than a thousand people, where there are no pharmacies. Pharmacies are maybe 20-30 miles away, as David pointed out earlier in his comments. So, a lot of these people have trouble getting to these, would have trouble getting to a pharmacy. Just because they can get to their nearest pharmacy doesn't assume that they're gonna have access to products. A lot of the pharmacies may not carry CGM products, especially some of the smaller mom and pop pharmacies. If they do carry the products, they may not offer the full product offered. So, depending upon the endocrinologists, the treating clinicians, and physicians they may prescribe a specific product based on that patient's specific needs. And so, even if you have access to a pharmacy, or you have to drive a long way to get there, when you get there, they may not carry the products that you need, that are compatible, perhaps with the type of pump that you're on. So, there are a lot of variables involved in this equation. On behalf of all the DMEs I know that we are DME owners, and I think this is a little bit of an exception to the rule, we're all willing, and recognize the importance of having access. So, none of us have issues with pharmacies being able to distribute these products. What we're specifically asking is this is a dual benefit, and that you don't carve out the DME industry, who two years ago fought very hard to work very closely with Medicaid, as you guys introduced this into the marketplace and allowed patients to get access. I think that was a tremendous thing, but it's taken a long time to figure out what's required from a documentation standpoint. What's the process. That took a lot of coordination and trial and error with Arkansas Medicaid to figure those things out. So, you know, we as DME owners fulfill a very important role in providing services, especially to these rural Arkansans, and they don't have to be rural either, it's the ability to get patients products in a timely manner. It's our constant communication that occurs with these patients. We're communicating with these patients often on a monthly basis, in order to ensure that they're getting their supplies in a timely manner. And obviously, that's not really the role of a pharmacy. That's not something that's gonna be able to fill in the way that the DME provider does. So, I'll have had a number of conversations with some of our state representatives in different districts where I live, districts where our business is located. Those are some ongoing conversations, some of which are scheduled for later today. And I will tell you what's become pretty clear in those conversations with all these representatives, this Act 393, the intent of this was to broaden access. Again, access to the pharmacies on top of the DME. That was the intent of this, based on all my conversations to date. Based on the intent as those who sponsored the act. And we again, as DME owners, we support, we absolutely support broadening access. We think that's a tremendously positive thing for patients around the state. So, pharmacies having access to these products, we fully support. Again, we're asking that we are not carved out and removed from the equation. I will touch base real quickly on the cost. You know I understand the potential savings of 1.2-1.5 million dollars may be appealing on the front end. But I would point out that those costs are gonna be quickly absorbed and exceed that number if we remove the DMEs from the equation. There are a number of comorbidities related to diabetes that we could go into and talk about the cost of health care and patients who are not compliant. The one thing that's become very evident to me after being in the diabetes industry for the last 20 to 25 years is the technology now such with these CGMs, it allows these patients to truly manage their diabetes effectively. And what we're

seeing with compliance is numbers that are tremendously higher than they've ever been with the traditional CGM products. That compliance is critical. Testing your blood glucose levels, knowing where you are at all times. That creates the baseline for these patients, their clinicians, and their treating physicians to be able to keep these patients in range and keep their blood glucose levels at a therapeutic range, so that they don't have a lot of these comorbidities and associated problems. One patient developing a diabetic foot ulcer can become an expense and an ongoing expense that that patient deals with, not for days or weeks, but for months and even years. These diabetic foot ulcers often take months to heal. Then they reoccur even after they're healed. Theres tremendous cost in treating those things. So, the more we can keep these patients' incompliance and from developing problems like this, the more money that we as a state are gonna save. And more importantly, the better health care we're gonna provide to these patients. That diabetic foot ulcer could also ultimately lead to an amputation. I'm happy to provide some research and some information around amputations from national publications like the NIH that really speak to the cost associated with amputations. The cost of a small digit amputation on a toe can be 5 to 10,000 dollars. As you get into the upper leg extremities, it can run 50, 60, 70, even pushing a hundred thousand dollars in some cases. So that's a progression. It starts with a toe, then the foot, then it's the bottom of the leg, then it's the upper leg. And so those cost alone with one patient would be into the hundreds of thousands of dollars over the course of a few years. So again, I hope that you will strongly consider the ability for us as DME providers to continue to participate and provide these very valuable services to these patients. We all appreciate your consideration of this language and looking at that to ensure that we're able to do so moving forward. Thank you.

Mac: Thank you, Mr. McCoy. We appreciate your comment. If there is anyone else at this time that would like to make a comment, please utilize the raise hand feature. If you would like to make a comment by email, you can email my office at ORP@dhs.arkansas.gov.

I'll pause for a moment to give everyone the opportunity to raise their hand if they would like to make a comment.

It does not appear that anyone else wishes to make a comment today. We thank everyone for attending this public hearing. And again, we will consider your responses to all the public comments given today along with all written public comments that we receive at the end of the public comment period. We thank you for your time today and have a good day.