

### DEPARTMENT OF HUMAN SERVICES, DIVISION OF MEDICAL SERVICES

SUBJECT: Continuous Glucose Monitors and Diabetic Supplies Coverage & REPEALS: DDS Policy 3018 – Reporting of Denial of Access to Services; DDS Policy 3018 – Mortality Review of Deaths of Persons Receiving Alternative Community Services Waiver Services

# **DESCRIPTION:**

# Statement of Necessity

The Division of Medical Services (DMS) revises the Arkansas Medicaid state plan and corresponding provider manuals to comply with Act 393 of 2023. The Act requires Arkansas Medicaid to cover continuous glucose monitors (CGMs) as a pharmacy benefit. It also mandates pharmacy coverage of CGMs for certain individuals with diabetes allowing for blood glucose levels to be monitored at set intervals without finger sticks. Eligible 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.

While reviewing the financial impact, it was determined that blood glucose monitors (BGMs) and other diabetic supplies should be added to the rule to streamline administrative procedures and to increase access to care for beneficiaries.

This rule began promulgation in October 2023. A public comment period ran from October 14, 2023, to November 12, 2023. DHS reviewed all public comments received and in response revised the rule and published it for a second public comment period with the responsive changes incorporated into the rule.

# Summary

The following provider manuals and state plan amendment (SPA) pages will be updated in compliance with the Act and for the other reasons stated above.

### **Medicaid Provider Manuals:**

### ARKids First B

• Section 221.100 – Deleted "Continuous Glucose Meters (CGM) and CGM supplies" and added "Including diabetic supplies". Added the statement "For billing information to include Continuous Glucose Monitors (CGM), CGM supplies, patch or tubeless insulin pumps, blood glucose monitors (BGMs), and glucose testing supplies see the DHS contracted Pharmacy Vendor's website."

### Home Health

• Section 242.150 – Changed Bullet A to state that Home Blood Glucose supplies include all beneficiaries. Deleted HCPCS code information for Home Blood Glucose supplies.

# Pharmacy

- Section 212.000 Deleted "glucose monitoring devices and supplies."
- Section 216.100 Added "and glucose monitors and supplies" to bullet point D. Deleted "Glucose home monitors with supplies" from bullet point J.
- Section 216.101 Added new section concerning Medical Supplies Covered as a Pharmacy Benefit.

#### **Prosthetics**

- Section 212.206 Changed the title of the section from "(DME) Home Blood Glucose Monitor, Pregnant Women Only, All Ages" to "Home Blood Glucose Monitor and Supplies All Ages". Deleted all previous information and added the statement "Effective 4/1/2024, Medicaid beneficiaries are eligible for diabetic and blood sugar testing supplies processed as a pharmacy claim submission by pharmacies or DME providers. Home blood sugar meters and supplies (strips, lancets, calibration solution, etc.) are available without a prior authorization. See the DHS Pharmacy Vendor's website for specific information for coverage details."
- Section 212.207 Deleted "DME" from the title. Added the statement "Effective 4/1/2024, patch or tubeless insulin pumps are covered as a pharmacy claim submission while traditional insulin pumps requiring tubing and cannula type supplies remain processed as a medical claim. Beneficiaries with Medicare Part B benefits continue to be serviced for all of their needs under the DME program." Also added the statement "When submitting prior authorization requests for the patch or tubeless insulin pumps see the DHS Pharmacy Vendor's website for specific information for coverage details."
- Section 212.208 Bullet point A Deleted "The Arkansas Medicaid Program provides coverage for a continuous glucose monitor (CGM) for the treatment of a Medicaid client if the client has:" and added "Effective 4/1/2024, continuous glucose monitors (CGMs) are covered as a pharmacy claim submission by pharmacies or DME providers. Beneficiaries must meet the following criteria for coverage:" Changed number 1 under this bullet point to remove "more than two times daily" and added #3 to state "See the DHS Pharmacy Vendor's website for specific information for coverage details."
- Deleted bullet point C which stated "Additional requirements are set out in Section 242.113." Added the statement" Beneficiaries with Medicare Part B benefits continue to be serviced under the DME program."
- Section 242.112 deleted in its entirety.
- Section 242.113 deleted in its entirety.

#### **Medicaid State Plan:**

Page 4.19-B 2g

Added 7B.

"Effective for dates of service on or after April 1, 2024, reimbursement for Continuous Glucose Monitors (CGM) and related supplies including patch type insulin pumps is based on wholesale acquisition cost (WAC) plus applicable professional dispensing fee. Traditional insulin pumps will remain at the Medicare non-rural rate as stated in A. above."

# Arkansas Child Health Plan Under Title XXI Of The Social Security Act Children's Health Insurance Program (CHIP SPA):

- SPA # 14 adds the statement "The purpose of this SPA is to improve access to continuous glucose monitors (CGMs) through pharmacy claim submission processing for reimbursement to pharmacies and DME providers. Beneficiaries eligible for CGMs 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. Patch type insulin pumps, blood glucose monitors (BGMs) and testing supplies will be covered in the same manner. Coverage is being extended to comply with Arkansas Act 393 of 2023."
- Section 6.2 Adds "and diabetic supplies" to the Prescription Drugs section in the chart. Also adds the statement "\*The Prescription Drugs and diabetic supplies category includes prescription drugs, Continuous Glucose Monitors (CGMs) with CGM supplies, patch type insulin pumps, and blood glucose monitors (BGMs) with blood glucose testing supplies (test strips, calibration solution)."
- Section 8.2 \*The Prescription Drugs and diabetic supplies category includes prescription drugs, Continuous Glucose Monitors (CGMs) with CGM supplies, patch type insulin pumps, and blood glucose monitors (BGMs) with blood glucose testing supplies (test strips, calibration solution).

Repeals pursuant to the Governor's Executive Order 23-02:

- (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.

**PUBLIC COMMENT:** A public hearing was held on this rule on October 25, 2023. The public comment period expired on November 12, 2023. The agency amended the rule in response to public comment and opened a second public comment period. A second public hearing was held on February 14, 2024. The second public comment period expired on March 4, 2024.

The agency provided a public comment summary for each public comment period. Due to length, both public comment summaries are attached separately.

Lacey Johnson, an attorney with the Bureau of Legislative Research, asked the following question and received the following response:

**Q.** Section 212.208(A)(1)(a) of the Prosthetics manual removes the requirement that a beneficiary use insulin "more than two (2) times daily." However, it appears that this language is still in the statute (see A.C.A. § 20-77-148(b)(1)(A)(i)). Why was it removed from the rule?

**RESPONSE:** The requirement for Medicaid to cover a continuous glucose monitor for a beneficiary who uses insulin more than two (2) times daily remains in state law. DHS is in compliance even though Medicaid's rule has been revised to remove the restriction that insulin has to be used more than twice a day before the use of a CGM can be covered. The restriction was removed to allow Medicaid to conform with the CMS revised coverage guidelines and National Diabetes Association groups' clinical guidelines for dispensing the product. The change in the Medicaid rule will allow more access to the use of improved blood monitoring products for beneficiaries who are insulin dependent regardless of the number of times per day their insulin must be injected.

The proposed effective date is pending legislative review and approval.

**FINANCIAL IMPACT:** The agency indicated that this rule has a financial impact.

Per the agency, the cost to implement this rule is \$300,047 for the current fiscal year (\$84,013 in general revenue and \$216,034 in federal funds) and \$213,589 for the next fiscal year (\$59,805 in general revenue and \$153,784 in federal funds). The total estimated cost by fiscal year to state, county, or municipal government to implement this rule is \$84,013 for the current fiscal year and \$59,805 for the next fiscal year.

**LEGAL AUTHORIZATION:** The Department of Human Services has the responsibility to administer assigned forms of public assistance and is specifically authorized to maintain an indigent medical care program (Arkansas Medicaid). *See* Ark. Code Ann. §§ 20-76-201(1), 20-77-107(a)(1). The Department has the authority to make rules that are necessary or desirable to carry out its public assistance duties. Ark. Code Ann. § 20-76-201(12). The Department and its divisions also have the authority to promulgate rules as necessary to conform their programs to federal law and receive federal funding. Ark. Code Ann. § 25-10-129(b).

This rule implements Act 393 of 2023. The Act, sponsored by Representative Aaron Pilkington, modified the coverage of continuous glucose monitors in the Arkansas Medicaid Program.

# **Table of Contents**

**State/Territory Name: Arkansas** 

State Plan Amendment (SPA) AR: 24-0006

This file contains the following documents in the order listed:

- 1) Approval Letter
- 2) CMS 179 Form/Summary Form (with 179-like data)
- 3) Approved SPA Pages

### DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services Center for Medicaid & CHIP Services 233 North Michigan Ave., Suite 600 Chicago, Illinois 60601



# Financial Management Group

March 19, 2024

Janet Mann
Deputy Secretary and Medicaid Director
Arkansas Department of Human Services
112 West 8<sup>th</sup> Street, Slot S401
Little Rock, AR 72201-4608

RE: TN 24-0006

Dear Director Mann:

We have reviewed the proposed Arkansas State Plan Amendment (SPA) to Attachment 4.19-B, AR 24-0006, which was submitted to the Centers for Medicare & Medicaid Services (CMS) on February 6, 2024. This plan amendment proposes to reimburse for Continuous Glucose Monitors (CGM), and related Diabetic Supplies at Wholesale Acquisition Cost (WAC) plus the applicable professional dispensing fee.

Based upon the information provided by the State, we have approved the amendment with an effective date of April 1, 2024. We are enclosing the approved CMS-179 and a copy of the new state plan pages.

If you have any additional questions or need further assistance, please contact Robert Bromwell at 410-786-5914 or Robert.bromwell@cms.hhs.gov.

Sincerely,

**Todd McMillion** 

Todd McMillion

Director

Division of Reimbursement Review

**Enclosures** 

TRANSMITTAL AND NOTICE OF APPROVAL OF	1. TRANSMITTAL NUMBER	2. STATE
STATE PLAN MATERIAL		
FOR: CENTERS FOR MEDICARE & MEDICAID SERVICES	3. PROGRAM IDENTIFICATION: TITLE C	OF THE SOCIAL
	SECURITY ACT XIX	XXI
TO: CENTER DIRECTOR	4. PROPOSED EFFECTIVE DATE	
CENTERS FOR MEDICAID & CHIP SERVICES DEPARTMENT OF HEALTH AND HUMAN SERVICES		
5. FEDERAL STATUTE/REGULATION CITATION	6. FEDERAL BUDGET IMPACT (Amou	unts in WHOLE dollars)
	a. FFY\$\$	
7. PAGE NUMBER OF THE PLAN SECTION OR ATTACHMENT	8. PAGE NUMBER OF THE SUPERSE OR ATTACHMENT (If Applicable)	DED PLAN SECTION
9. SUBJECT OF AMENDMENT		
40 COVERNOR'S REVIEW (Charle One)		
10. GOVERNOR'S REVIEW (Check One)		
GOVERNOR'S OFFICE REPORTED NO COMMENT COMMENTS OF GOVERNOR'S OFFICE ENCLOSED NO REPLY RECEIVED WITHIN 45 DAYS OF SUBMITTAL	OTHER, AS SPECIFIED:	
11. SIGNATURE OF STATE AGENCY OFFICIAL S. Vizabeth Pitman	15. RETURN TO	
12. TYPED NAME		
13. TITLE		
14. DATE SUBMITTED		
FOR CMS U	ISE ONLY	
	17. DATE APPROVED	
February 6, 2024	March 19, 2024	
PLAN APPROVED - ON 18. EFFECTIVE DATE OF APPROVED MATERIAL	<i>IE COPY ATTACHED</i> 19. SIGNATURE OF APPROVING OFFICE	IAI
April 1, 2024	Todd McMillion	AL
20. TYPED NAME OF APPROVING OFFICIAL	21. TITLE OF APPROVING OFFICIAL	
Todd McMillion	Director, Division of Reimbursement Rev	view .
22. REMARKS		

# STATE PLAN UNDER TITLE XIX OF THE SOCIAL SECURITY ACT MEDICAL ASSISTANCE PROGRAM STATE OF <u>ARKANSAS</u>

ATTACHMENT 4.19-B Page 2g

# METHODS AND STANDARDS FOR ESTABLISHING PAYMENT RATES - OTHER TYPES OF CARE

**April 1, 2024** 

- 7. Home Health Services (Continued)
  - c. Medical Supplies, Equipment and Appliances Suitable for Use in the Home (continued)
    - (5) Aerochamber Device

Effective for dates of service on or after October 1, 1997, reimbursement is based on the lesser of the provider's actual charge for the service or the Title XIX (Medicaid) maximum. The Title XIX (Medicaid) maximum established was based on a 1997 survey of Durable Medical Equipment (DME) providers. The information obtained in the survey indicated there is only one major manufacturer and distributor of the aerochamber devices (with or without mask) to providers enrolled in the Arkansas Medicaid Program. It was determined the aerochamber devices are sold to each provider for the same price. As a result, the current Title XIX (Medicaid) maximum for the aerochamber devices (with or without mask) was established based on the actual manufacturer=s list prices. Thereafter, adjustments will be made based on the consumer price index factor to be implemented at the beginning of the appropriate State Fiscal Year, July 1.

(6) Specialized Wheelchairs, Seating and Rehab Items

Reimbursement is based on the lesser of the provider's actual charge for the service or the Title XIX (Medicaid) maximum. Effective for claims with dates of service on or after May 1, 1995, the Title XIX (Medicaid) maximums were established utilizing the manufacturer's current published suggested retail price less 15%. The 15% is the median of Oklahoma Medicaid which is currently retail less 12% and Texas Medicaid which is currently retail less 18%. Effective for claims with dates of service on or after September 1, 1995, the following Kaye Products, procedure codes Z2059, Z2060, Z2061 and Z2062, are reimbursed at the manufacturer's current published suggested retail price. The State Agency and affected provider association representatives will review the rates annually and negotiate any adjustments.

(7) DME/Continuous Glucose Monitors.

Procedure Codes and Rates.

- A. Rates. Effective for dates of service on or after January 1, 2022, reimbursement for Continuous Glucose Monitors (CGM) and related supplies is based on the Medicare non-rural rate for the State of Arkansas (effective as of July 28, 2021, and subject to change when Medicare rates are adjusted) for the allowable procedure codes. All rates are published on the <a href="agency's website">agency's website</a>. Except as otherwise noted in the plan, state developed fee schedule rates are the same for both governmental and private providers.
- B. Effective for dates of service on or after April 1, 2024, reimbursement for Continuous Glucose Monitors (CGM) and related Diabetic Supplies including patch type insulin pumps is based on Wholesale Acquisition Cost (WAC) plus applicable professional dispensing fee. Traditional insulin pumps will remain at the Medicare non-rural rate as stated in A. above.

TN:24-0006 Approval: March 19, 2024 Effective Date:4-1-2024

Supersedes TN:21-0015



# Office of Policy and Rules

P.O. Box 1437, Slot S295, Little Rock, AR 72203-1437 P: 501.320.6383 F: 501.404.4619

February 1, 2024

Mrs. Rebecca Miller-Rice Administrative Rules Review Section Arkansas Legislative Council Bureau of Legislative Research #1 Capitol, 5<sup>th</sup> Floor Little Rock, AR 72201

Dear Mrs. Rebecca Miller-Rice:

# Re: Continuous Glucose Monitors and Diabetic Supplies Coverage

Please arrange for this rule to be reviewed by the ALC-Administrative Rules Subcommittee. If you have any questions or need additional information, please contact me at 501-320-6383 or by emailing Mac.E.Golden@dhs.arkansas.gov.

Sincerely,

Mac Golden

Mac Golden

Deputy Chief

Attachments

# QUESTIONNAIRE FOR FILING PROPOSED RULES WITH THE ARKANSAS LEGISLATIVE COUNCIL

	PARTMENT
	ARD/COMMISSION
	ARD/COMMISSION DIRECTOR
	NTACT PERSON
	DRESS
PHO	ONE NO EMAIL
NAM	ME OF PRESENTER(S) AT SUBCOMMITTEE MEETING
PRE	SENTER EMAIL(S)
	INSTRUCTIONS
Ques what	rder to file a proposed rule for legislative review and approval, please submit this Legislative stionnaire and Financial Impact Statement, and attach (1) a summary of the rule, describing t the rule does, the rule changes being proposed, and the reason for those changes; (2) both a kup and clean copy of the rule; and (3) all documents required by the Questionnaire.
of Ro	the rule is being filed for permanent promulgation, please email these items to the attention ebecca Miller-Rice, miller-ricer@blr.arkansas.gov, for submission to the Administrative es Subcommittee.
Dire	e rule is being filed for emergency promulgation, please email these items to the attention of ctor Marty Garrity, <a href="mailto:garritym@blr.arkansas.gov">garritym@blr.arkansas.gov</a> , for submission to the Executive committee.
Pleas	se answer each question completely using layman terms.
****	******************************
1.	What is the official title of this rule?
2.	What is the subject of the proposed rule?
3.	Is this rule being filed under the emergency provisions of the Arkansas Administrative Procedure Act? Yes No
	If yes, please attach the statement required by Ark. Code Ann. § $25-15-204(c)(1)$ .
	If yes, will this emergency rule be promulgated under the permanent provisions of the Arkansas Administrative Procedure Act? Yes No

4.	Is this rule being filed for permanent promulgation? Yes No
	If yes, was this rule previously reviewed and approved under the emergency provisions of the Arkansas Administrative Procedure Act? Yes No
	If yes, what was the effective date of the emergency rule?
	On what date does the emergency rule expire?
5.	Is this rule required to comply with a <i>federal</i> statute, rule, or regulation? Yes No
	If yes, please provide the federal statute, rule, and/or regulation citation.
6	Is this rule required to comply with a <i>state</i> statute or rule? Yes No
6.	Is this rule required to comply with a <i>state</i> statute or rule? Yes No
	If yes, please provide the state statute and/or rule citation.
7.	Are two (2) rules being repealed in accord with Executive Order 23-02? Yes No
	If yes, please list the rules being repealed.
	If no, please explain.
8.	Is this a new rule? Yes No
	Does this repeal an existing rule? Yes No If yes, the proposed repeal should be designated by strikethrough. If it is being replaced with a new rule, please attach both the proposed rule to be repealed and the replacement rule.
	Is this an amendment to an existing rule? Yes No If yes, all changes should be indicated by strikethrough and underline. In addition, please be

sure to label the markup copy clearly as the markup.

9.	What is the state law that grants the agency its rulemaking authority for the proposed rule, outside of the Arkansas Administrative Procedure Act? Please provide the specific Arkansas Code citation(s), including subsection(s).
10.	Is the proposed rule the result of any recent legislation by the Arkansas General Assembly? Yes No
	If yes, please provide the year of the act(s) and act number(s).
11.	What is the reason for this proposed rule? Why is it necessary?

12.	Please provide the web address by which the proposed rule can be accessed by the public as provided in Ark. Code Ann. § 25-19-108(b)(1).
13.	Will a public hearing be held on this proposed rule? Yes No
	If yes, please complete the following:
	Date:
	Time:
	Place:
Pleas	se be sure to advise Bureau Staff if this information changes for any reason.
14.	On what date does the public comment period expire for the permanent promulgation of the rule? Please provide the specific date.
15.	What is the proposed effective date for this rule?
16.	Please attach (1) a copy of the notice required under Ark. Code Ann. § 25-15-204(a)(1) and (2) proof of the publication of that notice.
17.	Please attach proof of filing the rule with the Secretary of State, as required by Ark. Code Ann. § 25-15-204(e)(1)(A).
18.	Please give the names of persons, groups, or organizations that you anticipate will comment on these rules. Please also provide their position (for or against), if known.
19.	Is the rule expected to be controversial? Yes No
	If yes, please explain.

#### 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, the Arkansas Children's Health Insurance Program (CHIP) State Plan, and corresponding Medicaid Provider Manuals to implement Act 393 of 2023 of the 94th General Assembly. The Act requires Arkansas Medicaid to cover continuous glucose monitors (CGMs) as a pharmacy benefit and mandates pharmacy coverage of CGMs for certain individuals with diabetes allowing for blood glucose levels to be monitored at set intervals without finger sticks. Eligible 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. Blood glucose monitors (BGMs) and other diabetic supplies are added to streamline administrative procedures and to increase access to care for beneficiaries.

To effectuate the above, DMS amends the following Medicaid Provider Manuals: ARKids First B (§221.100), Home Health (§242.150), Pharmacy (§§212, 216.100, and 216.101), and Prosthetics (§§212.206 and 212.207). Those sections of relevant manuals were updated to explain coverage for the expanded group of beneficiaries and supplies by pharmacies and DME providers as required by the Act. The revisions specify which claims are processed as a medical claim or a pharmacy claim.

DMS amends the Medicaid State Plan and CHIP state plan to establish reimbursement effective for dates of service on or after April 1, 2024. Specifically, reimbursement for CGM and related supplies, including patch type insulin pumps, will be based on wholesale acquisition cost (WAC) plus applicable professional dispensing fee. Traditional insulin pumps will remain at the Medicare non-rural rate. The CHIP state plan updates include comparable revisions to those outlined above. The updates include explanation of eligible beneficiaries, covered supplies with the addition of diabetic supplies to the prescription drugs category which ensures coverage for prescription drugs, CGMs with CGM supplies, patch type insulin pumps, and BGMs with blood glucose testing supplies.

The projected annual cost of this change for state fiscal year (SFY) 2024 is \$300,047.00 (of which \$216,034.00 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 <u>ar.gov/dhs-proposed-rules</u>. 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: <a href="ORP@dhs.arkansas.gov">ORP@dhs.arkansas.gov</a>. All public comments must be received by DHS no later than March 04, 2024. 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.

A public hearing will be held by remote access through Zoom. Public comments may be submitted at the hearing. The details for attending the Zoom hearing appear at <u>ar.gov/dhszoom</u>.

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.

4502172997

Elizabeth Pitman, Director Division of Medical Services From: Legal Ads
To: Lisa Teague

**Subject:** Re: Full Run AD (r. 243)

**Date:** Friday, February 2, 2024 9:34:34 AM

## [EXTERNAL SENDER]

Will run Sun 2/4, and again on Mon 2/5 and Tues 2/6.

You will receive two invoices: One for Sun, the other for Mon/Tues.

Thank you.

Gregg Sterne, Legal Advertising Arkansas Democrat-Gazette legalads@arkansasonline.com

From: "Lisa Teague" <Lisa.Teague@dhs.arkansas.gov>

To: "legalads" <legalads@arkansasonline.com>

Cc: "Jack Tiner" < jack.tiner@dhs.arkansas.gov>, "Lakeya Gipson"

<Lakeya.Gipson@dhs.arkansas.gov>, "Elaine Stafford"

<elaine.stafford@dhs.arkansas.gov>

**Sent:** Friday, February 2, 2024 9:25:45 AM

Subject: Full Run AD (r. 243)

Good morning,

Please run the attached Notice of Public Hearing in the *Arkansas Democrat-Gazette* on the following days:

- · Sunday, February 4, 2024
- · Monday, February 5, 2024
- Tuesday, February 6, 2024

I am aware that the print version will only be provided to all counties on Sundays.

Invoice to: AR Dept of Human Services

P.O. Box 1437

**Slot S535** 

Little Rock, AR 72203

**ATTN: Elaine Stafford** 

Elaine.stafford@dhs.arkansas.gov

Or email invoices to: <a href="mailto:dms.invoices@arkansas.gov">dms.invoices@arkansas.gov</a>

NOTE: Please reply to this email using "REPLY ALL"

Thank you,

Lisa Teague | Arkansas Department of Human Services DHS Program Administrator Office of Policy and Rules Office of Legislative and Intergovernmental Affairs Donaghy Plaza South 700 Main St. | Slot S295 | Little Rock, AR 72203

Phone: 501-396-6428

Email: lisa.teague@dhs.arkansas.gov

#### Sensitive

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From: <u>Lisa Teague</u>
To: <u>Arkansas Register</u>

Cc: Mac Golden; Jack Tiner; Lakeya Gipson; JAMIE EWING

Subject: DHS/DMS- Proposed Filing- Continuous Glucose Monitors and Diabetic Supplies Coverage (r. 243)

Date:Friday, February 2, 2024 11:46:00 AMAttachments:SOS revised initial filing CGM - 2-2-24.pdf

Attached is the proposed filing for Continuous Glucose Monitors and Diabetic Supplies Coverage. The public notice will appear in the Arkansas- Democrat Gazette February 4, 5, and 6, 2024. The public comment period ends March 4, 2024.

**Note**: This rule began promulgation in October 2023. A public comment period ran from October 14, 2023, to November 12, 2023. DHS reviewed all public comments received and in response revises the rule and publishes it for a second public comment period with the responsive changes incorporated into the rule. It was originally posted as 016.29.23-010P. Please post this with that.

Thank you,

Lisa Teague | Arkansas Department of Human Services DHS Program Administrator Office of Policy and Rules Office of Legislative and Intergovernmental Affairs Donaghy Plaza South 700 Main St. | Slot S295 | Little Rock, AR 72203

Phone: 501-396-6428

Email: <u>lisa.teague@dhs.arkansas.gov</u>

#### Sensitive

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# FINANCIAL IMPACT STATEMENT

# PLEASE ANSWER ALL QUESTIONS COMPLETELY.

DEI	PARTMENT_
	ARD/COMMISSION
PER	RSON COMPLETING THIS STATEMENT
TEL	LEPHONE NOEMAIL
emai	comply with Ark. Code Ann. § 25-15-204(e), please complete the Financial Impact Statement and il it with the questionnaire, summary, markup and clean copy of the rule, and other documents. se attach additional pages, if necessary.
TIT	LE OF THIS RULE
1.	Does this proposed, amended, or repealed rule have a financial impact? Yes No
2.	Is the rule based on the best reasonably obtainable scientific, technical, economic, or other evidence and information available concerning the need for, consequences of, and alternatives to the rule?  Yes  No
3.	In consideration of the alternatives to this rule, was this rule determined by the agency to be the least costly rule considered? Yes No
	If no, please explain:
	(a) how the additional benefits of the more costly rule justify its additional cost;
	(b) the reason for adoption of the more costly rule;
	(c) whether the reason for adoption of the more costly rule is based on the interests of public health, safety, or welfare, and if so, how; and
	(d) whether the reason for adoption of the more costly rule is within the scope of the agency's statutory authority, and if so, how.
4.	If the purpose of this rule is to implement a <i>federal</i> rule or regulation, please state the following:

(a) What is the cost to implement the federal rule or regulation?

General Revenue	General Revenue
Federal Funds	Federal Funds
Cash Funds	Cash Funds
Special Revenue	Special Revenue
Other (Identify)	Other (Identify)
Total	Total
(b) What is the additional cost of the sta	te rule?
Current Fiscal Year	Next Fiscal Year
General Revenue	General Revenue
Federal Funds	Federal Funds
Cash Funds	Cash Funds
Special Revenue	Special Revenue
Other (Identify)	Other (Identify)
Total	Total
	year to any private individual, private entity, or private ed, or repealed rule? Please identify those subject to the  Next Fiscal Year  \$
business subject to the proposed, amend rule, and explain how they are affected.  Current Fiscal Year  \$  What is the total estimated cost by fiscal	year to any private individual, private entity, or private ed, or repealed rule? Please identify those subject to the
business subject to the proposed, amend rule, and explain how they are affected.  Current Fiscal Year  \$	year to any private individual, private entity, or private ed, or repealed rule? Please identify those subject to the  Next Fiscal Year  \$

7. With respect to the agency's answers to Questions #5 and #6 above, is there a new or increased cost or obligation of at least one hundred thousand dollars (\$100,000) per year to a private individual, private entity, private business, state government, county government, municipal government, or to two (2) or more of those entities combined?

Yes No

If yes, the agency is required by Ark. Code Ann. § 25-15-204(e)(4) to file written findings at the time of filing the financial impact statement. The written findings shall be filed simultaneously with the financial impact statement and shall include, without limitation, the following:

- (1) a statement of the rule's basis and purpose;
- (2) the problem the agency seeks to address with the proposed rule, including a statement of whether a rule is required by statute;
- (3) a description of the factual evidence that:
  - (a) justifies the agency's need for the proposed rule; and
  - (b) describes how the benefits of the rule meet the relevant statutory objectives and justify the rule's costs:
- (4) a list of less costly alternatives to the proposed rule and the reasons why the alternatives do not adequately address the problem to be solved by the proposed rule;
- (5) a list of alternatives to the proposed rule that were suggested as a result of public comment and the reasons why the alternatives do not adequately address the problem to be solved by the proposed rule;
- (6) a statement of whether existing rules have created or contributed to the problem the agency seeks to address with the proposed rule and, if existing rules have created or contributed to the problem, an explanation of why amendment or repeal of the rule creating or contributing to the problem is not a sufficient response; and
- (7) an agency plan for review of the rule no less than every ten (10) years to determine whether, based upon the evidence, there remains a need for the rule including, without limitation, whether:
  - (a) the rule is achieving the statutory objectives;
  - (b) the benefits of the rule continue to justify its costs; and
  - (c) the rule can be amended or repealed to reduce costs while continuing to achieve the statutory objectives.

# Statement of Necessity and Rule Summary Continuous Glucose Monitors and Diabetic Supplies Coverage

# **Statement of Necessity**

The Division of Medical Services (DMS) revises the Arkansas Medicaid state plan and corresponding provider manuals to comply with Act 393 of 2023. The Act requires Arkansas Medicaid to cover continuous glucose monitors (CGMs) as a pharmacy benefit. It also mandates pharmacy coverage of CGMs for certain individuals with diabetes allowing for blood glucose levels to be monitored at set intervals without finger sticks. Eligible 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. While reviewing the financial impact, it was determined that blood glucose monitors (BGMs) and other diabetic supplies should be added to the rule to streamline administrative procedures and to increase access to care for beneficiaries.

Note: This rule began promulgation in October 2023. A public comment period ran from October 14, 2023, to November 12, 2023. DHS reviewed all public comments received and in response revises the rule and publishes it for a second public comment period with the responsive changes incorporated into the rule.

## **Summary**

The following provider manuals and state plan amendment (spa) pages will be updated in compliance with the Act and for the other reasons stated above.

# Medicaid Provider Manuals

### ARKids First B –

Section 221.100 – Deleted "Continuous Glucose Meters (CGM) and CGM supplies" and added "Including diabetic supplies". Added the statement "For billing information to include Continuous Glucose Monitors (CGM), CGM supplies, patch or tubeless insulin pumps, blood glucose monitors (BGMs), and glucose testing supplies see the <u>DHS</u> contracted Pharmacy Vendor's website."

#### Home Health-

• Section 242.150 – Changed Bullet A to state that Home Blood Glucose supplies include all beneficiaries. Deleted HCPCS code information for Home Blood Glucose supplies.

# Pharmacy -

- Section 212.000 Deleted "glucose monitoring devices and supplies"
- Section 216.100 Added "and glucose monitors and supplies" to bullet point D. Deleted "Glucose home monitors with supplies" from bullet point J.
- Section 216.101 Added new section concerning Medical Supplies Covered as a Pharmacy Benefit.

### Prosthetics -

- Monitor, Pregnant Women Only, All Ages" to "Home Blood Glucose Monitor and Supplies All Ages". Deleted all previous information and added the statement "
  "Effective 4/1/2024, Medicaid beneficiaries are eligible for diabetic and blood sugar testing supplies processed as a pharmacy claim submission by pharmacies or DME providers. Home blood sugar meters and supplies (strips, lancets, calibration solution, etc.) are available without a prior authorization. See the DHS Pharmacy Vendor's website for specific information for coverage details."
- Section 212.207 Deleted "DME" from the title. Added the statement "Effective 4/1/2024, patch or tubeless insulin pumps are covered as a pharmacy claim submission while traditional insulin pumps requiring tubing and cannula type supplies remain processed as a medical claim. Beneficiaries with Medicare Part B benefits continue to be serviced for all of their needs under the DME program." Also added the statement "When submitting prior authorization requests for the patch or tubeless insulin pumps see the **DHS Pharmacy Vendor's website** for specific information for coverage details."
- Section 212.208 Bullet point A deleted "The Arkansas Medicaid Program provides coverage for a continuous glucose monitor (CGM) for the treatment of a Medicaid client if the client has:" and added "Effective 4/1/2024, continuous glucose monitors (CGMs) are covered as a pharmacy claim submission by pharmacies or DME providers. Beneficiaries must meet the following criteria for coverage:" Changed number 1 under this bullet point to remove "more than two times daily" and added #3 to state "See the **DHS Pharmacy Vendor's website** for specific information for coverage details, '. Deleted bullet point C which stated "Additional requirements are set out in Section 242.113". Added the statement" Beneficiaries with Medicare Part B benefits continue to be serviced under the DME program."
- Section 242.112 deleted in its entirety.
- Section 242.113 deleted in its entirety.

# Medicaid State Plan:

# Page 4.19-B 2g

• Added 7B.

"Effective for dates of service on or after April 1, 2024, reimbursement for Continuous Glucose Monitors (CGM) and related supplies including patch type insulin pumps is based on wholesale acquisition cost (WAC) plus applicable professional dispensing fee. Traditional insulin pumps will remain at the Medicare non-rural rate as stated in A. above."

Arkansas Child Health Plan Under Title XXI Of The Social Security Act Children's Health Insurance Program (CHIP SPA)

• SPA # 14 adds the statement "The purpose of this SPA is to improve access to continuous glucose monitors (CGMs) through pharmacy claim submission processing for reimbursement to pharmacies and DME providers. Beneficiaries eligible for CGMs 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. Patch type insulin pumps, blood glucose monitors (BGMs) and testing supplies will be covered in the same manner. Coverage is being extended to comply with Arkansas Act 393 of 2023."
- Section 6.2 adds "and diabetic supplies" to the Prescription Drugs section in the chart. Also adds the statement "\*The Prescription Drugs and diabetic supplies category includes prescription drugs, Continuous Glucose Monitors (CGMs) with CGM supplies, patch type insulin pumps, and blood glucose monitors (BGMs) with blood glucose testing supplies (test strips, calibration solution).
- Section 8.2 \*The Prescription Drugs and diabetic supplies category includes prescription drugs, Continuous Glucose Monitors (CGMs) with CGM supplies, patch type insulin pumps, and blood glucose monitors (BGMs) with blood glucose testing supplies (test strips, calibration solution).

# **TOC** not required

## 221.100 ARKids First-B Medical Care Benefits

2-1-22<u>5-1-</u> 24

Listed below are the covered services for the ARKids First-B program. This chart also includes benefits, whether Prior Authorization or a Primary Care Physician (PCP) referral is required, and specifies the cost-sharing requirements.

Program Services	Benefit Coverage and Restrictions	Prior Authorization/ PCP Referral*	Co-payment/ Coinsurance/ Cost Sharing Requirement**
Ambulance (Emergency Only)	Medical Necessity	None	\$10 per trip
Ambulatory Surgical Center	Medical Necessity	PCP Referral	\$10 per visit
Audiological Services (only Tympanometry, CPT procedure code****, when the diagnosis is within the ICD range (View ICD codes.))	Medical Necessity	None	None
Certified Nurse- Midwife	Medical Necessity	PCP Referral	\$10 per visit
Chiropractor	Medical Necessity	PCP Referral	\$10 per visit
Dental Care	Routine dental care and orthodontia services	None – PA for interperiodic screens and orthodontia services	\$10 per visit
Durable Medical Equipment	Medical Necessity \$500 per state fiscal year (July 1 through June 30) minus the coinsurance/cost-share. Covered items are listed in Section 262.120	PCP Referral and Prescription	10% of Medicaid allowed amount per DME item cost-share
Emergency Dept. Serv	vices		
Emergency	Medical Necessity	None	\$10 per visit
Non-Emergency	Medical Necessity	PCP Referral	\$10 per visit
Assessment	Medical Necessity	None	\$10 per visit
Family Planning	Medical Necessity	None	None
Federally Qualified Health Center (FQHC)	Medical Necessity	PCP Referral	\$10 per visit

Program Services	Benefit Coverage and Restrictions	Prior Authorization/ PCP Referral*	Co-payment/ Coinsurance/ Cost Sharing Requirement**
Home Health	Medical Necessity (10 visits per state fiscal year (July 1 through June 30)	PCP Referral	\$10 per visit
Hospital, Inpatient	Medical Necessity	PA on stays over 4 days if age 1 or over	10% of first inpatient day
Hospital, Outpatient	Medical Necessity	PCP referral	\$10 per visit
Inpatient Psychiatric Hospital and Psychiatric Residential Treatment Facility	Medical Necessity	PA & Certification of Need is required prior to admittance	10% of first inpatient day
Immunizations	All per protocol	None	None
Laboratory & X-Ray	Medical Necessity	PCP Referral	\$10 per visit
Medical Supplies	Medical Necessity	PCP Prescriptions	None
	Benefit of \$125/mo. Covered supplies listed in Section 262.110	PA required on supply amounts exceeding \$125/mo	
Mental and Behavioral Health, Outpatient	Medical Necessity	PCP Referral PA on treatment services	\$10 per visit
School-Based Mental Health	Medical Necessity	PA Required (See Section 250.000 of the School-Based Mental Health provider manual.)	\$10 per visit
Nurse Practitioner	Medical Necessity	PCP Referral	\$10 per visit
Physician	Medical Necessity	PCP referral to specialist and inpatient professional services	\$10 per visit
Podiatry	Medical Necessity	PCP Referral	\$10 per visit
Prenatal Care	Medical Necessity	None	None
Prescription Drugs <u>Diabetic Supplies</u>	Medical Necessity	Prescription	Up to \$5 per prescription (Must use generic, if available)***
Preventive Health Screenings	All per protocol	PCP Administration or PCP Referral	None
Rural Health Clinic	Medical Necessity	PCP Referral	\$10 per visit

Program Services	Benefit Coverage and Restrictions	Prior Authorization/ PCP Referral*	Co-payment/ Coinsurance/ Cost Sharing Requirement**
Speech-Language	Medical Necessity	PCP Referral	\$10 per visit
Therapy	4 evaluation units (1 unit =30 min) per state fiscal year	Authorization required on extended benefit of services	
	4 therapy units (1 unit=15 min) daily		
Occupational	Medical Necessity	PCP Referral	\$10 per visit
Therapy	2 evaluation units per state fiscal year	Authorization required on extended benefit of services	
Physical Therapy	Medical Necessity	PCP Referral	\$10 per visit
	2 evaluation units per state fiscal year	Authorization required on extended benefit of services	
Vision Care			
Eye Exam	One (1) routine eye exam (refraction) every 12 months	None	\$10 per visit
Eyeglasses	One (1) pair every 12 months	None	None

<sup>\*</sup>Refer to your Arkansas Medicaid specialty provider manual for prior authorization and PCP referral procedures.

\*\*\*\*View or print the procedure codes for ARKids First-B procedures and services.

<sup>\*\*</sup>ARKids First-B beneficiary cost-sharing is capped at 5% of the family's gross annual income.

<sup>\*\*\*</sup>ARKids First-B beneficiaries will pay a maximum of \$5.00 per prescription. The beneficiary will pay the provider the amount of co-payment that the provider charges non-Medicaid purchasers up to \$5.00 per prescription. For billing information to include Continuous Glucose Monitors (CGM), CGM supplies, patch or tubeless insulin pumps, blood glucose monitors (BGMs), and glucose testing supplies see the DHS contracted Pharmacy Vendor's website.

# **TOC** not required

# 221.100 ARKids First-B Medical Care Benefits

5-1-24

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Certified Nurse- Midwife	Medical Necessity	PCP Referral	\$10 per visit
Chiropractor	Medical Necessity	PCP Referral	\$10 per visit
Dental Care	Routine dental care and orthodontia services	None – PA for interperiodic screens and orthodontia services	\$10 per visit
Durable Medical Equipment	Medical Necessity \$500 per state fiscal year (July 1 through June 30) minus the coinsurance/cost-share. Covered items are listed in Section 262.120	PCP Referral and Prescription	10% of Medicaid allowed amount per DME item cost-share
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Assessment	Medical Necessity	None	\$10 per visit
Family Planning	Medical Necessity	None	None
Federally Qualified Health Center (FQHC)	Medical Necessity	PCP Referral	\$10 per visit

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Hospital, Inpatient	Medical Necessity	PA on stays over 4 days if age 1 or over	10% of first inpatient day
Hospital, Outpatient	Medical Necessity	PCP referral	\$10 per visit
Inpatient Psychiatric Hospital and Psychiatric Residential Treatment Facility	Medical Necessity	PA & Certification of Need is required prior to admittance	10% of first inpatient day
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	Benefit of \$125/mo. Covered supplies listed in Section 262.110	PA required on supply amounts exceeding \$125/mo	
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Prenatal Care	Medical Necessity	None	None
Prescription Drugs Diabetic Supplies	Medical Necessity	Prescription	Up to \$5 per prescription (Must use generic, if available)***
Preventive Health Screenings	All per protocol	PCP Administration or PCP Referral	None
Rural Health Clinic	Medical Necessity	PCP Referral	\$10 per visit

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	4 evaluation units (1 unit =30 min) per state fiscal year	Authorization required on extended benefit of services	
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<sup>\*\*\*\*</sup>View or print the procedure codes for ARKids First-B procedures and services.

Home Health Section II

#### TOC not required

# 242.150 Home Health Medical Supplies

<del>2-1-22</del><u>5-1-</u> 24

The following Health Care Procedural Coding System (HCPCS) codes must be used when billing the Arkansas Medicaid Program for medical supplies. Providers must use the current HCPCS Book for code descriptions.

### View or print the procedure codes for Home Health services.

Listed below are medical supplies that require special billing or need prior authorization. These items are listed with the HCPCS codes and require modifiers. The asterisk denotes these items and the required modifiers.

A. \*Home Blood Glucose Supplies-<u>- Available to all beneficiaries</u>—Pregnant Women Only, All Ages

Codes must be billed either electronically or on paper with modifier NU for beneficiaries of all ages. When a second modifier is listed, that modifier must be used in conjunction with the NU modifier.

B. \*\*Gradient Compression Stocking (Jobst Stocking), All Ages

The gradient compression stocking (Jobst) is payable for beneficiaries of all ages. Before supplying the items, the Jobst stocking must be prior authorized by AFMC. <u>View or print form DMS-679A and instructions for completion</u>. Documentation accompanying form DMS-679A must indicate that the beneficiary has severe varicose with edema, or a venous stasis ulcer, unresponsive to conventional therapy such as wrappings, over-the-counter stocking and Unna boots. The documentation must include clinical medical records from a physician detailing the failure of conventional therapy.

Code must be manually priced.

Code requires a prior authorization (PA). See Section 221.000.

Code requires prior authorization (PA); see Section 221.000. Code is manually priced and is covered for beneficiaries ages 0-20 years of age.

C. \*\*\*Food Thickeners, All Ages

Food thickeners, including "Thick-it", "Simple Thick", "Thick and Easy" and "Thick and Clear" are not subjected to the medical supply benefit limit.

The modifier **NU** must be used with the code found in this section and when food thickeners are administered enterally, the modifier "**BA**" must be used in conjunction with the code.

When food thickeners are billed, total units are to be calculated to the nearest full ounce. Partial units may be rounded up. When a date span is billed, the product cannot be billed until the end date of the span has elapsed.

The maximum number of units allowed for food thickeners is 16 units per date of service.

The following HCPCS codes usage must match the Arkansas Medicaid code description and use of modifier(s).

\*The following HCPCS codes and modifiers are covered only for pregnant women.

Home Health Section II

#### **TOC** not required

### 242.150 Home Health Medical Supplies

5-1-24

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The gradient compression stocking (Jobst) is payable for beneficiaries of all ages. Before supplying the items, the Jobst stocking must be prior authorized by AFMC. <u>View or print form DMS-679A and instructions for completion</u>. Documentation accompanying form DMS-679A must indicate that the beneficiary has severe varicose with edema, or a venous stasis ulcer, unresponsive to conventional therapy such as wrappings, over-the-counter stocking and Unna boots. The documentation must include clinical medical records from a physician detailing the failure of conventional therapy.

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The following HCPCS codes usage must match the Arkansas Medicaid code description and use of modifier(s).

### **TOC** not required

#### 212.000 Exclusions

8-1-21<u>5-1-</u>

- A. Products manufactured by non-rebating pharmaceutical companies.
- B. Effective January 1, 2006, the Medicaid agency will not cover any drug covered by Medicare Part D for full-benefit dual eligible individuals who are entitled to receive Medicare benefits under Part A or Part B.
- C. The Medicaid agency provides coverage, to the same extent that it provides coverage for all Medicaid beneficiaries under § 1927 (d) of the Social Security Act, for the following excluded or otherwise restricted drugs or classes of drugs, or their medical uses; with the exception of those covered by Part D plans as supplemental benefits through enhanced alternative coverage as provided in 42 CFR § 423.104 (f) (1) (ii) (A),to full-benefit dual eligible beneficiaries under the Medicare Prescription Drug Benefit Part D.

The following excluded drugs are set forth on the <a href="DHS Contracted Pharmacy Vendorwebsite">DHS Contracted Pharmacy Vendorwebsite</a>.

- 1. Select agents when used for weight gain
- 2. Select agents when used for the symptomatic relief of cough and colds
- 3. Select prescription vitamins and mineral products, except prenatal vitamins and fluoride
- 4. Select nonprescription drugs
- 5. Select agents when used to promote smoking cessation
- D. Medical accessories are not covered under the Arkansas Medicaid Pharmacy Program. Typical examples of medical accessories are atomizers, nebulizers, hot water bottles, fountain syringes, ice bags and caps, urinals, bedpans, glucose monitoring devices and supplies, cotton, gauze and bandages, wheelchairs, crutches, braces, supports, diapers, and nutritional products.

# 216.100 Medical Supplies for Long-Term Care Facility Residents

<del>10-13-03</del><u>5-</u> 1-24

A pharmacy often supplies items that are not covered under the Arkansas Medicaid Program to Medicaid eligibles in a long-term care facility. Under the cost-related reimbursement system in which long-term care (LTC) facilities are reimbursed, many of these items are the financial responsibility of the facility; therefore, the patient or the patient's family should not be billed for these items. The facility must furnish the following items to Medicaid beneficiaries:

- A. First aid supplies (e.g., small bandages, merthiolate, mercurochrome, hydrogen peroxide, ointments for minor cuts and abrasions);
- B. Dietary supplies (e.g., salt and sugar substitutes, supplemental feedings, equipment for preparing and dispensing tube feedings);
- C. Items normally stocked by the facility in gross supply and distributed in small quantities (e.g., alcohol, hydrogen peroxide, applicators, cotton balls, tongue depressors);
- All over-the-counter drugs and glucose monitors and supplies;
- E. Enemas and douches—including equipment and solution (also disposables);

- F. Catheters;
- G. Special dressings (e.g., gauze, 4-by-4s, ABD pads, surgical and micropore tape, telfa gauze, ace bandages);
- H. Colostomy drainage bags and
- I. Equipment required for simple tests such as clinitest, acetest and dextrostix.

### 216.101 Medical Supplies Covered as a Pharmacy Benefit

**45-1-24** 

The pharmacy National Council for Prescription Drug Program (NCPDP) benefit for the Arkansas Medicaid pharmacy program covers continuous glucose monitors (CGMs) and other diabetic supplies. This coverage would include CGMs and supplies, patch type insulin pumps and supplies, and blood glucose monitors (BGMs) and supplies.

- A. Medicaid beneficiaries are eligible for diabetic supplies processed as a pharmacy claim submission by pharmacies or DME providers and the provider (DME or pharmacy) will be reimbursed at the Wholesale Acquisition Cost (WAC) plus the applicable professional dispensing fee.
- B. Traditional insulin pumps requiring tubing and cannula type supplies will remain processed as a medical benefit.
- C. Beneficiaries with Medicare Part B benefits will continue to be serviced under the Durable Medical Equipment (DME) program.
- D. For coverage details concerning prior authorization requirements and preferred product list see the **DHS Pharmacy Vendor's website** for specific information.

### **TOC** not required

212.000 Exclusions 5-1-24

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- A. First aid supplies (e.g., small bandages, merthiolate, mercurochrome, hydrogen peroxide, ointments for minor cuts and abrasions);
- B. Dietary supplies (e.g., salt and sugar substitutes, supplemental feedings, equipment for preparing and dispensing tube feedings):
- C. Items normally stocked by the facility in gross supply and distributed in small quantities (e.g., alcohol, hydrogen peroxide, applicators, cotton balls, tongue depressors);
- D. All over-the-counter drugs and glucose monitors and supplies;
- E. Enemas and douches—including equipment and solution (also disposables);
- F. Catheters;
- G. Special dressings (e.g., gauze, 4-by-4s, ABD pads, surgical and micropore tape, telfa gauze, ace bandages);

- H. Colostomy drainage bags and
- I. Equipment required for simple tests such as clinitest, acetest and dextrostix.

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5-1-24

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- A. Medicaid beneficiaries are eligible for diabetic supplies processed as a pharmacy claim submission by pharmacies or DME providers and the provider (DME or pharmacy) will be reimbursed at the Wholesale Acquisition Cost (WAC) plus the applicable professional dispensing fee.
- B. Traditional insulin pumps requiring tubing and cannula type supplies will remain processed as a medical benefit.
- C. Beneficiaries with Medicare Part B benefits will continue to be serviced under the Durable Medical Equipment (DME) program.
- D. For coverage details concerning prior authorization requirements and preferred product list see the **DHS Pharmacy Vendor's website** for specific information.

#### **TOC** required

212.206 (DME)-Home Blood Glucose Monitor and Supplies, Pregnant Women Only,

8-1-05<u>5-1-</u> 24

All Ages

Arkansas Medicaid covers the home blood glucose monitor for pregnant women of all ages. Prior authorization is not required for use of this device.

- A. Patient Eligibility
- Pregestational diabetes. Women on an oral hypoglycemic or insulin when the pregnancy is diagnosed.
- 2. Women that are being followed by a physician for elevated fasting hyperglycemia, but not on an oral hypoglycemic or insulin when the pregnancy is diagnosed.
- 3. Women demonstrating glucose intolerance during the pregnancy as demonstrated by an elevated three-hour glucose tolerance test.

Effective 4/1/2024, Medicaid beneficiaries are eligible for diabetic and blood sugar testing supplies processed as a pharmacy claim submission by pharmacies or DME providers. Home blood sugar meters and supplies (strips, lancets, calibration solution, etc.) are available without a prior authorization. See the DHS Pharmacy Vendor's website for specific information for coverage details.

- B. Criteria for glucose intolerance
  - Demonstration of an elevated one-hour glucose tolerance test of greater than 140 mg/deciliter on a non-fasting value.
  - 2. Elevation of two or more values on a three-hour glucose tolerance test above the accepted cut-off points of:
    - a. Fasting, less than 105
    - b. One-hour, less than 190
    - c. Two-hour, less than 165
- d. Three hour, less than 145Beneficiaries with Medicare Part B benefits continue to be serviced under the durable medical equipment (DME) program.

212.207 (DME) Insulin Pump and Supplies, All Ages

<del>8-1-21</del><u>5-1-</u> 24

Insulin pumps and supplies are covered by Arkansas Medicaid for beneficiaries of all ages. Effective 4/1/2024, patch or tubeless insulin pumps are processed as a pharmacy claim submission by pharmacies or DME providers while traditional insulin pumps requiring tubing and cannula type supplies remain processed as a medical claim. Beneficiaries with Medicare Part B benefits continue to be serviced for all of their needs under the DME program.

Prior authorization is required for the insulin pump. A prescription and proof of medical necessity are required. The patient must be educated on the use of the pump, but the education is not a covered service.

Insulin is covered through the prescription drug program.

The following criteria will be utilized in evaluating the need for the insulin pump:

A. Insulin-dependent diabetes that is difficult to control.

B. Fluctuation in blood sugars causing both high and low blood sugars in a patient on at least three (3), if not four (4), injections per day.

- C. Beneficiary's motivation level in controlling diabetes and willingness to do frequent blood glucose monitoring.
- D. Beneficiary's ability to learn how to use the pump effectively. This will have to be evaluated and documented by a professional with experience in the use of the pump.
- E. Determination of the beneficiary's suitability to use the pump should be made by a diabetes specialist or endocrinologist.
- F. Beneficiaries not included in one (1) of these categories will be considered on an individual basis.

Prior authorization requests for the traditional insulin pumps and supplies (cannula, tubing) must be submitted on form DMS-679A titled Prescription & Prior Authorization Request for Medical Equipment Excluding Wheelchairs & Wheelchair Components, to DHS or its designated vendor. View or print form DMS-679A and instructions for completion. View or print contact information for how to submit the request.

When submitting prior authorization requests for the patch or tubeless insulin pumps see the **DHS Pharmacy Vendor's website** for specific information for coverage details.

#### 212.208 Continuous Glucose Monitors

<del>1-1-22</del><u>5-1-</u> <u>24</u>

- A. The Arkansas Medicaid Program provides coverage for a continuous glucose monitor (CGM) for the treatment of a Medicaid client if the client has: Effective 4/1/2024, continuous glucose monitors (CGMs) are processed as a pharmacy claim submission by pharmacies or DME providers. Beneficiaries must meet the following criteria for coverage:
  - 1. Either:
    - a. A presence of type 1 diabetes or any other type of diabetes with the use of insulin-more than two (2) times daily; or
    - b. A presence of type 1 diabetes or any other type of diabetes with evidence of Level 2 or Level 3 hypoglycemia; or
    - c. Diagnosis of glycogen storage disease type 1a; or
    - d. Use of an insulin pump; and
  - 2. Regular follow-up with a healthcare provider at a minimum every six (6) months to assess for ongoing benefit.
  - 3. See the DHS Pharmacy Vendor's website for specific information for coverage details.
- B. Definition. As used in this section, "continuous glucose monitor" means an instrument or device, including repair and replacement parts, that:
  - 1. Is designed and offered for the purpose of aiding an individual with diabetes;
  - Automatically estimates blood glucose levels, also called blood sugar, throughout the day and night; Measures glucose levels at set intervals by means of a small electrode placed under the skin and held in place by an adhesive; and
  - 3 Is generally not useful to an individual who has not been diagnosed with diabetes.

C. Additional requirements are set out in Section 242.113. Beneficiaries with Medicare Part B benefits continue to be serviced under the DME program.

# 242.112 Home Blood Glucose Monitor and Supplies – Pregnant Women Only, All Ages

2-1-22

Procedure codes found in this section must be billed either electronically or on paper with modifier **NU** for individuals of all ages. When a second modifier is listed, that modifier must be used in conjunction with the **NU** modifier.

Modifiers in the section are indicated by the headings M1 and M2. Prior authorization is indicated by the heading PA.

<u>View or print the procedure codes and modifiers for Durable Medical Equipment (DME), oxygen equipment and supplies, orthotic appliances, prosthetic devices and medical supplies, procedures and services.</u>

#### 242.113 Continuous Glucose Monitors

1-1-22

- A. A Continuous Glucose Monitor (CGM) is covered by Arkansas Medicaid as set out in Section 212.208 of this provider manual.
- B. The correct procedure codes and modifiers are found in the following link:
- View or print the procedure codes and modifiers for Durable Medical Equipment (DME), oxygen equipment and supplies, orthotic appliances, prosthetic devices and medical supplies, procedures and services.
- C. A prior authorization (PA) is required for a CGM. Requests for prior authorization must be submitted to DHS or its designated vendor. View or print contact information for how to submit the request. Requests must be made on form DMS-679A titled Prescription & Prior Authorization Request for Medical Equipment Excluding Wheelchairs & Wheelchair Components. (View or print form DMS-679A and instructions for completion.)

#### **TOC** required

#### 212.206 Home Blood Glucose Monitor and Supplies, All Ages

5-1-24

- A. Effective 4/1/2024, Medicaid beneficiaries are eligible for diabetic and blood sugar testing supplies processed as a pharmacy claim submission by pharmacies or DME providers. Home blood sugar meters and supplies (strips, lancets, calibration solution, etc.) are available without a prior authorization. See the DHS Pharmacy Vendor's website for specific information for coverage details.
- B. Beneficiaries with Medicare Part B benefits continue to be serviced under the durable medical equipment (DME) program.

#### 212.207 Insulin Pump and Supplies, All Ages

5-1-24

Insulin pumps and supplies are covered by Arkansas Medicaid for beneficiaries of all ages. Effective 4/1/2024, patch or tubeless insulin pumps are processed as a pharmacy claim submission by pharmacies or DME providers while traditional insulin pumps requiring tubing and cannula type supplies remain processed as a medical claim. Beneficiaries with Medicare Part B benefits continue to be serviced for all of their needs under the DME program.

Prior authorization is required for the insulin pump. A prescription and proof of medical necessity are required. The patient must be educated on the use of the pump, but the education is not a covered service.

Insulin is covered through the prescription drug program.

The following criteria will be utilized in evaluating the need for the insulin pump:

- A. Insulin-dependent diabetes that is difficult to control.
- B. Fluctuation in blood sugars causing both high and low blood sugars in a patient on at least three (3), if not four (4), injections per day.
- C. Beneficiary's motivation level in controlling diabetes and willingness to do frequent blood glucose monitoring.
- D. Beneficiary's ability to learn how to use the pump effectively. This will have to be evaluated and documented by a professional with experience in the use of the pump.
- E. Determination of the beneficiary's suitability to use the pump should be made by a diabetes specialist or endocrinologist.
- F. Beneficiaries not included in one (1) of these categories will be considered on an individual basis.

Prior authorization requests for traditional insulin pumps and supplies (cannula, tubing) must be submitted on form DMS-679A titled *Prescription & Prior Authorization Request for Medical Equipment Excluding Wheelchairs & Wheelchair Components*, to DHS or its designated vendor.

<u>View or print form DMS-679A and instructions for completion.</u>
<u>View or print contact information for how to submit the request.</u>

When submitting prior authorization requests for the patch or tubeless insulin pumps see the **DHS Pharmacy Vendor's website** for specific information for coverage details.

A. Effective 4/1/2024, continuous glucose monitors (CGMs) are processed as a pharmacy claim submission by pharmacies or DME providers. Beneficiaries must meet the following criteria for coverage:

- 1. Either:
  - a. A presence of type 1 diabetes or any other type of diabetes with the use of insulin; or
  - b. A presence of type 1 diabetes or any other type of diabetes with evidence of Level 2 or Level 3 hypoglycemia; or
  - c. Diagnosis of glycogen storage disease type 1a; or
  - d. Use of an insulin pump; and
- 2. Regular follow-up with a healthcare provider at a minimum every six (6) months to assess for ongoing benefit.
- 3. <u>See the DHS Pharmacy Vendor's website</u> for specific information for coverage details.
- B. Definition. As used in this section, "continuous glucose monitor" means an instrument or device, including repair and replacement parts, that:
  - 1. Is designed and offered for the purpose of aiding an individual with diabetes;
  - Automatically estimates blood glucose levels, also called blood sugar, throughout the day and night;
  - 3 Is generally not useful to an individual who has not been diagnosed with diabetes.

Beneficiaries with Medicare Part B benefits continue to be serviced under the DME program.

# STATE PLAN UNDER TITLE XIX OF THE SOCIAL SECURITY ACT MEDICAL ASSISTANCE PROGRAM STATE OF ARKANSAS

ATTACHMENT 4.19-B Page 2g

# METHODS AND STANDARDS FOR ESTABLISHING PAYMENT RATES - OTHER TYPES OF CARE

<del>January 1, 2022</del><u>April 1,</u> 2024

- 7. Home Health Services (Continued)
  - c. Medical Supplies, Equipment and Appliances Suitable for Use in the Home (continued)
    - (5) Aerochamber Device

Effective for dates of service on or after October 1, 1997, reimbursement is based on the lesser of the provider's actual charge for the service or the Title XIX (Medicaid) maximum. The Title XIX (Medicaid) maximum established was based on a 1997 survey of Durable Medical Equipment (DME) providers. The information obtained in the survey indicated there is only one major manufacturer and distributor of the aerochamber devices (with or without mask) to providers enrolled in the Arkansas Medicaid Program. It was determined the aerochamber devices are sold to each provider for the same price. As a result, the current Title XIX (Medicaid) maximum for the aerochamber devices (with or without mask) was established based on the actual manufacturer=s list prices. Thereafter, adjustments will be made based on the consumer price index factor to be implemented at the beginning of the appropriate State Fiscal Year, July 1.

(6) Specialized Wheelchairs, Seating and Rehab Items

Reimbursement is based on the lesser of the provider's actual charge for the service or the Title XIX (Medicaid) maximum. Effective for claims with dates of service on or after May 1, 1995, the Title XIX (Medicaid) maximums were established utilizing the manufacturer's current published suggested retail price less 15%. The 15% is the median of Oklahoma Medicaid which is currently retail less 12% and Texas Medicaid which is currently retail less 18%. Effective for claims with dates of service on or after September 1, 1995, the following Kaye Products, procedure codes Z2059, Z2060, Z2061 and Z2062, are reimbursed at the manufacturer's current published suggested retail price. The State Agency and affected provider association representatives will review the rates annually and negotiate any adjustments.

(7) DME/Continuous Glucose Monitors.

**Procedure Codes and Rates.** 

A. Rates. Effective for dates of service on or after January 1, 2022, reimbursement for Continuous Glucose Monitors (CGM) and related supplies is based on the Medicare non-rural rate for the State of Arkansas (effective as of July 28, 2021, and subject to change when Medicare rates are adjusted) for the allowable procedure codes. All rates are published on the agency's website. Except as otherwise noted in the plan, state developed fee schedule rates are the same for both governmental and private providers.

A.B. Effective for dates of service on or after April 1,
2024, reimbursement for Continuous Glucose Monitors (CGM)
and related Diabetic Supplies including patch type insulin pumps
is based on Wholesale Acquisition Cost (WAC) plus applicable
professional dispensing fee. Traditional insulin pumps will

TN:21-0015 Approval: Effective Date:1-1-2022

Supersedes TN:02-0009



TN:21-0015 Approval: Effective Date:1-1-2022 Supersedes TN:02-0009

# STATE PLAN UNDER TITLE XIX OF THE SOCIAL SECURITY ACT MEDICAL ASSISTANCE PROGRAM STATE OF <u>ARKANSAS</u>

ATTACHMENT 4.19-B Page 2g

# METHODS AND STANDARDS FOR ESTABLISHING PAYMENT RATES - OTHER TYPES OF CARE

April 1, 2024

7. Home Health Services (Continued)

c. Medical Supplies, Equipment and Appliances Suitable for Use in the Home (continued)

(5) Aerochamber Device

Effective for dates of service on or after October 1, 1997, reimbursement is based on the lesser of the provider's actual charge for the service or the Title XIX (Medicaid) maximum. The Title XIX (Medicaid) maximum established was based on a 1997 survey of Durable Medical Equipment (DME) providers. The information obtained in the survey indicated there is only one major manufacturer and distributor of the aerochamber devices (with or without mask) to providers enrolled in the Arkansas Medicaid Program. It was determined the aerochamber devices are sold to each provider for the same price. As a result, the current Title XIX (Medicaid) maximum for the aerochamber devices (with or without mask) was established based on the actual manufacturer=s list prices. Thereafter, adjustments will be made based on the consumer price index factor to be implemented at the beginning of the appropriate State Fiscal Year, July 1.

(6) Specialized Wheelchairs, Seating and Rehab Items

Reimbursement is based on the lesser of the provider's actual charge for the service or the Title XIX (Medicaid) maximum. Effective for claims with dates of service on or after May 1, 1995, the Title XIX (Medicaid) maximums were established utilizing the manufacturer's current published suggested retail price less 15%. The 15% is the median of Oklahoma Medicaid which is currently retail less 12% and Texas Medicaid which is currently retail less 18%. Effective for claims with dates of service on or after September 1, 1995, the following Kaye Products, procedure codes Z2059, Z2060, Z2061 and Z2062, are reimbursed at the manufacturer's current published suggested retail price. The State Agency and affected provider association representatives will review the rates annually and negotiate any adjustments.

(7) DMF/Continuous Glucose Monitors.

Procedure Codes and Rates.

- A. Rates. Effective for dates of service on or after January 1, 2022, reimbursement for Continuous Glucose Monitors (CGM) and related supplies is based on the Medicare non-rural rate for the State of Arkansas (effective as of July 28, 2021, and subject to change when Medicare rates are adjusted) for the allowable procedure codes. All rates are published on the agency's website. Except as otherwise noted in the plan, state developed fee schedule rates are the same for both governmental and private providers.
- B. Effective for dates of service on or after April 1, 2024, reimbursement for Continuous Glucose Monitors (CGM) and related Diabetic Supplies including patch type insulin pumps is based on Wholesale Acquisition Cost (WAC) plus applicable professional dispensing fee. Traditional insulin pumps will remain at the Medicare non-rural rate as stated in A. above.

TN:24-0006 Approval: Effective Date:4-1-2024

Supersedes TN:21-0015

### SPA # 14, Purpose of SPA:

The purpose of this SPA is to improve access to continuous glucose monitors (CGMs) through pharmacy claim submission processing for reimbursement to pharmacies and DME providers. Beneficiaries eligible for CGMs 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. Patch type insulin pumps, blood glucose monitors (BGMs) and testing supplies will be covered in the same manner. Coverage is being extended to comply with Arkansas Act 393 of 2023.

Proposed effective date: April 1, 2024

Proposed implementation date: April 1, 2024

6.2 The State elects to provide the following forms of coverage to children: (Check all that apply. If an item is checked, describe the coverage with respect to the amount, duration and scope of services covered, as well as any exclusions or limitations) (Section 2110(a)) (42CFR 457.490)

#### **ARKids-B Program**

Ambulance (Emergency Only)

The Title XXI CHIP ARKids-B program's benefit package includes inpatient and outpatient hospital services, physician, surgical and medical services, laboratory and x-ray services, well baby care, including age-appropriate immunizations. Enrollees in ARKids-B are not eligible for the full range of Medicaid State Plan services. The chart below provides a description of the coverage and the amount, duration, and scope of services covered in certain services included in the ARKids-B benefit package, as well as any exclusions or limitations. The services checked below in the preprint are included in the ARKids-B benefit package.

	7 till balanco (Emergency City)
	Ambulatory Surgical Center
	Audiological Services (only Tympanometry, CPT procedure code 92567, when the diagnosis
	is within the ICD-9-CM range of 381.0 through 382.9)
	Certified Nurse Midwife
	Chiropractor
	Dental Care (routine dental care & orthodontia)
	Durable Medical Equipment (DME) (Limited to \$500 per State Fiscal Year (SFY) July 1 –
	June 30, excluding CGMs Drugs and diabetic supplies)
١	Emergency Dept. Services (Emergent, non-emergent, assessment)
	Family Planning
	Federally Qualified Health Center (FQHC)
	Home Health (10 visits per SFY (July 1 – June 30))
	Hospital, Inpatient
	Hospital, Outpatient
	Inpatient Psychiatric Hospital & Psychiatric Residential Treatment Facility

Immunizations (All per protocol)
Laboratory & X-Ray

Medical Supplies (Limited to \$125/month unless benefit extension is approved)

Mental & Behavioral Health, Outpatient

School-Based Mental Health

Nurse Practitioner

Physician
Podiatry
Prenatal Care
Prescription Drugs Drugs and diabetic supplies
Preventive Health Screenings (All per protocol)
Rural Health Clinic
Speech Therapy
Evaluation – Four 30 minute units/SFY (July 1 – June 30) unless benefit extension is
approved
Therapy – Four 15 minute units/day unless benefit extension is approved
Physical Therapy
Evaluation – Four 30 minute units/SFY (July 1 – June 30) unless benefit extension is
approved
Therapy – Four 15 minute units/day unless benefit extension is approved
Occupational Therapy
Evaluation – Four 30 minute units/SFY (July 1 – June 30) unless benefit extension is
approved
Therapy – Four 15 minute units/day unless benefit extension is approved
Substance Abuse Treatment Services (SATS), Outpatient
Vision
(Eye exam – One routine eye exam (refraction) every 12 months
Eyeglasses) – One pair every 12 months
Prescription Drugs and diabetic supplies category includes prescription drugs. (

\*The Prescription Drugs and diabetic supplies category includes prescription drugs, Continuous Glucose Monitors (CGMs) with CGM supplies, patch type insulin pumps, and blood glucose monitors (BGMs) with blood glucose testing supplies (test strips, calibration solution).

The diabetic supplies category requires a co-pay rather than inclusion in the DME \$500 per State

Fiscal Year (SFY) July 1 – June 30 limitation. While these products are reimbursable to both

pharmacies and DME providers, pricing methodology and billing processes have been aligned for both

categories.

## **CHIP Title XXI CHIP ARKids-B Program**

**8.1.3.** [X]

groups of enrolled the service for wh	ount of cost-sharing, any sliding scale based on income, the group or es that may be subject to the charge by age and income (if applicable) and nich the charge is imposed or time period for the charge, as appropriate.  1)(A)) (42CFR 457.505(a), 457.510(b) and (c), 457.515(a) and (c))
8.1.1.	Premiums:
8.1.2.	Deductibles:

Coinsurance or copayments:

Co-payments and co-insurance apply for all services with the exception of immunizations, preventive health screenings, family planning, and prenatal care. The Title XXI CHIP ARKids-B schedule of co-payments and co-insurance is outlined in the following table. The annual cumulative cost-sharing maximum cannot exceed 5% of the ARKids-B beneficiary's family's income.

Benefits/Limits	Co-Pay/Co-Insurance	
Ambulance (Emergency Only)	\$10 per trip	
Ambulatory Surgical Center	\$10 per visit	1
Audiological Services (only Tympanometry, CPT procedure code 92567, when the diagnosis is within the ICD-9-CM range of 381.0 through 382.9)	None	
Certified Nurse Midwife	\$10 per visit	
Chiropractor	\$10 per visit	
Dental Care (routine dental care & orthodontia)	\$10 per visit	
Durable Medical Equipment (DME) (Limited to \$500 per State Fiscal Year (SFY) July 1 – June 30, excluding CGMs and diabetic supplies)	10% of Medicaid allowed per DME item. excluding CGMs and diabetic supplies	Durable Medical \$500 per State F June 30)
Emergency Dept. Services (Emergent, non- emergent, assessment)	\$10 per visit	
Family Planning	None	
Federally Qualified Health Center (FQHC)	\$10 per visit	
Home Health (10 visits per SFY (July 1 – June 30))	\$10 per visit	
Hospital, Inpatient	10% of first inpatient day	
Hospital, Outpatient	\$10 per visit	
Inpatient Psychiatric Hospital & Psychiatric Residential Treatment Facility	10% of first inpatient day	
Immunizations (All per protocol)	None	
Laboratory & X-Ray	\$10 per visit	
Medical Supplies (Limited to \$125/month unless benefit extension is approved	None	
Mental & Behavioral Health, Outpatient	\$10 per visit	
School-Based Mental Health	\$10 per visit	
Nurse Practitioner	\$10 per visit	
Physician	\$10 per visit	
Podiatry	\$10 per visit	
Prenatal Care	None	
Prescription Drugs and diabetic supplies*	\$5 per prescription (Must use generic, if available)	
Preventive Health Screenings (All per protocol)	None	
Rural Health Clinic	\$10 per visit	
Speech Therapy Evaluation – Four 30 minute units/SFY (July 1 – June 30) unless benefit extension is		

approved Therapy – Four 15 minute units/day unless benefit extension is approved	\$10 per visit
Physical Therapy Evaluation – Four 30 minute units/SFY (July 1 – June 30) unless benefit extension is approved	
Therapy – Four 15 minute units/day unless benefit extension is approved	\$10 per visit
Occupational Therapy Evaluation – Four 30 minute units/SFY (July 1 – June 30) unless benefit extension is approved	
Therapy – Four 15 minute units/day unless benefit extension is approved	\$10 per visit
Substance Abuse Treatment Services (SATS), outpatient	\$10 per visit
Vision (Eye exam,	\$10 per visit
Eyeglasses)	No co-pay for eyeglasses

<sup>\*</sup>The Prescription Drugs and diabetic supplies category includes prescription drugs, Continuous Glucose Monitors (CGMs) with CGM supplies, patch type insulin pumps, and blood glucose monitors (BGMs) with blood glucose testing supplies (test strips, calibration solution). The diabetic supplies category requires a co-pay rather than inclusion in the DME \$500 per State Fiscal Year (SFY) July 1 – June 30 limitation and the 10% coinsurance required for other DME products. While these products are reimbursable to both pharmacies and DME providers, pricing methodology and billing processes have been aligned for both categories.

During the Federal COVID-19 public health emergency, cost sharing shall be waived for any in vitro diagnostic product described in section 2103(c)(10) of the Social Security Act and any other COVID-19 testing-related services regardless of setting type. In addition, the state will waive copayments for COVID treatment.

#### The Source of State Share Funds:

Please See ATTACHMENT E for State's projected one-year CHIP budget for revising rate methodology and member coinsurance requirements for Continuous Glucose Monitors (CGMs) with CGM supplies, patch type insulin pumps, and blood glucose monitors (BGMs) with blood.glucose testing supplies (test strips, calibration solution)...

- Planned use of funds, including:
  - Projected amount to be spent on health services;

- Projected amount to be spent on administrative costs, such as outreach, child health initiatives, and evaluation; and
- Assumptions on which the budget is based, including cost per child and expected enrollment.
- Projected expenditures for the separate child health plan, including but not limited to expenditures for targeted low income children, the optional coverage of the unborn, lawfully residing eligibles, dental services, etc.
- All cost sharing, benefit, payment, eligibility need to be reflected in the budget.
- Projected sources of non-Federal plan expenditures, including any requirements

- for cost-sharing by enrollees.
- Include a separate budget line to indicate the cost of providing coverage to pregnant women.
- States must include a separate budget line item to indicate the cost of providing coverage to premium assistance children.
- Include a separate budget line to indicate the cost of providing dental-only supplemental coverage.
- Include a separate budget line to indicate the cost of implementing Express Lane Eligibility.
- Provide a 1-year projected budget for all targeted low-income children covered under the state plan using the attached form. Additionally, provide the following:
  - Total 1-year cost of adding prenatal coverage
  - Estimate of unborn children covered in year 1

treatment.

Please See ATTACHMENT E for State's projected one-year budget for revising rate methodology and member coinsurance requirements for Continuous Glucose Monitors (CGMs) with CGM supplies, patch type insulin pumps, and blood glucose monitors (BGMs) with blood.glucose testing supplies (test strips, calibration solution).

### **CHIP Budget**

STATE:	FFY Budget
Federal Fiscal Year	
State's enhanced FMAP rate	
Benefit Costs	
Insurance payments	
Managed care	
per member/per month rate	
Fee for Service	
Total Benefit Costs	
(Offsetting beneficiary cost sharing payments)	
Net Benefit Costs	
Cost of Proposed SPA Changes – Benefit	
Administration Costs	
<u>Personnel</u>	
General administration	
Contractors/Brokers	
<u>Claims Processing</u>	
Outreach/marketing costs	
<u>Health Services Initiatives</u>	
<u>Other</u>	

Total Administration Costs	
10% Administrative Cap	
Cost of Proposed SPA Changes	
Federal Share	
State Share	
Total Costs of Approved CHIP Plan	

NOTE: Include the costs associated with the current SPA.

# **The Source of State Share Funds:**



### SPA # 14, Purpose of SPA:

The purpose of this SPA is to improve access to continuous glucose monitors (CGMs) through pharmacy claim submission processing for reimbursement to pharmacies and DME providers. Beneficiaries eligible for CGMs 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. Patch type insulin pumps, blood glucose monitors (BGMs) and testing supplies will be covered in the same manner. Coverage is being extended to comply with Arkansas Act 393 of 2023.

Proposed effective date: April 1, 2024

Proposed implementation date: April 1, 2024

**6.2** The State elects to provide the following forms of coverage to children: (Check all that apply. If an item is checked, describe the coverage with respect to the amount, duration and scope of services covered, as well as any exclusions or limitations) (Section 2110(a)) (42CFR 457.490)

#### **ARKids-B Program**

Ambulance (Emergency Only)

The Title XXI CHIP ARKids-B program's benefit package includes inpatient and outpatient hospital services, physician, surgical and medical services, laboratory and x-ray services, well baby care, including age-appropriate immunizations. Enrollees in ARKids-B are not eligible for the full range of Medicaid State Plan services. The chart below provides a description of the coverage and the amount, duration, and scope of services covered in certain services included in the ARKids-B benefit package, as well as any exclusions or limitations. The services checked below in the preprint are included in the ARKids-B benefit package.

Tanbalance (Emergency emy)
Ambulatory Surgical Center
Audiological Services (only Tympanometry, CPT procedure code 92567, when the diagnosis
is within the ICD-9-CM range of 381.0 through 382.9)
Certified Nurse Midwife
Chiropractor
Dental Care (routine dental care & orthodontia)
Durable Medical Equipment (DME) (Limited to \$500 per State Fiscal Year (SFY) July 1 –
June 30, excluding CGMs Drugs and diabetic supplies)
Emergency Dept. Services (Emergent, non-emergent, assessment)
Family Planning
Federally Qualified Health Center (FQHC)
Home Health (10 visits per SFY (July 1 – June 30))
Hospital, Inpatient
Hospital, Outpatient
Inpatient Psychiatric Hospital & Psychiatric Residential Treatment Facility

Immunizations (All per protocol)
Laboratory & X-Ray
Medical Supplies (Limited to \$125/month unless benefit extension is approved)
Mental & Behavioral Health, Outpatient

School-Based Mental Health

Nurse Practitioner

Physician	
Podiatry	

#### **Prenatal Care**

Prescription Drugs Drugs and diabetic supplies

Preventive Health Screenings (All per protocol)

Rural Health Clinic

Speech Therapy

Evaluation – Four 30 minute units/SFY (July 1 – June 30) unless benefit extension is approved

Therapy – Four 15 minute units/day unless benefit extension is approved

Physical Therapy

Evaluation – Four 30 minute units/SFY (July 1 – June 30) unless benefit extension is approved

Therapy – Four 15 minute units/day unless benefit extension is approved

Occupational Therapy

Evaluation – Four 30 minute units/SFY (July 1 – June 30) unless benefit extension is approved

Therapy – Four 15 minute units/day unless benefit extension is approved

Substance Abuse Treatment Services (SATS), Outpatient

Vision

(Eye exam – One routine eye exam (refraction) every 12 months

Eyeglasses) – One pair every 12 months

\*The Prescription Drugs and diabetic supplies category includes prescription drugs, Continuous Glucose Monitors (CGMs) with CGM supplies, patch type insulin pumps, and blood glucose monitors (BGMs) with blood glucose testing supplies (test strips, calibration solution).

The diabetic supplies category requires a co-pay rather than

inclusion in the DME \$500 per State Fiscal Year (SFY) July

1 – June 30 limitation. While these products are

reimbursable to both pharmacies and DME providers,

pricing methodology and billing processes have been

aligned for both categories.

#### CHIP Title XXI CHIP ARKids-B Program

**8.2** Describe the amount of cost-sharing, any sliding scale based on income, the group or groups of enrollees that may be subject to the charge by age and income (if applicable) and the service for which the charge is imposed or time period for the charge, as appropriate. (Section 2103(e)(1)(A)) (42CFR 457.505(a), 457.510(b) and (c), 457.515(a) and (c))

8.1.1.	Premiums:
812 🗆	Deductibles:

**8.1.3.** [X] Coinsurance or copayments:Co-payments and co-insurance apply for all services with the exception of immunizations, preventive health screenings, family planning, and prenatal care. The Title XXI CHIP ARKids-B schedule of co-payments and co-insurance is outlined in the following table. The annual cumulative cost-sharing maximum cannot exceed 5% of the ARKids-B beneficiary's family's income.

Benefits/Limits	Co-Pay/Co-Insurance	
Ambulance (Emergency Only)	\$10 per trip	
Ambulatory Surgical Center	\$10 per visit	
Audiological Services (only Tympanometry,		
CPT procedure code 92567, when the		
diagnosis is within the ICD-9-CM range of 381.0 through 382.9)	None	
Certified Nurse Midwife	\$10 per visit	
Chiropractor	\$10 per visit	
Dental Care (routine dental care & orthodontia)	\$10 per visit	
Durable Medical Equipment (DME) (Limited to		Durable Medical
\$500 per State Fiscal Year (SFY) July 1 – June	10% of Medicaid allowed per DME item,	\$500 per State F
30, excluding CGMs and diabetic supplies)	excluding CGMs and diabetic supplies	June 30)
Emergency Dept. Services (Emergent, non-		
emergent, assessment)	\$10 per visit	
Family Planning	None	
Federally Qualified Health Center (FQHC)	\$10 per visit	
Home Health (10 visits per SFY (July 1 – June	\$10 per visit	
30))		_
Hospital, Inpatient	10% of first inpatient day	
Hospital, Outpatient	\$10 per visit	
Inpatient Psychiatric Hospital & Psychiatric		
Residential Treatment Facility	10% of first inpatient day	
Immunizations (All per protocol)	None	
Laboratory & X-Ray	\$10 per visit	
Medical Supplies (Limited to \$125/month		
unless benefit extension is approved	None	
Mental & Behavioral Health, Outpatient	\$10 per visit	
School-Based Mental Health	\$10 per visit	
Nurse Practitioner	\$10 per visit	
Physician	\$10 per visit	
Podiatry	\$10 per visit	
Prenatal Care	None	
Prescription Drugs and diabetic supplies*	\$5 per prescription (Must use generic, if available)	
Preventive Health Screenings (All per protocol)	None	
Rural Health Clinic	\$10 per visit	

Speech Therapy
Evaluation – Four 30 minute units/SFY (July 1
<ul> <li>June 30) unless benefit extension is</li> </ul>



approved Therapy – Four 15 minute units/day unless benefit extension is approved	\$10 per visit
Physical Therapy Evaluation – Four 30 minute units/SFY (July 1 – June 30) unless benefit extension is approved	
Therapy – Four 15 minute units/day unless benefit extension is approved	\$10 per visit
Occupational Therapy Evaluation – Four 30 minute units/SFY (July 1 – June 30) unless benefit extension is approved Therapy – Four 15 minute units/day unless	\$10 per visit
benefit extension is approved  Substance Abuse Treatment Services (SATS), outpatient	\$10 per visit
Vision (Eye exam, Eyeglasses)	\$10 per visit No co-pay for eyeglasses

<sup>\*</sup>The Prescription Drugs and diabetic supplies category includes prescription drugs, Continuous Glucose Monitors (CGMs) with CGM supplies, patch type insulin pumps, and blood glucose monitors (BGMs) with blood glucose testing supplies (test strips, calibration solution). The diabetic supplies category requires a co-pay rather than inclusion in the DME \$500 per State Fiscal Year (SFY) July 1 – June 30 limitation and the 10% coinsurance required for other DME products. While these products are reimbursable to both pharmacies and DME providers, pricing methodology and billing processes have been aligned for both categories.

During the Federal COVID-19 public health emergency, cost sharing shall be waived for any in vitro diagnostic product described in section 2103(c)(10) of the Social Security Act and any other COVID-19 testing-related services regardless of setting type. In addition, the state will waive copayments for COVID treatment.

#### The Source of State Share Funds:

Please See ATTACHMENT E for State's projected one-year CHIP budget for revising rate methodology and member coinsurance requirements for Continuous Glucose Monitors (CGMs) with CGM supplies, patch type insulin pumps, and blood glucose monitors (BGMs) with blood.glucose testing supplies (test strips, calibration solution)..

- Planned use of funds, including:
  - Projected amount to be spent on health services;

- Projected amount to be spent on administrative costs, such as outreach, child health initiatives, and evaluation; and
- Assumptions on which the budget is based, including cost per child and expected enrollment.
- Projected expenditures for the separate child health plan, including but not limited to expenditures for targeted low income children, the optional coverage of the unborn, lawfully residing eligibles, dental services, etc.
- All cost sharing, benefit, payment, eligibility need to be reflected in the budget.
- Projected sources of non-Federal plan expenditures, including any requirements

- for cost-sharing by enrollees.
- Include a separate budget line to indicate the cost of providing coverage to pregnant women.
- States must include a separate budget line item to indicate the cost of providing coverage to premium assistance children.
- Include a separate budget line to indicate the cost of providing dental-only supplemental coverage.
- Include a separate budget line to indicate the cost of implementing Express Lane Eligibility.
- Provide a 1-year projected budget for all targeted low-income children covered under the state plan using the attached form. Additionally, provide the following:
  - Total 1-year cost of adding prenatal coverage
  - Estimate of unborn children covered in year 1

treatment.

Please See ATTACHMENT E for State's projected one-year budget for revising rate methodology and member coinsurance requirements for Continuous Glucose Monitors (CGMs) with CGM supplies, patch type insulin pumps, and blood glucose monitors (BGMs) with blood.glucose testing supplies (test strips, calibration solution).

**CHIP Budget** 

STATE:	FFY Budget
Federal Fiscal Year	
State's enhanced FMAP rate	
Benefit Costs	
Insurance payments	
Managed care	
per member/per month rate	
Fee for Service	
<b>Total Benefit Costs</b>	
(Offsetting beneficiary cost sharing payments)	
Net Benefit Costs	
Cost of Proposed SPA Changes – Benefit	
Administration Costs	
Personnel	
General administration	
Contractors/Brokers	
Claims Processing	
Outreach/marketing costs	
Health Services Initiatives	
Other	

<b>Total Administration Costs</b>	
10% Administrative Cap	
Cost of Proposed SPA Changes	
Federal Share	
State Share	
Total Costs of Approved CHIP Plan	

NOTE: Include the costs associated with the current SPA.

# **The Source of State Share Funds:**



# Stricken language would be deleted from and underlined language would be added to present law. Act 393 of the Regular Session

1	State of Arkansas	As Engrossed: \$3/15/23
2	94th General Assembly	A Bill
3	Regular Session, 2023	HOUSE BILL 1008
4		
5	By: Representative Pilkingt	on
6	By: Senator B. Davis	
7		
8		For An Act To Be Entitled
9	AN ACT TO MODIFY THE COVERAGE OF CONTINUOUS GLUCOSE	
10	MONITORS IN THE ARKANSAS MEDICAID PROGRAM; AND FOR	
11	OTHER PU	RPOSES.
12		
13		
14		Subtitle
15	TO	MODIFY THE COVERAGE OF CONTINUOUS
16	GLU	COSE MONITORS IN THE ARKANSAS MEDICAID
17	PRO	GRAM.
18		
19		
20	BE IT ENACTED BY THE	GENERAL ASSEMBLY OF THE STATE OF ARKANSAS:
21		
22	SECTION 1. Ar	cansas Code § 20-7-142 is repealed for reenactment in a
23	more appropriate sec	cion within the Arkansas Code.
24	<del>20-7-142. Con</del>	<del>cinuous glucose monitor - Definition.</del>
25	(a) As used i	this section, "continuous glucose monitor" means an
26	instrument or device	, including repair and replacement parts, that:
27	<del>(1) Is (</del>	lesigned and offered for the purpose of aiding an
28	individual with diab	etes;
29	<del>(2) Mea</del>	sures glucose levels at set intervals by means of a small
30	electrode placed und	er the skin and held in place by an adhesive; and
31	<del>(3) Is </del>	generally not useful to an individual who has not been
32	diagnosed with diabe	<del>CES.</del>
33	(b) The Arkan	sas Medicaid Program shall provide coverage for a
34	continuous glucose m	onitor for the treatment of an individual if the
35	individual has:	
36	(1) Eit	<del>ner:</del>

As Engrossed: S3/15/23 HB1008

1	(A) A presence of type 1 diabetes or any other type of
2	diabetes with:
3	(i) The use of insulin more than two (2) times
4	<del>daily; or</del>
5	(ii) Evidence of Level 2 or Level 3 hypoglycemia; or
6	(B) Diagnosis of glycogen storage disease type la; and
7	(2) Regular follow-up with a healthcare provider at a minimum
8	every six (6) months to assess for ongoing benefit.
9	
10	SECTION 2. Arkansas Code Title 20, Chapter 77, Subchapter 1, is
11	amended to add an additional section to read as follows:
12	20-77-148. Continuous glucose monitor — Definition.
13	(a) As used in this section, "continuous glucose monitor" means an
14	instrument or device, including repair and replacement parts, that:
15	(1) Is designed and offered for the purpose of aiding an
16	individual with diabetes;
17	(2) Measures glucose levels at set intervals by means of a small
18	electrode placed under the skin and held in place by an adhesive; and
19	(3) Is generally not useful to an individual who has not been
20	diagnosed with diabetes.
21	(b) The Arkansas Medicaid Program shall provide coverage for a
22	continuous glucose monitor for the treatment of an individual if the
23	individual has:
24	(1) Either:
25	(A) A presence of type l diabetes or any other type of
26	diabetes with:
27	(i) The use of insulin more than two (2) times
28	daily; or
29	(ii) Evidence of Level 2 or Level 3 hypoglycemia; or
30	(B) Diagnosis of glycogen storage disease type la; and
31	(2) Regular follow-up visits with a healthcare provider at a
32	minimum of every six (6) months to assess for ongoing benefit of the
33	continuous glucose monitor.
34	(c) Coverage for a continuous glucose monitor under the Arkansas
35	Medicaid Program shall allow the beneficiary to obtain a continuous glucose
36	monitor through a prescription at a pharmacy and be eligible for rebates as a

As Engrossed: S3/15/23 HB1008

1	pharmacy benefit.	
2		
3		/s/Pilkington
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6		APPROVED: 3/30/23
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# **RULES SUBMITTED FOR REPEAL**

# **Rule #1:**

DDS Policy 3018 – Reporting of Denial of Access to Services

# **Rule #2:**

DDS Policy 3018 – Mortality Review of Deaths of Persons Receiving Alternative Community Services Waiver Services

<u>Policy Type</u> <u>Subject of Policy</u> <u>Policy No.</u>

Service Reporting of Denial of Access to Services

3018

- 1. <u>Purpose</u>. This policy has been established to ensure compliance with the Americans with Disabilities Act (ADA) PL 101-336; 42 USC 12101 et. seq. This policy establishes reporting requirements and processing criteria for denial of access to services to eligible or qualifying persons with developmental disabilities.
- 2. <u>Scope.</u> This policy applies to all Division of Developmental Disabilities Services (DDS) programs and services and their employees.
- 3. Definitions.
  - A. ADA Americans with Disabilities Act (PL 101-336; 42 USC 12101 et. seq.). The purpose of the act is to prohibit discrimination against people with disabilities in employment, transportation, public accommodation, communications, and activities of state and local government.

Section 302 Prohibits persons who own lease operate public accommodations from the lasis of a disability. 23 – 02

- B. Eligibility Criteria See Act 513 of 1981 and DDS Interpretive Guidelines in making service eligibility determination. Eligibility Criteria should identify those persons who are eligible to receive services.
- C. Program and Services The operation of the Department of Human Services Division of Developmental Disabilities Services Community Programs and Services licensed, or funded wholly or in part by the Division of Developmental Disabilities.
- D. Public Accommodation Includes health care providers, offices, hospitals, other service establishments, private schools, or other places of education; and social service center establishments.

Effective Date: December 1, 1993 Sheet 1 of 4

References: Public Law 101-356 of 1990; Ark. Statute 20-48-101.

Administrative Rules & Regulations Sub Committee of the Arkansas Legislative Council: November 4, 1993.

Policy Type Subject of Policy Policy No.

Service Reporting of Denial of Access to Services

3018

- E. Discrimination includes:
  - 1. The establishment of eligibility criteria that tend to screen out applicants with disabilities unless it is shown that the criteria is necessary for the delivery of services;
  - 2. A failure to make reasonable modifications in the policies, practices, or procedures to accommodate people with disabilities unless it can be demonstrated that such modifications would require fundamental alterations to the provider's service;
  - 3. Failure to provide auxiliary aids for persons with disabilities unless it can be demonstrated the provision of aids would fundamentally alter the nature of the provider's services or would result in an undue burden;
  - 4. Refailure to remove architectural barriers and communications barriers where removal seedily achievable 23-02
- F. Reasonable Accommodation Any change in the work environment (program) or in the way things are ordinarily done (why the program is operated) that results in equal employment opportunity (equal access to services) for an individual with a disability.

Example: Making existing facilities used by service recipients readily accessible to, and usable by, an individual with a disability. Acquiring or modifying equipment or devices.

G. Undue Burden – An action that is excessively costly, extensive, substantial, or disruptive, or that would fundamentally alter the nature or operation.

Factors: Nature and cost of the accommodation in relation to the size, the financial resources, the nature and structure of employer's operation.

Impact of the accommodation on the facility providing the accommodation.

Effective Date: December 1, 1993 Sheet 2 of 4

Policy Type Subject of Policy Policy No.

**Service** 

Reporting of Denial of Access to Services

3018

- 4. <u>Access.</u> DDS shall have access to the premises and records of programs and services at all times for the purpose of reviewing compliance with this policy and applicable licensure standards.
- 5. <u>Development of Program Procedures.</u>
  - A. Each DDS Program and Service shall develop and implement uniform procedures for access to services and conforming to the guidelines set forth herein and in accordance with ADA. Each service provider shall refer the applicant, who has been denied services, to another service provider. Uniform procedures shall be implemented by promulgation of licensing standards, policy and directives.
  - B. DDS Programs and Services shall develop procedures for documenting and reporting denial of access to services to designated DDS Staff.
  - C. A copy of each DDS Program's procedures will be submitted to DDS Licensure Staff of approval EAL-EO 23-02
  - D. For the purpose of this policy, implementation shall include communication to managers, supervisors, and responsible persons (within a community program) regarding the duties and obligations imposed by this policy.
- 6. Reporting Requirements. Denial of access to services shall be reported verbally within twenty-four (24) hours to DDS Client Services (682-8677) and written confirmation submitted to DDS Licensure within three (3) working days of occurrence. (See Form ADA-1.)

The report shall include at least the following:

- 1. Name of program
- Full name of individual
- 3. Date of birth
- 4. Sex
- 5. Race
- 6. Social Security Number
- 7. County of Residence
- 8. Name, address and telephone number of individual or parent/guardian (if applicable)

Effective Date: December 1, 1993 Sheet 3 of 4

Policy Type Subject of Policy Policy No. Reporting of Denial of Access to Services **Service** 3018 9. **Date of application** Name of all services requested 10. 11. Name of service requested and denied Specific reason for denial of access to service 12. Undue burden b. Fundamental change to a program <del>13.</del> Where the individual was referred 14. Results of the referral (s)

- 7. <u>Outcome</u>. Verified failure to adhere to this policy could jeopardize the licensure or contract status of a program or service.
- 8. <u>Appeal.</u> Should a Program/Service Director disagree with a decision made, he/she may appeal that decision by following procedures outlined in DDS Policy # 1076.
- PEPEAL-EO 23-02

Developmental Disabilities Services Department of Human Services P.O. Box 1437, Slot 2500 Little Rock, Arkansas 72203-1437

Telephone Number: (501) 682-8665

Effective Date: December 1, 1993 Sheet 4 of 4

Policy Type	Subject of Policy	Policy No.
Administration	Mortality Review of Deaths of Persons Receiving	3018
	Alternative Community Services Waiver Services	

#### INTRODUCTION

The Alternative Community Services (ACS) Mortality Review is an integral part of the Continuous Quality Improvement process for the Division of Developmental Disabilities Services (DDS). The mortality review is a process that entails a review of the specific circumstances of the death of an individual by at least one of two committees as well as a review of cumulative data regarding information on all deaths occurring within specific periods.

The review is not investigative in nature. Rather, the purpose is to facilitate Continuous Quality Improvement by gathering information to identify systemic issues that may benefit from scrutiny and analysis in order to make system improvement and to provide opportunities for organizational learning.

### I. Purpose

The purpose of the review is to identify issues and trends related to deaths of Alternative Community Services Waiver service recipients in order to improve Division and Provider practices by:

- 1. Identifying social, health and systems strengths and weaknesses as they impact circumstances leading to death,
- 2. Recommending changes in procedures, resources and service delivery systems that impact circumstances leading to death,
- 3. Influencing the development of policies and laws regarding provision of ACS Waiver services, and
- 4. Gathering data about deaths among individuals with developmental disabilities, such as cause of death and demographic information so that the DDS may aggregate data over time to identify and analyze trends.

#### II. Intent

The intent of the review is to facilitate a better understanding of factors contributing to deaths and to develop enhanced strategies for addressing preventable deaths, developing recommendations for appropriate care, and, ultimately, to prevent the occurrence of future preventable deaths.

#### **III. Definitions**

Division – The Division of Developmental Disabilities Services, Department of Human Services.

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<u>Expected Death</u> – A death that is natural or a death that is medically determined, based on a death certificate and supporting documentation, to have resulted solely from a diagnosed degenerative condition or similar circumstance or a death that occurs as the result of an undiagnosed condition resulting from an explained condition, such as the aging process.

<u>Full Review</u> – A review of the death of an individual in which no identifying information regarding the decedent or the Provider is available for consideration by the Mortality Review Committee.

Mortality Review Committee – A group, made up of individuals identified in Section VIII of this document, who conduct a Full Review of all deaths designated as unexplained or unexpected, as well as some deaths designated as expected.

<u>Mortality Review Coordinator</u> – The individual responsible for gathering specific information regarding deaths of persons receiving ACS Waiver services and for coordinating meetings of the Review Team and Mortality Review Committee.

Preliminary Review of the death of an individual is which all identifying information regarding the decident and the P ovider's available for consideration by the Review Team. The purpose of the review is to determine the designation of the death as unexpected, unexplained or expected.

<u>Provider</u> – The entity licensed or certified by DDS providing services to the individual whose death is under review.

<u>Record</u> – The written or electronic file containing information pertaining to the individual, including relevant facts, dates, and actions taken related to the individual, and contacts made and the results of those contacts.

<u>Review Team – A group, made up of specified individuals who conduct a Preliminary Review of the deaths of all persons receiving ACS Waiver services.</u>

<u>Reviewable Death</u> – The death of a person who is receiving waiver services, whose waiver status is in abeyance, or whose waiver status had been closed within 60 days prior to their death.

<u>Unexpected death</u> – A death that occurs as the result of an accident, an undiagnosed condition, suicide, homicide or suspected maltreatment, abuse, or neglect.

<u>Unexplained death</u> – A death in which the cause of death noted on a person's death certificate is not supported by documentation found in the person's medical history and other documentation on file with the Provider, the DDS Waiver Section, or other source.

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#### IV. Preliminary Review

During the Preliminary Review, the Review Team will analyze the information regarding a reviewable death that the Mortality Review Coordinator has provided to them in order to determine if they will designate the death expected, unexpected, or unexplained. The Team may also recommend that the Mortality Review Committee review a death designated as expected. All members must be present in order for the Team to convene to review any death.

The Mortality Review Committee must conduct reviews of all deaths considered by the Review Team to be unexpected or unexplained, as determined by their Preliminary Review.

The Review Team will consist of the following individuals:

- 1. DDS Assistant Director for Quality Assurance,
- 2. DDS Licensure and Certification Administrator,
- 3. DDS Children's Services Registered Nurse,
- DDS Mortality Review Coordinator,
   DDS Medica Hirector, (available for telephone consultation, as needles), and
   Representative from the Provider or Providers of ACS Waiver services for the person
- whose death is under review (optional, at the discretion of the Provider and non-voting).

The Review Team will hold Preliminary Review meetings at least quarterly to review and analyze the information referenced above. The Mortality Review Coordinator will present a brief written and verbal description of the facts and circumstances surrounding the death. Members of the team will take into consideration all information presented to make a determination regarding how to categorize the death and whether the Mortality Review Committee should review it.

Members of the Review Team may request additional information and delay assigning a designation until after receipt and review of that information.

#### **V. Review Disposition**

The Review Team must reach a unanimous decision regarding the designation and the recommendation for review by the Mortality Review Committee. If the team cannot reach a unanimous decision, then the Mortality Review Committee must review the death.

The Team may request that the DDS Investigations Unit conduct an investigation of the circumstances of the death. In such case, the Team must refer the death to the Mortality Review Committee for review.

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## VI. Mortality Review Committee - Objectives and Tasks

The Mortality Review Committee provides a forum to ensure that relevant information is shared and available to determine why an individual has died and to understand better all the contributing factors leading to a death. The benefits of sharing information and clearly understanding Division and Provider responsibilities can make the process worthwhile even if new information does not surface at a review.

- 1. The Mortality Review Committee conducts reviews by discussing each death individually. The review should include a discussion of the following:
  - a. The circumstances surrounding the death,
  - b. Identification of the primary risk factors involved in the death,
  - c. The appropriateness and coordination of care as planned, delivered, and overseen by the ACS Waiver Provider, up to and at the time of the person's death,
  - d. Issues that arose near the time of the person's death which were under the control of an ACS Waiver Provider that may require further review for quality improvement.
  - f. If, and the degree to which, the death was believed to be preventable.
- 2. The Mortality Review Committee will review information on all deaths that occurred over a specified period. The purpose of the review of the aggregated data will be to identify any patterns or trends. The Committee will review information regarding at least the following:
  - a. Age
  - b. Gender
  - c. Residence
  - d. Place of death
  - e. Cause of death as designated on the Death Certificate

#### **VII. Review Disposition**

Prior to moving to review of the next death, all Committee members should express confidence that they understood all information as presented or ask for further clarification. The Mortality Review Committee will provide disposition as follows:

- 1. Close review
- 2. Hold for additional review, due to the following:

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- a. The Committee requests that the Mortality Review Coordinator obtain additional information from a Provider or other source,
- b. Final findings from the medical examiner are not available, if an autopsy was performed, and
- c. Any other reason deemed acceptable by the Committee.

#### **VIII. Mortality Review Committee Membership**

The circumstances involved in most deaths are multidimensional. As a result, the responsibility for review should not rest in any one profession. The membership of the Committee must include representatives of agencies or stakeholder groups, who may, based on their individual professional experience and knowledge, address the complex dimensions of a death. The Mortality Review Committee membership must include the following individuals or representatives of the following departments, agencies or organizations:

- 1. DDPA Member, who is also a certified ACS Waiver Provider (2 positions),
- 2. The Arkansas Waiver Association (2 positions),
- Tof Waiya Sovice ocipient (2 positions), 3. Waiver Service Recipient or Family Member
- 4. DDS Dire
- 5. DDS Licensure and Certification Administrator,
- 6. DDS Ombudsman.
- 7. DDS Medical Director,
- 8. DMS Quality Assurance,
- DDS Registered Nurse,
- 10. DDS Waiver Services Administrative Staff,
- 11. Member-At-Large who is not a member of any organization represented by positions 1 or 2, and
- 12. Representative from the Arkansas protection and advocacy agency

The Committee may designate ad hoc members when they need additional information or expertise.

## IX. Mortality Review Committee Organization

The Committee will elect a chairperson and vice chairperson, who are not DHS staff, who serve in that role for a period of at least 1 year.

1. Persons in positions 1, 2 and 3 as described above, will serve three-year terms. Initial members will draw lots to determine initial term length so that term expiration is staggered.

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- 2. By unanimous approval of those attending the meeting, the Committee membership may dismiss a member for repeated failure to attend Committee meetings.
- 3. The Committee will meet as determined by the Committee, but no less than quarterly if there are deaths that have been determined to require review.

### X. Role of the Mortality Review Committee Members

The role of Mortality Review Committee members should be flexible in order to meet the needs of the particular issue under review. The Committee should recognize and utilize the individual abilities of each member in order to enhance the Committee's effectiveness. Each member should:

- 1. Contribute information from his or her expertise and experience,
- 2. Provide definitions of professional terminology,
- 3. Understand and apply Division procedures and policies,
- 4. Understand and explain the legal responsibilities, such as mandated reporting, or limitations of his or her profession,
- 5. Be aware and arknowledge that the Mortality Rosiew Committee is not an investigative body,
- 6. Review all death review reports and participate in the decision to approve submission of the report, and
- 7. Review aggregated data regarding deaths in order to identify patterns or trends.

All Mortality Review Committee members must have a clear understanding of their own and other professional and individual roles and responsibilities in their community's response to the death of a service recipient. In addition, Committee members should be aware of and respect the expertise and resources offered by each profession and individual who is a part of the Committee.

#### **XI. ACS Waiver Provider Responsibilities**

The ACS Waiver Provider Executive Director of the program providing service to the person whose death is under review or designee will:

- 1. Submit initial required materials and any other additional materials as requested by the DDS Mortality Review Coordinator, and
- 2. Send knowledgeable staff, at their discretion, to the Preliminary Review meeting.

#### XII. Mortality Review Coordinator Responsibilities

The Mortality Review Coordinator will attend all Preliminary Review and Mortality Review

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Committee meetings and will facilitate by providing necessary information and following up on any requests made by Review Team or Mortality Review Committee members. He will retrieve all written information from each Review Team or Mortality Review Committee member at the close of each meeting. He will either destroy all documents or retain the documents in a secure manner until the next meeting, depending on the disposition of the review.

The DDS Mortality Review Coordinator or designee will gather information concerning the facts and circumstances surrounding all reported deaths, utilizing a standard process. The Coordinator will obtain the information according to the following time frames:

- 1. The Mortality Review Coordinator will request information from the Provider no sooner than 14 calendar days after receipt of the notice of a death.
- 2. The Mortality Review Coordinator will request that the Provider respond to the request by providing the information within 20 calendar days from the date the Provider received the request from DDS.

The Mortality Review Coordinator will compile the following information for analysis by members of the Review Teams

- The Face Sheet from the Provider record.
- 2. A printout from the Incident Reporting Information System (IRIS) or, if unavailable, then a copy of the Incident Report of a death submitted by the Provider,
- 3. A summary prepared by the Provider for the exclusive use of the Mortality Review Committee, describing the events leading up to the death of the individual to include, at the discretion of the Provider, a suggested classification of the death, using one of the three categories included in the Mortality Review policy,
- 4. The most recent Individualized Program Plan, including any Behavior plan,
- 5. Daily case notes from Direct Care staff for the previous month,
- 6. Case manager notes for the last 6 months,
- 7. A list of current medications, if not on the Face Sheet,
- 8. Current diagnosis, if not on the Face Sheet,
- The most recent (within one month) and pertinent records contained in the Provider file
  from physicians, nursing staff and hospitals. (If the Review Team determines that records
  from these entities are essential in determining antecedent causes of death, the DDS
  Mortality Review Coordinator will attempt to obtain these records directly from the
  appropriate entity),
- 10. Verification of any Guardianship or Power of Attorney,
- 11. The most recent physical examination (within one year), if available,
- 12. Behavior and Incident Reports for three months prior to the death,
- 13. Death certificate (obtained by the DDS Mortality Review Coordinator) and
- 14. A written summary of the events surrounding the death.

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When the Mortality Review Coordinator has compiled the necessary information listed above, he will place the death on the schedule for review at the next quarterly Preliminary Review meeting. The Coordinator will:

- 1. Prepare a packet of information comprised of the documents listed in Section XII for distribution at the time of the meeting,
- 2. Notify Review Team members of the date, time and location of the meeting, and
- 3. Notify the Provider or Providers of services to the decedent that they may, at their discretion, attend the Preliminary Review.

If the Review Team makes a recommendation for review by the Mortality Review Committee, the Mortality Review Coordinator will:

- 1. Place the review on the Mortality Review Committee schedule,
- 2. Prepare a packet of information, comprised of pertinent information gathered for the Preliminary Review as well as any other information obtained subsequent to that review,
- 3. Ensure that the packet of information contains poinformation that might identify the Provider of the face tent, and
- 4. Make the packet of information available to each member of the Mortality Review Committee at least 10 calendar days in advance of the meeting date.

If the Review Team makes a recommendation not to refer for review by the Mortality Review Committee, the Mortality Review Coordinator will notify the Provider in writing that the review has been completed.

The Mortality Review Coordinator will, on a quarterly basis:

- 1. Prepare and submit to the DDS Licensure and Certification Administrator a list of all deaths determined not to meet the requirements for review, and
- 2. Ensure that the list contains a summary of the facts that supported the recommendation not to review, and
- 3. Prepare a quarterly report that summarizes data detailed in Section VI, 2 regarding each death that occurred during that quarter.

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Policy Type	Subject of Policy	Policy No.
Administration	Mortality Review of Deaths of Persons Receiving	3018
	Alternative Community Services Waiver Services	

# XIII. DDS Responsibilities

#### DDS will ensure that:

- 1. The DDS Quality Assurance Section will provide staff for Review Team and Mortality Review Committee support activities, such as making copies of materials, scheduling meetings and preparing reports,
- 2. The DDS Licensure and Certification Administrator will submit a list of all deaths not reviewed by the Mortality Review Committee to the DDS Director for final approval of the recommendation not to review, and
- 3. If the Director overturns a decision, the Mortality Review Coordinator will place the death on the agenda for review at the next scheduled Mortality Review Committee meeting.
- 4. The Annual Report produced by the Committee is distributed as appropriate and posted on the DHS website.

### XIV. Mortality Review Reporting

The Committee state prepare an innual report that describes and summerizes any findings or issues and contains any recommendations suggested by the Committee. It shall address as appropriate, the issues described in Section I of this document. It shall contain an annual summary of the quarterly data gathered during the year.

The report should address any trend identified by the Committee as well as the identification of any prevention activities proposed because of any review. The report should contain recommendations regarding specific actions, such as:

- 1. Revision of Provider or Division policy or forms,
- 2. Development of new Provider or Division policy to address systemic issues discovered in the review process.
- 3. Training, either on a statewide or individual Provider basis,
- Facilitation of best practice, including new risk-prevention practices, through dissemination of recommendations for development of or modification to Provider policies, or
- 5. Issuance of a statewide safety alert.

The Mortality Review Coordinator will distribute a copy of the Mortality Review Committee's Annual Report to the DHS Director's office and to the Director of the Department of Developmental Disabilities Services.

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Policy Type	Subject of Policy	Policy No.
Administration	Mortality Review of Deaths of Persons Receiving	3018
	<b>Alternative Community Services Waiver Services</b>	

Recipients of the report should consider all recommendations made by the Mortality Review Committee and take appropriate action as deemed necessary. In the determination of what may be deemed necessary action, DHS representatives will be mindful that the purpose of the Review Committee is to gather information to identify systemic issues that may benefit from scrutiny and analysis in order to make system improvements. In the event that any sanction of a Provider is necessary, the DDS Licensure and Certification Unit will determine and issue the sanction, in accordance with applicable policies and procedures.

The Mortality Review Committee will review any Department of Human Services or DDS policy change or other action taken by the Department or Division in response to the Committee's recommendations. If requested, the Committee will review ACS Waiver Community Provider policy changes or other actions taken by the Provider in response to Mortality Review Committee recommendations.

# REPEAL-EO 23-02

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# DHS Responses to Public Comments Regarding Rule 243 – Continuous Glucose Monitors / Diabetic Supplies

#### DHS response to general recommendation of stakeholders:

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 effective dates of service 4/1/2024. 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 dates of service beginning 4/1/2024.

# <u>Craig Douglas</u> <u>Vice President of Payer and Member Relations</u> VGM & Associates

**Comment:** I represent several DME providers in the state of Arkansas. I would like to discuss with you at your convenience the transition of the coverage of continuous glucose monitors (CGM) and related supplies from being covered under the durable medical equipment (DME) medical benefit to being covered under the pharmacy benefit for Arkansas Medicaid. This transition is slated to begin on January 1, 2024. Several DME providers have received an announcement from Arkansas Medicaid that reads, in part,

"...Beginning on Jan. 1, 2024, diabetic supplies will move to a pharmacy benefit rather than under the Durable Medical Equipment (DME) benefit for all beneficiaries except those with Medicare Part B benefits. Those with Medicare Part B benefits will continue to be serviced under the DME program. Currently, the diabetic supplies have been an Arkansas Medicaid medical benefit while the insulins and other various drugs are a pharmacy benefit. Beginning Jan. 1, most diabetic supplies will move to a pharmacy benefit. The only exception is traditional insulin pumps requiring tubing and cannula type supplies. These will remain a medical benefit under DME billing rules..."

CGM devices meet the definition of DME. The provision of DME products and related services is regulated through the Arkansas State Pharmacy Board and requires a license issued by that same Pharmacy Board. Any entity dispensing the DME items must have a dual license in order to dispense both prescription drugs and DMEPOS items. CGM's themselves are not drugs. Therefore any pharmacy that is going to dispense DMEPOS as a pharmacy would have to be a dual licensed pharmacy. Just because an insurance company or Medicaid says that non-drug items are going to be a pharmacy benefit only doesn't mean that the local laws agree. If a DME provider wants to provide CGM's, they are

required to add that product category to their national accreditation registry before they can begin to dispense CGMs. They also have to incorporate those changes into their policy and procedure and employee training to do so! how many pharmacies in Arkansas even meet the national accreditation requirement or have the required DME license in place? I'm not saying I'm against adding pharmacies as an option for patients to get their CGMs from, but I think patients should still have choice in whether they get them from a pharmacy or from their DME provider.

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 effective for dates of service beginning 4/1/2024.

#### **Alvin Simmons, PharmD**

**Comment:** I hope this letter finds you well. I am writing to bring to your attention a critical matter that has a profound impact on the healthcare landscape in Arkansas, particularly in relation to diabetic patient care.

As you may be aware, Arkansas Medicaid has recently made a significant policy change, shifting the coverage of diabetic supplies from the Durable Medical Equipment (DME) benefit to the Pharmacy benefit, effective January 1, 2024. DME providers have been an integral part of diabetic patient care for the past 40 years, and they are now facing exclusion from providing this vital service.

DME personnel possess unparalleled expertise and experience in dealing with diabetic patients and the necessary equipment. They are one of the few healthcare providers who routinely go to patients' homes, often serving individuals who lack access to transportation, have mobility challenges, and various other limitations. DME providers have played a crucial role in preventing falls (via home inspections and evaluations) and managing the unique needs of diabetic patients. The diabetic patient population is particularly vulnerable and has significant DME requirements, which DME providers have been diligently addressing for decades.

We firmly believe that the exclusion of DME providers from this essential service is a decision that lacks common sense and jeopardizes the well-being of diabetic patients across Arkansas. We are reaching out to stakeholders such as yourself to seek support and advocate for the continuation of our services. Here are the key concerns:

- 1. Specialized Expertise: DME providers have unmatched expertise in serving diabetic patients and ensuring their specific needs are met.
- 2. In-Home Services: DME providers are unique in their ability to deliver products to patients' homes, a service that is often crucial for individuals who cannot drive, lack transportation, or face other mobility challenges.
- 3. Fall Prevention: DME providers have a proven track record of preventing falls and improving the overall quality of life for diabetic patients.

4. Patient Well-Being: Diabetic patients rely on the support and services provided by DME personnel, and their exclusion raises significant concerns about the continuity of care.

We kindly request your assistance in championing this cause. Your support can make a substantial difference in ensuring that the diabetic patient population continues to receive the high-quality care they deserve.

We are willing to provide any additional information, data, or personal testimonies to further demonstrate the value of our services and the importance of overturning this exclusion.

Please let us know if you are available for a meeting or discussion to explore potential avenues for advocacy. Your support will undoubtedly have a positive impact on the healthcare landscape in Arkansas.

Thank you for your attention to this critical matter. We look forward to your response and the opportunity to work together in ensuring the best possible care for diabetic patients in our state.

Response: Thank you for communicating your concerns regarding this policy. We have considered all comments received and will instead allow CGMs and diabetic supplies to be provided by both DME providers and pharmacies effective for dates of service beginning 4/1/2024.

#### Sarah Wimberly

**Comment:** I am writing regarding the proposed change of CGM's from a DME benefit to a pharmacy benefit. I am a mother to a diabetic child. My son is on the Dexcom G6 Continuous Glucose Monitor and has had great success with it. We credit a lot of his success to the fact that his supplies arrive ON TIME, every month, directly to our home. There is no pre-ordering involved. No having to drive to the pharmacy and wait in lines, and zero possibility that the item may be "out of stock". Our local Arkansas DME provider has been wonderful for us the last 8 years and this proposed change will no doubt negatively impact a lot of Arkansans.

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 away from a pharmacy and those that are high risk pregnancies or handicapped that rely solely on delivery to get their much-needed medical devices, such as their CGM's. Making this item a pharmacy only benefit shows complete disregard towards those patients and their needs.

Are the pharmacies in Arkansas equipped to handle the surge in CGM patients? Most pharmacies I have spoken to regarding this change are not optimistic. For a DME company, it is as simple as having the item drop shipped from a distributor and shipped directly to the patient in 2-3 business days. What happens if a patient goes to their pharmacy to pick up their CGM only to be told it is out of stock? It will

need to be ordered & delivered to the pharmacy, then the patient can come to pick it up. This is not having the patient's best interest and healthcare in mind. If a patient does not have 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. A lot of patients are also on Insulin Pumps and have their CGM linked. This will cause another issue when they are out of supplies, and they must manually input BG values into the pump.

I do not think this is the right option for the State of Arkansas. 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 that are diagnosed each day. Our pharmacies are 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.

Response: Thank you for communicating your concerns regarding this policy. We have considered all comments received and will instead allow CGMs and diabetic supplies to be provided by both DME providers and pharmacies effective for dates of service beginning 4/1/2024.

#### Jeris Ezell

**Comment:** I am writing my concern that diabetic supplies only dispersed through pharmacies will inhibit a large proportion of poor and elderly people from getting the vital supplies that are needed for control and management of their diabetes. Many people are home bound or live in very rural areas or don't have transportation to get to pharmacies. Please review for pharmacy and DME providers to supply these items to people covered by Medicaid.

Response: Thank you for communicating your concerns regarding this policy. We have considered all comments received and will instead allow CGMs and diabetic supplies to be provided by both DME providers and pharmacies effective for dates of service beginning 4/1/2024.

# Charis Rock New Beginnings

**Comment:** Please do NOT make it where I can not have my diabetic supplies shipped to me. I was getting them from the pharmacy at one time. It seemed as though they could never have it in stock when I needed it, causing me to have to go without my diabetic supplies until they were able to get them.

Having the DME fill my supplies has been a blessing! They stay right on schedule and ALWAYS have my supplies when I need them. I would actually love to be able to do all of my prescriptions this way. It would save a lot in gas money and frustration compared to me having to fill at the pharmacy. I get that sometimes you run low because you are filling for so many people, BUT DIABETIC supplies are an exception that can NOT run out. It could literally be life or death. I have unpredictable highs and lows. My Dexcom keeps me alerted to these. Sometimes I can't feel it until it's too late. I have ended up having ambulances called because my glucose was so low and my daughter couldn't get it up. Dexcom

and Tandem X-slim 2 has changed that for me. I still have lows if i am out and didn't bring anything with me, but at least I know before it gets bad and I am in a mess.

Please change this and continue to allow our trustworthy, on time DME's to provide our supplies

Response: Thank you for communicating your concerns regarding this policy. We have considered all comments received and will instead allow CGMs and diabetic supplies to be provided by both DME providers and pharmacies effective for dates of service beginning 4/1/2024.

#### **Justin Havens**

**Comment:** Restricting the supplies to a local pharmacy will have a negative impact on my ability to access my necessary medical supplies. If the local pharmacy has limited stock or doesn't carry the specific brand of supplies that I need, I would have to travel to other locations to find them. This could result in extra time, expenses, and inconvenience for me. Additionally, if the local pharmacy experiences a shortage or unexpected demand, my access to necessary supplies could be further delayed or disrupted. Ultimately, limiting supply options would lead to challenges in obtaining the crucial medical supplies I require.

Response: Thank you for communicating your concerns regarding this policy. We have considered all comments received and will instead allow CGMs and diabetic supplies to be provided by both DME providers and pharmacies effective for dates of service beginning 4/1/2024.

#### **Bradley Donald**

**Comment:** Restricting the supplies to a local pharmacy will have a negative impact on my ability to access my necessary medical supplies. If the local pharmacy has limited stock or doesn't carry the specific brand of supplies that I need, I would have to travel to other locations to find them. This could result in extra time, expenses, and inconvenience for me. Additionally, if the local pharmacy experiences a shortage or unexpected demand, my access to necessary supplies could be further delayed or disrupted. Ultimately, limiting supply options would lead to challenges in obtaining the crucial medical supplies I require. I am type 1 diabetic I am 15 yrs old. My name is Bradley Donald I live in Desha Arkansas.

Response: Thank you for communicating your concerns regarding this policy. We have considered all comments received and will instead allow CGMs and diabetic supplies to be provided by both DME providers and pharmacies effective for dates of service beginning 4/1/2024.

# <u>David Chandler</u> <u>Senior Director of Payer Relations</u> American Association for Homecare

**Comment:** Several organizations have reached out to our association regarding Arkansas Medicaid's intention to remove CGM coverage from the DME benefit.

The American Association for Homecare (AAHomecare) would be opposed to this change. CGMs are covered by Medicare and most other payers under the DME benefit so this not only confuses recipients, but it also narrows access opportunities for people living with diabetes. Some DME companies have specialized diabetes programs that provide CGM and DME suppliers show significantly higher retention rates compared to the pharmacy benefit. We would not oppose coverage under both channels to improve access. Please see the attached document outlining how CGMs provided by DME suppliers improves patient care and reduces costs.



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.

Response: Thank you for communicating your concerns regarding this policy. We have considered all comments received and will instead allow CGMs and diabetic supplies to be provided by both DME providers and pharmacies effective for dates of service beginning 4/1/2024.

Shawn McCoy
Owner and Co-founder
Eclipse Medical

**Comment:** As the owner and co-founder of Eclipse Medical, a local Arkansas based DME here in central Arkansas I am writing to ask that you please reconsider the language in Act 393 to included BOTH pharmacy and DME as providers for CGM products to Medicaid patients around the state. We have worked extremely hard to build our business in the last few years and I am proud to say have gone from one employee in 2018 to 9 employees in 2023.

As a small business owner we pride ourselves on customer service and providing this patient population with the diabetes supplies they need. If the DME's are removed from the equation and only pharmacies are allowed to provide CGM products it will not only eliminate access to thousands of poor and rural Arkansans but it will also jeopardize the business my wife and I have worked so hard to build. At a minimum it would likely mean having to let staff go and set us back on years of work.

I am asking that you strongly consider the implications of not allowing DMEs to provide this service starting in 2024. As a DME owner I have no issues with pharmacies being able to provide these products as well. This competition allows for greater access and opens up other choices for clinics and patients alike by providing them with additional options. We should be providing additional access, not further reducing and in particular to those rural patients who don't have access to a pharmacy. My wife is from a very small town in Arkansas (Carthage) which not only doesn't have a local pharmacy but the nearest pharmacy is 25-30 miles away. Carthage is representative of many small towns across the state and even the small communities that have a "mom and pop" pharmacy doesn't mean that pharmacy will carry and offer the differently varieties of CGM products the patient desires or was prescribed by their treating physician.

The cost to quality of health care and outcomes for this very vulnerable population is tremendous. I am attaching just two studies of reference tied to the cost of amputations. There are so many health care cost tied to patients with diabetes that we could look at but I will focus for a moment on the tremendously high cost for amputations (upwards of \$100k in many cases). Aside from the cost is the impact to quality AND length of life for these patients. Amputations are a very real concern for the diabetic population which is why prevention is so critical. One diabetic foot ulcer can easily lead to an amputation which is why compliance by the patient must be maintained. If only a dozen patients around the state end up having an amputation because they lost access to CGM supplies and simply were no longer compliant in keeping their glucose levels in targeted therapeutic range you could easily exceed \$1M in amputation(s) cost and treatment over their lifetimes.

I am graciously asking that you do not exclude all of the DME providers around Arkansas that fill this important role in getting CGM and other diabetes supplies to these Medicaid patients. Please feel free to contact me at any point in time if I can be of further assistance or answer any questions.

Please see the attached studies along with areas I have highlighted as to the cost of amputations to the healthcare systems alone.







Assessment of healthcare costs of ¿Long-Term Outcome

Response: Thank you for communicating your concerns regarding this policy. We have considered all comments received and will instead allow CGMs and diabetic supplies to be provided by both DME providers and pharmacies effective for dates of service beginning 4/1/2024.

#### Misty Rae

Comment: Please for the love of God don't kill my son. Understand that we have been trying to source Dexcom supplies at our pharmacies in Northwest Arkansas for YEARS. They don't carry them, or if they do, they are so shortchanged there's not enough to go around for all the diabetic customers and are consistently out. Finnegan has been the only consistent source of Dexcom supplies for my son, Jacob

Schad since he was diagnosed with Type 1 Diabetes at 9 years old. Because of God's grace and their consistency, he is turning 18. Y'all are making a big mistake not including one of the biggest diabetic advocates in our state. Having options of both DME and pharmacy coverage helps our tax payers save money by keeping them home and out of the hospital. Don't throw the baby out with the bath water. People should have the option to have DME coverage if there's no pharmacy coverage or pharmacy willing to take on Passe/Medicaid clients. They stood with us and fought for him to not have to go inpatient into a nursing home since Jacob is a very brittle Type 1 who also has Autism. As y'all are considering it, you're going to kill him the way it's written. Without Jacob having access to DME coverage (which provides home delivery) for his diabetic supplies in addition to pharmacy coverage which is where he gets his insulin. If y'all don't kill him, (which is what will happen if he doesn't have the Dexcom from Finnegan's,) y'all are fixing to start paying nursing home rates if he's not able to stay home with this life saving Diabetes equipment. They deliver right to our door and many times it's been the only thing keeping him out of the hospital as it is what makes his insulin pump work. As it is, we have to order many things out of state because THERE are ZERO pump supply companies in our state. Pharmacy coverage doesn't work out of state, DME DOES. I have personally had to help navigate and locate supplies more times than can count. Taking Jacob off of an insulin pump and Dexcom could quite literally kill him. He requires multiple daily micro injections, a background basal rate, exercise rate, sleep rate and it's constantly updating with new blood sugar values every five minutes. We do all of that at home, where I am an unpaid caregiver, just doing what I can every day to help him live his life with this equipment. There's nothing wrong with allowing pharmacy coverage for those who can get it, but the sad reality is that it doesn't exist for many of our supplies and DME coverage is our lifeline. Our Passe has tried to get pharmacies to stock what Jacob needs and they won't because of the lack of reimbursement. Please, reconsider and feel free to call me at any time to find out how many thousands of dollars we have saved the state of Arkansas using this equipment, using DME coverage. Thank you for actually reading a desperate Mother's email. Best Regards,

MistyRae Drain aka Jacob's Mom.

Response: Thank you for communicating your concerns regarding this policy. We have considered all comments received and will instead allow CGMs and diabetic supplies to be provided by both DME providers and pharmacies effective for dates of service beginning 4/1/2024.

## **Jennifer Gordon**

**Comment:** I was just notified that starting in February we can no longer get dme supplies by mail order pharmacies. This is absolutely ridiculous and unacceptable. Why would you make it harder on parents of kids that are medically fragile to get them the care they need. Very few pharmacies even carry a dme license with Medicaid. You are essentially restricting the care our children receive to where only corporate pharmacies can get them their supplies. Corporations do not care about our children and their medical care will suffer if you follow through with this decision.

Response: Thank you for communicating your concerns regarding this policy. We have considered all comments received and will instead allow CGMs and diabetic supplies to be provided by both DME providers and pharmacies effective for dates of service beginning 4/1/2024.

#### **Angel Engelhardt**

Comment: I have received a notification from the DME company I receive my diabetic supplies through (Finnegan) stating Medicaid will no longer allow us the insured to use them for our diabetic supplies. This is a negative impact on not only me as a type 1 diabetic, but also some of the diabetics I see as a nurse who use Finnegan as a DME company. Some if not most of the time our local pharmacies will not have the necessary diabetic supplies that we NEED to control our disease which is beyond life threatening, however Finnegan does and always provides our supplies in a more than timely manner. I feel like this needs to be discussed with whoever is deciding this change and thinks it is more resourceful with also asking the people it actually affects (us the insured diabetics). Being in Arkansas it is hard to gain access for diabetic supplies, education, etc. Making this change will only make it harder on us and more detrimental with our deadly disease. Please reconsider this decision and fight for our right to easier access to diabetic medical supplies which would be continued with Finnegan.

Response: Thank you for communicating your concerns regarding this policy. We have considered all comments received and will instead allow CGMs and diabetic supplies to be provided by both DME providers and pharmacies effective for dates of service beginning 4/1/2024.

#### Lee Morton

**Comment:** I have been contacted by Finnegan medical supply company out of Little Rock that as of Jan 2024, Medicaid will not allow them to mail our diabetic supplies. This is very disappointing. I really do hope this change doesn't happen. We have a type 1 diabetic child and receiving supplies through the mail is so helpful!

Response: Thank you for communicating your concerns regarding this policy. We have considered all comments received and will instead allow CGMs and diabetic supplies to be provided by both DME providers and pharmacies effective for dates of service beginning 4/1/2024.

#### **Kelly Lofthouse**

Comment: My son receives all his diabetic supplies through Finnegan in the mail. We were informed that this will no longer be an option due to new rules and that we will have to get supplies through the pharmacy. I have a huge problem with this. I myself am disabled and sometimes I can not drive. Which means my son would go without the necessary supplies to maintain his health. If we lived in an area where the pharmacy was just 5 minutes down the road it wouldn't be an issue. Also, after checking I have found that the closest pharmacy that carries my son's dexcom and other supplies is 45 minutes away. That on a good day is difficult to get to because of health reasons and gas prices but add in any bad weather and we definitely could not get there. By doing this you are making it more difficult for people to live a healthy life. Please reconsider this. My son's life is literally on the line of you move forward with not allowing us to get his supplies through the mail. Thank you, A very concerned mom.

Response: Thank you for communicating your concerns regarding this policy. We have considered all comments received and will instead allow CGMs and diabetic supplies to be provided by both DME providers and pharmacies effective for dates of service beginning 4/1/2024.

#### **Brenda Walters**

**Comment:** My grandson is type 1 Diabetic. Which means his body does not produce insulin. These supplies are life saving. Allow Dexcom/Libre CGM and blood glucose testing supplies to be available as a Medical Benefit AND a Pharmacy Benefit. It is important to have easy access to these supplies for managing your diabetes.

Restricting the supplies to a local pharmacy will have a negative impact on my grandsons ability to access his necessary medical supplies. If the local pharmacy has limited stock or doesn't carry the specific brand of supplies that he needs, he would have to travel to other locations to find them. This could result in extra time, expenses, and inconvenience for him and his family. Additionally, if the local pharmacy experiences a shortage or unexpected demand, his access to necessary supplies could be further delayed or disrupted. Ultimately, limiting supply options would lead to challenges in obtaining the crucial medical supplies he requires.

Response: Thank you for communicating your concerns regarding this policy. We have considered all comments received and will instead allow CGMs and diabetic supplies to be provided by both DME providers and pharmacies effective for dates of service beginning 4/1/2024.

#### James R. Mccoy & JoAnn Mccoy

**Comment:** I am a resident of Searcy, 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 many Arkansas Medicaid patients will not be able to get CGM supplies from their durable medical equipment (DME) provider and will have to get them from a pharmacy.

While this may seem like a mere administrative change, it poses a significant inconvenience for us. Previously, these patients had the benefit of having their essential CGM supplies delivered directly to their homes by local durable medical equipment providers. With the upcoming changes, they will now be required to travel, in many cases, many miles to acquire these necessary supplies from a pharmacy.

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. Their 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 instead allow CGMs and diabetic supplies to be provided by both DME providers and pharmacies effective for dates of service beginning 4/1/2024.

#### **Allison Neal**

Comment: I have worked in the DME arena for over 15 years, out of state owning my own DME and now as a resident of AR working for an AR owned DME company that supplies Medicaid patients with diabetic supplies. I am sending in my concern because the idea that patients will only be able to obtain their diabetic supplies via a pharmacy only is frightening. Working out in the field with these types of patients and directly seeing the conditions in which some of them live is how I absolutely know that if the change is put into place, you will see more diabetics either dying or amputations occurring if they are required by law to only get their supplies from a pharmacy. Many and I mean many, of these patients rely upon DME companies to service and provide them with their supplies because they even have troubles getting to their medical appointments. Many have to rely upon family/friends or even public transportation to help them get to just their medical appointments which can be very challenging for them. They will become overwhelmed and frustrated resulting in them putting their Rx to the side which will result in mismanagement of their diabetes. Thus, more deaths and amputations. I URGE the DHS to foresee the potential issues and put a DUAL option into place where patients can choose what's best for THEIR situation not the State's. This will help safeguard their lives. Truly.

Please see the attached letter of concern as well.



Thank you for your attention to this matter and I pray that you do what's best for these patients.

Response: Thank you for communicating your concerns regarding this policy. We have considered all comments received and will instead allow CGMs and diabetic supplies to be provided by both DME providers and pharmacies effective for dates of service beginning 4/1/2024.

#### **Shawn Irving**

Comment: To Whom It May Concern,

The original intent of the bill was to add pharmacies to the existing DME benefit and add phanrmiefs as another option for diabetic supplies. However, excluding DME's is going to restrict patient choices. Many patients receive diabetic supplies from DME's and are delivered to their door monthly so they do not have to worry about transportation. Excluding DME's will prevent the ability to have suplies delvers. For many individuals, this change poses more than just a mere inconvenience. There are numerous home-bound patients, expecting mothers, individuals without regular access to transportation, individuals who live in rural communities 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 diabetic supplies altogether, risking severe health complications.

There is a lack of pharmacies in rural areas which will result in a lack of CGMs being distributed to patients' doors

Don't let the state make this detrimental shift, limiting access to diabetic supplies

Thank you for your time and help with this issue

Response: Thank you for communicating your concerns regarding this policy. We have considered all comments received and will instead allow CGMs and diabetic supplies to be provided by both DME providers and pharmacies effective for dates of service beginning 4/1/2024.

#### **Tonyia Chitwood**

**Comment:** My name is is Tonyia chitwood, I have medicaid, I am a type 2 diabetic and dependon my testing supplies, I use the DexcomG7, after January 1st they said I would have to get them from my pharmacy but none of the pharmacy stores around me carry them, so what am i supposed to do?

Response: Thank you for communicating your concerns regarding this policy. We have considered all comments received and will instead allow CGMs and diabetic supplies to be provided by both DME providers and pharmacies effective for dates of service beginning 4/1/2024.

#### **Shayla Swanson**

**Comment:** My daughter is 6 years old. She is a type 1 diabetic.

She relies on getting her some of her diabetic supplies such as testing strips & lancets through DME providers.

Please don't remove this right and force us to pick these supplies up from a pharmacy.

There is already so much mental load that comes from caring for and living with diabetes daily. Please don't add to this task.

Please keep Medicaid recipients with the right to be able to receive these supplies through DME & not the pharmacy.

Response: Thank you for communicating your concerns regarding this policy. We have considered all comments received and will instead allow CGMs and diabetic supplies to be provided by both DME providers and pharmacies effective for dates of service beginning 4/1/2024.

#### **Heather Clayton**

**Comment:** This will be very hard on me. I would greatly appreciate you not stopping my diabetic supplies from being delivered to me! Thank you in advance for your cooperation!

Response: Thank you for communicating your concerns regarding this policy. We have considered all comments received and will instead allow CGMs and diabetic supplies to be provided by both DME providers and pharmacies effective for dates of service beginning 4/1/2024.

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

Comment: Arkansas Medicaid currently spends over \$2 billion a year in direct diabetic patient care and this yearly total has only been increasing. Considering the resounding large-scale studies performed by the American Diabetes Association (ADA), broad CGM technology availability is a necessity if we hope to stop the constant increase in yearly diabetes cost to the Arkansas tax payer. So true is this statement and the research studies from the ADA that CMS/Medicare has taken recent policy changes to expand CGM coverage and access beyond any other payor or program in America. I feel it is negligent for any leader to create policies that restrict access to necessary diabetic device technology, regardless of any short-term pharmacy rebate plan savings. Arkansas' rural and marginalized Medicaid population deserves the broadest CGM access policy from DHS leadership. Every Arkansan deserves the ability to manage their diabetes with CGM technology so that they can successfully step into the 21st century of diabetes care. Reducing Arkansas' diabetes expense starts with diabetics trading delayed A1c based diabetes management for the life changing "Time In Range" daily lifestyle guide that is only possible through Continuous Glucose Monitoring. Based on the ADA studies, the Arkansan Medicaid budget savings opportunity that is available to DHS through a dual CGM benefit will be monumental compared to the token savings from pharmacy rebates. No one's health should be sacrificed for a short term budget saving plan. I also propose that DHS embrace a dual benefit plan for CGMs that includes both Pharmacy and DME access for patients because DME has a better CGM Rx compliance efficacy than Pharmacy dispensed CGMs and a higher rate of full technology platform integration. This higher CGM Rx compliance rate and remote monitoring platform integration assistance is key for Arkansas Diabetics if they are to have the best chance at reversing their dependence on external insulin sources. My point is that it is not enough to just fill the CGM prescription only to leave the CGM in the box on the kitchen table. CGM patient's need continued assistance and education to fully integrate CGM technology

completely. DME has proven to have the resources necessary to ensure the above CGM Rx goals are met. This higher compliance and efficacy with CGM platforms and technology not only saves Arkansas tax dollars, but also improves Arkansas patient outcomes! Now that is a Win/Win for every Arkansan!

Response: Thank you for communicating your concerns regarding this policy. We have considered all comments received and will instead allow CGMs and diabetic supplies to be provided by both DME providers and pharmacies effective for dates of service beginning 4/1/2024.

#### Andrea Tappe, RD, LD, CDCES

**Comment:** It is my understanding that starting January 1, 2024, CGMs will go from DME benefit to Rx benefit due to DHS' interpretation of Act 393

The original intent of the bill was to add pharmacies to the existing DME benefit. Adding pharmacies will expand access for consumers, while replacing DMEs with pharmacies will limit the front door delivery many are used to.

So many of my pregnant patients rely on this home delivery service! Without it they will not be able to check their glucose as frequently or affordably. Savings on the front does not equal what the state will lose in resulting health issues due to lack of medical equipment accessibility.

From my understanding the state projects \$1.2MM in savings shifting CGMs to a pharmacy-only benefit, but limiting access to these supplies will result in fewer treatment options and more long-term health costs.

There is a lack of pharmacies in rural areas which will result in a lack of CGMs being distributed to patients' doors.

Please don't limit access to diabetic supplies for those who need it the most, just to save \$1.2MM on the front end!

Patients will suffer as well as their unborn babies whom I serve. 2

Response: Thank you for communicating your concerns regarding this policy. We have considered all comments received and will instead allow CGMs and diabetic supplies to be provided by both DME providers and pharmacies effective for dates of service beginning 4/1/2024.

<u>David Chandler</u> <u>Senior Director of Payer Relations</u> American Association for Homecare

Comment: CGMs Provided by DME Suppliers Improves Patient Care and Reduces Costs

Thank you for the opportunity to provide written comments regarding the proposed rule that would eliminate coverage of continuous glucose monitors and diabetic supplies under the Durable Medical Equipment (DME) benefit. The American Association for Homecare (AAHomecare) strongly recommends that Arkansas Medicaid continue to cover continuous glucose monitors (CGMs) under the

DME benefit in addition to expanding coverage under the pharmacy benefit. CGMs supplied by DME suppliers promote patient access, patient choice, therapy adherence, and reduced healthcare costs.

#### <u>About American Association for Homecare (AAHomecare)</u>

AAHomecare is the national association representing 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 across the nation.

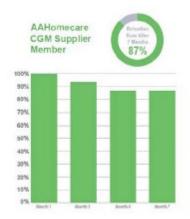
#### About Continuous Glucose Monitors (CGMs) Medicaid Coverage

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

<u>HIGH RETENTION UNDER DME CHANNEL</u> – 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 pallents have a higher risk of serious health complications and increased health care costs.
- Diabetes palents 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
- See related chart showing retention rates through seven months on next page.



<u>CGM USE REDUCES DIABETES-RELATED HOSPITALIZATIONS AND COSTS</u>—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.

DME Suppliers Advance Health Equity for Diabetes Patient Population

<u>DME SUPPLIERS ARE BETTER SUITED TO SUPPLY CGMS TO THE GROWING POPULATION OF PEOPLE</u>
<u>LIVING WITH DIABETES</u> 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

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

**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 palents.

- 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 pallents.

DME SUPPLIERS SUPPORT CONTINUITY OF CARE – DME suppliers are proactive about ensuring palents 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 pallents, 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 pallents to prevent delays in needed therapy.
- CGM parents 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..."

OVERAGE 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.

<u>FORMULARY RESTRICTIONS UNDER PHARMACY</u>— 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.



Response: Thank you for communicating your concerns regarding this policy. We have considered all comments received and will instead allow CGMs and diabetic supplies to be provided by both DME providers and pharmacies effective for dates of service beginning 4/1/2024.

Cole Riddell
General Counsel
Total Medical Supply

**Comment:** I write today on behalf of my employer, Total Medical Supply, Inc., located in the great twin city of Texarkana. Total Medical Supply is a family-owned durable medical equipment ("DME") company, and we currently operate in 48 states across the country. 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. Because of your interpretation of Act 393 of 2023, thousands of patients will no longer be allowed to get CGMs and other diabetic supplies from DME providers. As such, I urge you to please allow CGMs to be available as both a medical benefit and a pharmacy benefit.

As a family-owned business, we pride ourselves on customer service and providing our patients with the diabetes supplies they need. If DME's are removed from the equation and only pharmacies are allowed to provide CGM products, it will eliminate access for thousands of Arkansans, especially those who live in rural areas. This rule change will significantly impact thousands of diabetic patients across the State of Arkansas and hinder their ability to access the necessary medical supplies they need to manage their diabetes on a daily basis. We should be expanding access for Arkansans to receive diabetic supplies, but your interpretation of Act 393 and proposed rule do the exact opposite.

I am asking that you strongly consider the implications of not allowing DMEs to provide this service starting in 2024. As one of the largest durable medical equipment providers in Arkansas, we have no issues with pharmacies being able to provide these products as well. This competition allows for greater access and opens up other choices for clinics and patients alike by providing them with additional options. Again, we should be providing additional access to patients, not further reducing it, particularly

to those rural patients who don't have immediate access to a pharmacy. For years, thousands of patients across the State of Arkansas received their diabetic supplies on their doorstep every month; if this rule is adopted as written, these patients will be forced to drive 30+ miles away to receive the same supplies. There are numerous home-bound patients, expecting mothers, 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 prevent them from obtaining their supplies altogether, risking severe health complications.

Further, the cost and quality of healthcare and outcomes for this very vulnerable population are tremendous. There are so many healthcare costs tied to patients with diabetes that we could look at, but I will focus for a moment on the tremendously high cost of amputations (upwards of \$100,000 in many cases). Aside from the cost, there is also the impact on quality and length of life for these patients. Amputations are a very real concern for the diabetic population, which is why prevention is so critical. One diabetic foot ulcer can easily lead to an amputation, which is why compliance by the patient must be maintained. If only a dozen patients around the state end up having an amputation because they lost access to their CGM supplies and were no longer compliant with keeping their glucose levels within the targeted therapeutic range, you could easily exceed \$1 million in amputation(s) cost and treatment over their lifetimes.

As a company and a concerned individuals for diabetics in Arkansas, we are graciously asking that you not exclude all of the DME providers that fill this important role in getting CGMs and other diabetes supplies to these Medicaid patients. Please allow CGMs to be available as both a medical benefit and a pharmacy benefit.

Response: Thank you for communicating your concerns regarding this policy. We have considered all comments received and will instead allow CGMs and diabetic supplies to be provided by both DME providers and pharmacies effective for dates of service beginning 4/1/2024.

#### **Tommy Duffel**

**Comment:** I am contacting you regarding a change in the Medicaid rules affecting Dexcom 6 sensors used by son in conjunction with his insulin pump.

I have been informed by our Dexcom supplier, Finnegan Health Services out of Little Rock, that as of January 1, 2024, they will no longer be able to supply my son, who has Type 1 diabetes, with the sensor he needs. This is because someone decided to change it from a medical benefit for Durable Medical Equipment to a pharmacy benefit which requires the sensors to be picked up through a local pharmacy. When we started my son on his pump, it was a struggle to find someone who could provide what he needs. I could find no pharmacies in the Jonesboro area that could provide the equipment he needs. By disrupting his method of obtaining his supplies, this decision puts my son's life at risk.

Was public input provided or even requested regarding this change? I never heard anything about it until after the fact. Do not make decisions regarding a group's healthcare without checking with them first.

The current system works well. Dedicated professionals supply my son with what he needs. If it ain't broke, don't fix it!

Response: Thank you for communicating your concerns regarding this policy. We have considered all comments received and will instead allow CGMs and diabetic supplies to be provided by both DME providers and pharmacies effective for dates of service beginning 4/1/2024.

#### **Laura Wise**

**Comment:** Please allow Dexcom/Libre CGM and blood glucose testing supplies to be available as a Medical Benefit AND a Pharmacy Benefit. My son has Type 1 diabetes and already struggles with supplies of insulin at pharmacies. Thanks,

Response: Thank you for communicating your concerns regarding this policy. We have considered all comments received and will instead allow CGMs and diabetic supplies to be provided by both DME providers and pharmacies effective for dates of service beginning 4/1/2024.

#### **Denise Bailey**

**Comment:** I received a letter from Finnegan that has been supplying my diabetes testing strips and lancets for years. The letter says Medicaid and Medicaid passes will have to start getting their supplies at a local pharmacy. This poses problem for me. I live in a rural area and do not drive. Please please let Finnegan continue to mail my diabetic supplies to me. This could make difference of do I have supplies to check my blood sugar or not having the supplies. Please please do not let this happen.

Response: Thank you for communicating your concerns regarding this policy. We have considered all comments received and will instead allow CGMs and diabetic supplies to be provided by both DME providers and pharmacies effective for dates of service beginning 4/1/2024.

#### Tammy Barnard

**Comment:** PLEASE DONT STOP THEM FROM BEING SHIPPED TO OUR HOME !!! Some of us have no way to go to the store to pick them up.

Response: Thank you for communicating your concerns regarding this policy. We have considered all comments received and will instead allow CGMs and diabetic supplies to be provided by both DME providers and pharmacies effective for dates of service beginning 4/1/2024.

#### **Kimberly Jagers**

**Comment:** I would really love to continue to receive my diabetic supplies through DME.

Response: Thank you for communicating your concerns regarding this policy. We have considered all comments received and will instead allow CGMs and diabetic supplies to be provided by both DME providers and pharmacies effective for dates of service beginning 4/1/2024.

#### **David Chandler**

**Comment:** 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.

Response: Thank you for communicating your concerns regarding this policy. We have considered all comments received and will instead allow CGMs and diabetic supplies to be provided by both DME providers and pharmacies effective for dates of service beginning 4/1/2024.

#### **Geoffrey Yamauchi**

#### Habibi's Durable Medical

Comment: 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.

Response: Thank you for communicating your concerns regarding this policy. We have considered all comments received and will instead allow CGMs and diabetic supplies to be provided by both DME providers and pharmacies effective for dates of service beginning 4/1/2024.

#### Misty Rae Drain

**Comment:** 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.

Response: Thank you for communicating your concerns regarding this policy. We have considered all comments received and will instead allow CGMs and diabetic supplies to be provided by both DME providers and pharmacies effective for dates of service beginning 4/1/2024.

#### Sarah Wimberly

**Comment:** 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.

Response: Thank you for communicating your concerns regarding this policy. We have considered all comments received and will instead allow CGMs and diabetic supplies to be provided by both DME providers and pharmacies effective fore dates of service beginning 4/1/2024.

# Shawn McCoy, President Eclipse Medical

**Comment:** 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.

Response: Thank you for communicating your concerns regarding this policy. We have considered all comments received and will instead allow CGMs and diabetic supplies to be provided by both DME providers and pharmacies effective for dates of service beginning 4/1/2024.

#### **Angela Brown**

**Comment:** Hello, THIS IS ANGELA BROWN /I'm writing regarding my Blood Sugar Sensor from: Total Medical: I would love to see you there business to keep supplies my sensors. It really helps me to keep my sugar goals on track. It takes away the finger sticks. I would like to keep getting sensors from Total Medical. Thank You

Response: Thank you for communicating your concerns regarding this policy. We have considered all comments received and will instead allow CGMs and diabetic supplies to be provided by both DME providers and pharmacies effective for dates of service beginning 4/1/2024.

# Rob Schlissberg President of at-Home Solutions Cardinal Health

Comment: Re: Public Comment: Continuous Glucose Monitors and Diabetic Supplies as a Pharmacy Benefit Dear Ms. Pitman, Thank you for the opportunity to provide comments on the proposed Act 393 of 2023 of the 94<sup>th</sup> General Assembly, which would require Medicaid to cover continuous glucose monitors (CGMs) under the pharmacy benefit and mandates pharmacy coverage of CGMs for certain individuals with diabetes or hypoglycemia. For background, Cardinal Health is a distributor of pharmaceuticals, a global manufacturer and distributor of medical and laboratory products, and a provider of performance and data solutions for healthcare facilities. Cardinal Health at-Home Solutions is a business unit of Cardinal Health and a leading medical supplies provider serving people with chronic and serious health conditions in the U.S., including diabetes. We're committed to helping our more than 5 million customers per year - including those who live in Arkansas communities - to manage their health conditions from the comfort of their homes. Within Cardinal Health at-Home Solutions are two divisions, both of which distribute CGMs, blood glucose monitors (BGMs) and diabetic maintenance supplies to Medicaid patients' doorsteps: Cardinal Health™ at-Home and Edgepark®. Edgepark operates as both Edgepark Medical and Edgepark Pharmacy, serving customers under medical and pharmacy benefits. At Cardinal Health, we applaud any efforts that attempt to make diabetic devices and supplies more accessible, especially to those who face more barriers than others in their path to care. While we believe the intention of Act 393 is to broaden access, we respectfully request that the medical director reevaluate this proposed rule. As written, this proposal could unintentionally impact patient outcomes and create a greater burden on the continuum of care. Durable medical equipment suppliers (DMEs) like Cardinal Health at-Home Solutions stand ready and capable to supply these products to the growing diabetic population. The benefits of working with a DME supplier include: 1. DMEs are in regular contact with beneficiaries. The resources we have built into our business models mean we often check in with patients about their adherence to therapy. 2. DMEs have strong relationships with payors and are experienced in documentation and coverage requirements. Cardinal Health Cardinal Health at-Home Solutions 7000 Cardinal Place Dublin, Ohio 43017 cardinalhealth.com 3. DMEs often also employ specialized diabetes management staff dedicated to ensuring patients on devices like CGMs have access to critical resources or can get answers about their therapy in between doctor's visits. 4. For patients on automated insulin devices covered under a medical benefit, DMEs offer the ability for a patient to get their supplies all from one source, simplifying the reorder process for those individuals. 5. Due to our distribution models, DMEs maintain broad inventory, therefore helping patients avoid potential out-ofstock situations. We share the sentiment that increased and easier access to critical innovations like CGM technology is paramount for the outcomes of patients living with diabetes, and we can't thank you enough for the important work you're doing in this space. Keeping the door open for Medicaid beneficiaries to fill their CGMs and other diabetic supplies through DMEs under the medical benefit will aid in creating a better path to care. We look forward to your consideration of our comments and suggestions related to Act 393.

Response: Thank you for communicating your concerns regarding this policy. We have considered all comments received and will instead allow CGMs and diabetic supplies to be provided by both DME providers and pharmacies effective for dates of service beginning 4/1/2024.

#### **Tonya Elmore**

**Comment:** Please don't change the way we get our much need supplies for our Type 1 diabetic child.

We have a lot to manage already. Every single minute of the day.

We want a CHOICE on where we get your diabetic supplies.

Our local pharmacies are flooded with tons of sick people and long wait times with prescription and delivery issues already.

for us and local pharmacies - It is a LOT to keep up with daily, weekly and monthly! Especially the supplies that are LIFE SAVING and used each minute of everyday that helps and gives us the ability to help school nurses manage chronic diseases along with all the other children's health issues.

WE already have to track too much just to keep enough supplies on hand for the next change cycles.

WHY would we need to change a system that is working so well for those of us that are juggling so much?

With deep consideration, PLEASE consider giving us the option of staying with our trusted and smooth running DME supplier on our LIFE SAVING supplies for our children.

#ChooseToCARE

Response: Thank you for communicating your concerns regarding this policy. We have considered all comments received and will instead allow CGMs and diabetic supplies to be provided by both DME providers and pharmacies effective for dates of service beginning 4/1/2024.

## Simay Okyay CCS Medical

**Comment:** On behalf of CCS Medical, please accept the attached comment letter in response to the "Continuous Glucose Monitors and Diabetic Supplies as a Pharmacy Benefit" proposed rule.



Response: Thank you for communicating your concerns regarding this policy. We have considered all comments received and will instead allow CGMs and diabetic supplies to be provided by both DME providers and pharmacies effective for dates of service beginning 4/1/2024.

#### **Harrison McCarty**

**Comment:** My name is Harrison McCarty and I am a resident of Little Rock. 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 many Arkansas Medicaid patients will not be able to get CGM supplies from their durable medical equipment (DME) provider and will have to get them from a pharmacy.

While this may seem like a mere administrative change, it poses a significant inconvenience for us. Previously, these patients had the benefit of having their essential CGM supplies delivered directly to their homes by local durable medical equipment providers. With the upcoming changes, they will now be required to travel, in many cases, many miles to acquire these necessary supplies from a pharmacy.

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. Their 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 instead allow CGMs and diabetic supplies to be provided by both DME providers and pharmacies effective for dates of service beginning 4/1/2024.

## Geoffrey Yamauchi, VP Sales and Marketing Habibis Durable Medical Equipment, Inc.

**Comment:** I am writing in regards to the potential movement of continuous glucose meters from a DME benefit to a pharmacy benefit only. This has been tried in other states with disastrous results. The first state to try this was California, after less than one year the health associated costs of diabetes shot through the roof, due mostly to the inability of pharmacies to handle both the influx of patients and the

inability of patients to get to the pharmacies. Not only that pharmacy retention rates plummeted wheras DME's retain 87% of their patients. The other growing healthcare expenses that shot up were cardio vascular events and amputations. What California found was costs increased the further away the supplier was from the patient. the worse the outcomes. I cannot tell you how many patients tell us they are so appreciative of someone taking the time to speak with them and explain things to them train them Habibis Durable Medical is not an impersonal 800 number. We hope you will reconsider making this item an only pharmacy benefit.

Response: Thank you for communicating your concerns regarding this policy. We have considered all comments received and will instead allow CGMs and diabetic supplies to be provided by both DME providers and pharmacies effective for dates of service beginning 4/1/2024.

Veronica De La Garza

<u>Director, State Government Affairs</u>

American Diabetes Association

Comment: RE: Arkansas Medicaid draft CGM policy Dear Arkansas Division of Medical Services: Thank you for your continued work on Continuous Glucose Monitor (CGM) coverage for Arkansas Medicaid beneficiaries. The American Diabetes Association® (ADA) appreciates all the work you have done to eliminate barriers to CGM coverage for Medicaid beneficiaries with diabetes. As you know, an estimated 307,00 Arkansans have diabetes, a chronic illness that requires continuing medical care and ongoing patient self-management to prevent acute complications and reduce the risk of long-term complications, such as blindness, amputation, kidney failure, heart attack, and stroke. The ADA appreciates the opportunity to comment on the CGM draft policy moving CGM to a pharmacy benefit. We raise for you several suggestions that we hope you will consider. Suggestions for the Arkansas Provider manuals Prosthetics: Section 212.208 In Section B it states: "As used in this section, continuous glucose monitor" means an instrument or device, including repair and replacements parts, that: 1. Is designed and offered for the purpose of aiding an individual with diabetes: 2. Measures glucose levels at set intervals by means of a small electrode placed under the skin and held in place by an adhesive:" The ADA recommends line 2 state "Continuous glucose monitoring means using a device to automatically estimate your blood glucose level, also called blood sugar, throughout the day and night." 1 The ADA would like to broadly ensure that the reporting requirements for Arkansas Medicaid are the least burdensome for clients and treating practitioners as possible, fully knowing that oftentimes barriers to access exist solely with the Medicaid population due to onerous paperwork challenges and other nonmedical requirements. We encourage Arkansas Medicaid to continue to ensure the program's rules encourage as wide access as possible, especially for clients who may lack access to consistent wi-fi and other connectivity challenges.

1 Definition used by National Institute of Diabetes and Digestive Kidney Diseases, accessed on 11.9.23; https://www.niddk.nih.gov/health-information/diabetes/overview/managing-diabetes/continuous-glucose-monitoring#what

The American Diabetes Association is grateful to Arkansas Medicaid for your partnership, and for all your work to expand access to CGM devices to the broad population of Arkansas Medicaid clients with diabetes.

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 effective for dates of service beginning 4/1/2024. Additionally, the Prosthetics Manual, Section 212.208(B)(2) will be revised according to your recommendation and administrative procedures will be aligned between the medical and pharmacy benefit. Provider training will be available.

#### **Terrie Davis**

**Comment:** I am writing in regards to a concerning notice that diabetic testing supplies and Dexcom supplies will be moving to a pharmacy only benefit. I have called 5-6 pharmacies and have been told that they do not stock these supplies and they are not sure if they will even carry the supplies, especially the Dexcom. Some are not even familiar with the Dexcom.

What will happen January 1st when the pharmacy does not have these supplies immediately on hand and the supplies run out? How would we find out where they will be available? I am concerned how these supplies will be delivered to the home? Most pharmacies do not deliver, have a limited delivery range or they charge a fee. Home Delivery is important as sometimes there are issues with having dependable transportation or the hours of operation of the pharmacy for pick up are inconvenient or it's just too far away.

Please reconsider allowing customers to stay with their current company that offers free home delivery and that have staff available to help with questions or concerns and are familiar with the products. Adding additional access through a pharmacy is good for some, if the pharmacy is willing to carry the product, but it is not a good fit for everyone. Of course we would love to see more access to these supplies, but not less.

It is important that current access remains available so supplies are not interrupted or delayed and free home delivery is still an option.

Thank you for your consideration.

Response: Response: Thank you for communicating your concerns regarding this policy. We have considered all comments received and will instead allow CGMs and diabetic supplies to be provided by both DME providers and pharmacies effective for dates of service beginning 4/1/2024.

#### **Bethany Humphries**

**Comment:** We've been informed by the medical company that ships my daughter's dexcom glucose monitors for her type 1 diabetes that as of January 1st Medicaid will no longer allow this option and we will have to use a local pharmacy. We don't have a problem with that except that many Arkansas pharmacies won't keep dexcom in stock and we could deal with unavailability and/or backorders. Having her dexcom monitors when we need them is crucial not only to know her glucose numbers but also because she has to have it to sync with her insulin pump. Her insulin pump is vital to her health as is the glucose monitor. Please continue the option of allowing for choice in this matter and giving the option of shipment from medical companies.

Response: Response: Thank you for communicating your concerns regarding this policy. We have considered all comments received and will instead allow CGMs and diabetic supplies to be provided by both DME providers and pharmacies effective for datse of service beginning 4/1/2024.

## Monty V. Baugh Attorney

**Comment:** I am writing to express my concern and opposition to the proposed modifications to DHS Rule 221.100, promulgated pursuant to Act 393 of the 2023. The proposed rule removes the benefit coverage and availability of continuous glucose monitors (CGMs) for patients from durable medical equipment (DME) vendors. Arkansans with diabetes have used CGM devices for years now, a considerable percentage of them purchasing from accounts and DMEs under a doctor's prescription for the CGM devices.

The General Assembly's purpose in adopting Act 393 was to make CGM devices more readily available to Medicaid patients. The proposed rule, however, will require that Medicaid patients who presently purchase their CGM devices and supplies from an authorized DME vendor to find a pharmacy that can and will accept Medicaid payment and that deals in the patient's particular brand of CGM device. Thus, the proposed rule will have the effect of making CGM devices less available to Medicaid patients.

For this reason I opposed the proposed modifications to rule 221.100 and ask that DHS consider broadening the rule to define "pharmacy" to include DME vendors.

Response: Response: Thank you for communicating your concerns regarding this policy. We have considered all comments received and will instead allow CGMs and diabetic supplies to be provided by both DME providers and pharmacies effective for dates of service beginning 4/1/2024.

#### **Christian Cuffie**

**Comment:** I am writing this let in request to allow Dexcom/Libre CGM and blood glucose testing supplies to be available as a Medical Benefit AND a Pharmacy Benefit.

Response: Response: Thank you for communicating your concerns regarding this policy. We have considered all comments received and will instead allow CGMs and diabetic supplies to be provided by both DME providers and pharmacies effective for dates of service beginning 4/1/2024.

## 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.

While this may seem like a mere administrative change, it poses a significant inconvenience for this patient population. Previously, these patients had the benefit of having their essential CGM supplies delivered directly to their homes by local durable medical equipment providers. With the upcoming changes, they will now be required to travel, in many cases, many miles to acquire these necessary supplies from a providing pharmacy. We know that many of the local pharmacies will NOT deliver these products nor will they be willing to stock them.

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. 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.

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.

#### 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.

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.

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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.

#### 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.

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.

While this may seem like a mere administrative change, it poses a significant inconvenience for this patient population. Previously, these patients had the benefit of having their essential CGM supplies delivered directly to their homes by local durable medical equipment providers. With the upcoming changes, they will now be required to travel, in many cases, many miles to acquire these necessary supplies from a providing pharmacy. We know that many of the local pharmacies will NOT deliver these products, nor will they be willing to stock them.

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.

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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.

#### **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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Lurge 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.

#### 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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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.

#### 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.

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.

#### 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.

While this may seem like a mere administrative change, it poses a significant inconvenience for this patient population. Previously, these patients had the benefit of having their essential CGM supplies delivered directly to their homes by local durable medical equipment providers. With the upcoming changes, they will now be required to travel, in many cases, many miles to acquire these necessary supplies from a providing pharmacy. We know that many of the local pharmacies will NOT deliver these products, nor will they be willing to stock them.

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. 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.

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.

#### **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.

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.

While this may seem like a mere administrative change, it poses a significant inconvenience for this patient population. Previously, these patients had the benefit of having their essential CGM supplies delivered directly to their homes by local durable medical equipment providers. With the upcoming changes, they will now be required to travel, in many cases, many miles to acquire these necessary supplies from a providing pharmacy. We know that many of the local pharmacies will NOT deliver these products nor will they be willing to stock them.

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affect a vulnerable portion of our states 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.

#### **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.

While this may seem like a mere administrative change, it poses a significant inconvenience for this patient population. Previously, these patients had the benefit of having their essential CGM supplies delivered directly to their homes by local durable medical equipment providers. With the upcoming changes, they will now be required to travel, in many cases, many miles to acquire these necessary supplies from a providing pharmacy. We know that many of the local pharmacies will NOT deliver these products nor will they be willing to stock them.

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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.

#### **Cole Griffeth**

**Comment:** My name is Cole 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. 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.

While this may seem like a mere administrative change, it poses a significant inconvenience for this patient population. Previously, these patients had the benefit of having their essential CGM supplies delivered directly to their homes by local durable medical equipment providers. With the upcoming changes, they will now be required to travel, in many cases, many miles to acquire these necessary supplies from a providing pharmacy. We know that many of the local pharmacies will NOT deliver these products nor will they be willing to stock them.

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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.

#### 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.

While this may seem like a mere administrative change, it poses a significant inconvenience for this patient population. Previously, these patients had the benefit of having their essential CGM supplies delivered directly to their homes by local durable medical equipment providers. With the upcoming changes, they will now be required to travel, in many cases, many miles to acquire these necessary supplies from a providing pharmacy. We know that many of the local pharmacies will NOT deliver these products nor will they be willing to stock them.

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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.

#### 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.

While this may seem like a mere administrative change, it poses a significant inconvenience for this patient population. Previously, these patients had the benefit of having their essential CGM supplies delivered directly to their homes by local durable medical equipment providers. With the upcoming changes, they will now be required to travel, in many cases, many miles to acquire these necessary

supplies from a providing pharmacy. We know that many of the local pharmacies will NOT deliver these products nor will they be willing to stock them.

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. 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.

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.

#### **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.

# <u>Dee Ann Stahly</u> <u>Director, State Government Relations & Policy</u> <u>Dexcom</u>

**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.

<u>Craig Douglas</u>
<u>Vice President of Payer & Member Relations</u>
<u>VGM & Associates</u>

**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.

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.

<u>David Chandler</u> <u>Senior Director of Payer Relations</u> 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.



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

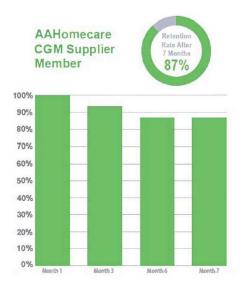
CGM is an innovative diabetes monitoring technology that measures blood glucose levels continuously in real- time. In 2017, Medicaid programs expanded coverage to include CGMs, either covering under the Durable Medical Equipment channel and/or the Pharmacy channel. Based on feedback from DME suppliers, 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

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

- 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.



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<u>CGM USE REDUCES DIABETES-RELATED HOSPITALIZATIONS AND COSTS</u>—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.

DME Suppliers Advance Health Equity for Diabetes Patient Population

DME SUPPLIERS ARE BETTER SUITED TO SUPPLY CGMS TO THE GROWING POPULATION OF PEOPLE
LIVING

<u>WITH DIABETES</u><sup>vi</sup>—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.
- Low-income individuals are disproportionately more likely to be diagnosed with diabetes and have co-morbidities, which makes accessing and maintaining prescribed therapy crucial.<sup>x</sup>

<u>DME SUPPLIERS PROVIDE ADDITIONAL NEEDED SUPPORT FOR PEDIATRIC DIABETES PATIENTS</u>—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

<u>DME SUPPLIERS HAVE CGM PRODUCT EXPERTISE</u> – 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.

<u>DME SUPPLIERS PROVIDE CGM PATIENT RESOURCES</u> – 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.

<u>DME SUPPLIERS SUPPORT CONTINUITY OF CARE</u> – 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.

<u>DME SUPPLIERS ARE KNOWLEDGEABLE OF DOCUMENTATION AND COVERAGE REQUIREMENTS</u> – 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

<u>DME SUPPLIERS PROVIDES PATIENT CONVENIENCE</u> – 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.

<u>PATIENTS REPORTS HIGHER SATISFACTION WITH DME SUPPLIERS</u>—Patients that have switched from the pharmacy channel to the DME channel have voiced greater satisfaction with service under the DME channel.<sup>xv</sup>

- 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!"
- o "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..."

<u>COVERAGE ALIGNMENT FOR DUAL ELIGIBLES</u> — 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.

<u>FORMULARY RESTRICTIONS UNDER PHARMACY</u>— 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:**

<sup>&</sup>lt;sup>1</sup> Based on information shared by Diabetes Council CGM supplier members.

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/

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/

ixhttps://www.cdc.gov/pcd/issues/2018/18\_0148.htm#:~:text=Medicaid%20is%20especially%20important%20for,%2C%20h

ad%20diabetes%20(4).

- \* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4902718/
- <sup>xi</sup> 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
- 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.

#### <u>Carson Moore</u> <u>Director</u> <u>Aeroflow Diabetes</u>

**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 <a href="https://humanservices.arkansas.gov/wp-content/uploads/Continuous-Glucose-Monitors-and-Diabetic-Supplies-Coverage-r.-2-2-24.pdf">https://humanservices.arkansas.gov/wp-content/uploads/Continuous-Glucose-Monitors-and-Diabetic-Supplies-Coverage-r.-2-2-24.pdf</a>

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.