EXHIBIT M

DEPARTMENT OF HUMAN SERVICES, DIVISION OF MEDICAL SERVICES

SUBJECT: Continuous Glucose Monitors

DESCRIPTION:

Statement of Necessity

The purpose of this Rule is to implement the requirements of Act 643 of 2021. Act 643 requires that Continuous Glucose Monitors (CGM) and related supplies be covered by Arkansas Medicaid. The Act defines a CGM, and the criteria for coverage. A Prior Authorization (PA) will be required.

Additionally, the procedure codes will be updated to the National procedure codes used by Medicare, and Medicaid will pay the Medicare rates, according to established State Plan reimbursement methodology. See the attached CGM Fact Sheet for additional information about the rates and procedure codes.

Rule Summary

Medicaid is updating a provider manual and amending the Medicaid State Plan coverage pages to comply with Act 643.

The Provider Manual is the Prosthetic/DME (Durable Medical Equipment) Provider Manual. Two (2) new sections will be added to the provider manual to include the information listed above. A link will allow providers to view or print the authorized procedure codes.

Finally, the SPA will be updated to include the coverage criteria (amount, duration, and scope).

PUBLIC COMMENT: A public hearing was held on this rule on October 20, 2021. The public comment period expired on November 11, 2021. The agency provided the following summary of the public comments it received and its responses to those comments:

Commenter's Name: Erika Gee, Attorney, on behalf of Wright, Lindsey & Jennings LLP

1. Thank you. We will be submitting a written comment as well, but I would like to take this opportunity to briefly give this comment during the hearing regarding the proposed rule. It our position that this rule does not appropriately implement Act 643, because the Act that was passed by the legislature broadly defines the types of CGMs which shall be covered by the program, but this proposal instead limits the types of CGMs that the program will cover to the procedure codes used by Medicare. That is in conflict with the requirements of Act 643, which does not reference or limit CGM coverage to the

Medicare program or to align with the Medicare program. It is our request that this rule will be modified to actually implement the requirements of Act 643. Thank you.

RESPONSE: Arkansas Medicaid follows the Medicare program codes and rates for DME whenever available. Division of Medical Services is in the process of reviewing all DME products to ensure consistency with the Medicare rates. The absence of specific language related to how Medicaid is to cover continuous glucose monitors in Act 643 does not preclude Arkansas Medicaid from following its own rules and regulations for how it covers DME products.

2. Please accept this as a public comment on the proposed rule regarding Continuous Glucose Monitors (CGM), which was released for public comment on October 11, 2021.

This rule has been drafted with the intent of implementing the provisions of Act 643 of 2021, which became effective on July 28, 2021. Act 643 directs the Arkansas Medicaid program to provide coverage for CGMs for certain individuals with diabetes and broadly defines the types of CGMs which shall be covered by the program. See Act 643 §1, codified at Ark. Code Ann. § 20-7-141(a).

However, the proposed rule does not implement Act 643. Instead, it limits the types of CGMs that the program will cover to "align with procedure codes used by Medicare." See Proposed Rule, Attachment 4.19B, at p. 2g. This language is in conflict with the requirements of Act 643, which does not reference Medicare or limit CGM coverage to "align with" the Medicare program. Instead, the provisions of Act 643 broadly cover CGMs which meet certain criteria, which would encompass not only procedure codes K0553 and K04554 as proposed, but also A9276 and A9277.

We request that the rule be modified to fully implement Act 643 by adding the additional procedure codes for qualifying CGM devices. I have also enclosed a redlined version of the proposed rule with our requested change.

Thank you for your consideration of this matter.

RESPONSE: Arkansas Medicaid follows the Medicare program codes and rates for DME whenever available. Division of Medical Services is in the process of reviewing all DME products to ensure consistency with the Medicare rates. The absence of specific language related to how Medicaid is to cover continuous glucose monitors in Act 643 does not preclude Arkansas Medicaid from following its own rules and regulations for how it covers DME products. Please note that HCPCS and other codes are not published within the State Plan.

Commenter's Name: Dee Ann Stahly, Director, State Government Affairs, on behalf of Dexcom, Inc.

COMMENT: First, we would like to thank the Arkansas Department of Human Services for its considerations, analysis, and the opportunity to provide comments on the proposed

rule draft for Continuous Glucose Monitoring Coverage for Medicaid beneficiaries with diabetes. 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 and we would like to comment on a few specific areas in which we believe that it could be strengthened.

The proposed rule provides coverage for a CGM if the client has a presence of type 1 diabetes or any other type of diabetes with the use of insulin more than two (2) times daily. We encourage DHS to explicitly include language that also includes coverage for a client that is using an insulin pump. Insulin pumps are frequently used by people with many forms of diabetes that require exogenous, injected insulin and specifically noting this in the rule is of utmost importance to guarantee access for these populations. While it is common to require a Prior Authorization (PA) for CGM coverage in Medicaid programs, we encourage DHS to ensure that patient access is not comprised by a burdensome PA review process that could result in the delay of a patient receiving a CGM. This is especially important for reauthorization of a CGM. A patient must remain on a CGM and be guaranteed continuation of care to receive the full benefits of the technology.

Finally, the most cost-effective channel for Medicaid patients to receive a CGM is through the pharmacy. Costs to the state for the CGM systems can be up to 50% lower if they choose to manage CGM as a pharmacy benefit and receive rebates.

Currently, 21 state Medicaid programs manage CGM through the pharmacy channel with more agencies moving to this model in 2022. 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, and it saves the state money. We encourage DHS to consider moving CGM to a pharmacy benefit.

We applaud the Department's commitment to Medicaid patients with this proposed rule, and we urge you to make that access even stronger with these minor changes to the policy. Patients with better management of their diabetes have better health outcomes, a higher quality of life, and cost significantly less to the state.

Thank you for reviewing our comments. We hope that you will take them under consideration. 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.

RESPONSE: 1. Requests for those who use an insulin pump would meet the more than 2 times per day criteria already. The use of an insulin pump indicates medical need for insulin more frequently than two times per day. We will add language to clarify that use of an insulin pump meets the qualifications.

2. PA process- The current PA process is streamlined and may be submitted via portal. If a provider has questions, we can have their provider representative do onsite education or education over the phone/zoom/teams meeting. The provider must complete the request and submit the required documents for the review to be completed.

3. Continuous Glucose Monitors are not a drug, rather a device, so they have been historically billed as a medical professional claim. Any changes to move them from a medical or DME type claim to a pharmacy claim would require large changes to both the medical and pharmacy systems.

Commenter's Name: Joseph Henske, MD, FACE, Associate Professor of Medicine, Director of the UAMS Diabetes Center, University of Arkansas for Medical Sciences, Division of Endocrinology and Metabolism

COMMENT: I am writing to comment on the updated changes to the Prosthetic/DME Provider Manual and Medicaid State Plan to include coverage for Continuous Glucose Monitors (CGM) as required by Act 643 of the 93rd General Assembly, effective 1/1/22. I am sincerely appreciative of the efforts of all who have worked to pass this bill into law. I am grateful for the opportunity to provide further comment at this stage.

I have several points of emphasis that I would like to make with respect to the current language:

1. Who is qualified. Under section 1(a.), this should more explicitly include language to include coverage for both type 1 or type 2 diabetes not only using insulin injections but also for those using an insulin pump. This may not be clear from the current language as written "with use of insulin more than two times daily" that use of insulin pump would also meet criteria.

2. The PA process. I understand that prior authorization may be needed to verify that the patient meets the above criteria and ongoing reauthorization at regular intervals. I want to be sure that this prior authorization/review process should be:

a. Streamlined (i.e. minimal burden to clinical staff) with use of simple check boxes that can be easily completed by clinic staff using office visit notes every 6 months indicating persistent diabetes, ongoing use of insulin or ongoing risk of sever hypoglycemic events, and compliance with routine follow up, etc.

b. Efficient so as to not delay reauthorization/reapproval of refills, particularly when patient continues to meet criteria which are most likely lifelong in nature after being first qualified.

3. Pharmacy Channel. Opportunity to fill CGM as a pharmacy benefit would be most efficient for patients (who can pick up Rx with the rest of their medications and insulin) and would be a up to 50% cost savings to the state. Most commercial plans use the pharmacy channel for CGM distribution as well as >21 states include this in their Medicaid plans. Solely distributing via a DME (durable medical equipment) pathway would create unnecessary complexity, increase delays in care, and increase unnecessary costs to the system. It should be noted that CGM prescription should not require use of a Medicaid "slot", similar to how it is handled for refills of other diabetes testing and insulin pump supplies.

Please carefully consider these recommendations. As director of the Diabetes Center at UAMS, I lead a large team of providers taking care of the most challenging cases of diabetes in the state. I appreciate that we now will be able to use continuous glucose monitoring to assist in our care of Medicaid patients, and want to ensure that the process to obtain these much-needed devices is streamlined and efficient to maximize the benefit for the individuals and minimize the costs to the program.

RESPONSE: 1. Requests for those who use an insulin pump would meet the more than 2 times per day criteria already. The use of an insulin pump indicates medical need for insulin more frequently than two times per day. We will add language to clarify that use of an insulin pump meets the qualifications.

2. PA process- The current PA process is streamlined and may be submitted via portal. If a provider has questions, we can have their provider representative do onsite education or education over the phone/zoom/teams meeting. The provider must complete the request and submit the required documents for the review to be completed.

3. Continuous Glucose Monitors are not a drug, rather a device, so they have been historically billed as a medical professional claim. Any changes to move them from a medical or DME type claim to a pharmacy claim would require large changes to both the medical and pharmacy systems.

Commenter's Name: C. Rachel Kilpatrick, MD, Washington Regional Endocrinology

COMMENT: Regarding the changes for Medicaid diabetes patients as it relates to continuous glucose monitoring systems, I would like to encourage our lawmakers to ensure that these devices are made available through pharmacies (rather than through durable medical equipment). The ability to go through pharmacy reduces the paperwork burden to obtain the devices and ensures a consistent supply in patients who are prescribed these devices. Thank you for your consideration.

RESPONSE: Continuous Glucose Monitors are not a drug, rather a device, so they have been historically billed as a medical professional claim. Any changes to move them from a medical or DME type claim to a pharmacy claim would require large changes to both the medical and pharmacy systems.

Commenter's Name: John Vinson, Pharm.D., Chief Executive Officer & Executive Vice-President, on behalf of the Arkansas Pharmacists Association

COMMENT: The Arkansas Pharmacists Association appreciates the opportunity to provide feedback on the proposed rules on coverage of continuous glucose monitors for patients with diabetes in Arkansas Medicaid, dated 10/13/2021 to 11/11/2021 related to Arkansas Act 643 of 2021. Access and coverage of continuous glucose monitoring for many patients with diabetes can save lives and reduce disease complications from a very difficult disease to treat and manage.

Patients with diabetes that use insulin and are Medicaid beneficiaries often visit their local Arkansas community pharmacist more than 30 times a year. These local pharmacists have trusted relationships with these patients and are accessible in all 75 counties. Arkansas community pharmacists will be more likely to provide this service to Arkansas Medicaid beneficiaries if Arkansas Medicaid would amend the current proposed rule to also provide coverage for continuous glucose monitoring products through the pharmacy benefits (Magellan).

In addition, the available continuous glucose monitoring products are eligible products for significant rebates and substantial financial savings to taxpayers and the program if covered through the Medicaid pharmacy benefit rather than the medical benefit. A significant number of state Medicaid programs around the country are either already covering these products through the pharmacy benefit or will in the near future because of the costs savings and increased access through pharmacy benefits.

The Arkansas state employees and public-school employees program, Employee Benefits Division (EBD), recently moved coverage of these continuous glucose monitoring products to the pharmacy benefit with pharmacy claims processed by MedImpact because of similar reasons as stated above. Their policy decision has improved access, improved patient care, and resulted in significant cost savings to the state through rebate negotiations with 100% pass through discounts from the manufacturers to the state. The Arkansas Medicaid program would likely benefit to an even greater degree financially than the Employee Benefits Division because of the deep discounts available for covered National Drug Codes (NDCs) required under the Medicaid Drug Rebate Program in federal law or Section 1927 of the Social Security Act.

Thank you for your consideration and we look forward to further discussion with your team about these suggested enhancements to the proposed rule.

RESPONSE: Continuous Glucose Monitors are not a drug, rather a device, so they have been historically billed as a medical professional claim. Any changes to move them from a medical or DME type claim to a pharmacy claim would require large changes to both the medical and pharmacy systems.

Commenter's Name: Jennifer O'Donnell

COMMENT: I have two questions on this proposal:

1. The link to the pricing does not work. Can you please advice the proposed reimbursements?

2. Are there any brick-and-mortar requirements by Arkansas Medicaid? Or can out-of-state durable medical equipment providers provide these items to members?

Thank you.

Response: 1. The link will not be activated until after the rule has been completely promulgated and the effective date has arrived. In the meantime, the proposed rates are:

Code	Modifier	Description	Rate	Notes
K0553		Supply allowance for therapeutic continuous glucose monitor (CGM), includes all supplies and accessories, 1 month supply = 1 unit of service Class II system	$222.77	The supply allowance for supplies used with a therapeutic CGM system encompasses all items necessary for the use of the device and includes, but is not limited to: CGM sensor, CGM transmitter, home BGM and related BGM supplies (test strips, lancets, lancing device, calibration solutions) and batteries. Supplies or accessories billed separately will be denied as unbundling
K0553	KF	Supply allowance for therapeutic continuous glucose monitor (CGM), includes all supplies and accessories, 1 month supply = 1 unit of service Class III system	$259.20	The supply allowance for supplies used with a therapeutic CGM system encompasses all items necessary for the use of the device and includes, but is not limited to: CGM sensor, CGM transmitter, home BGM and related BGM supplies (test strips, lancets, lancing device, calibration solutions) and batteries. Supplies or accessories billed separately will be denied as unbundling
K0554		Receiver (monitor), dedicated, for use with therapeutic glucose continuous monitor system Class II system	$243.30	Purchased device and limit of 1 per 12 months
K0554	KF	Receiver (monitor), dedicated, for use with therapeutic glucose continuous monitor system Class III system	$270.14	Purchased device and limit of 1 per 12 months

2. Out of state providers may participate. The provider must enroll and have an active Arkansas Medicaid provider ID to participate.

Commenter's Name: Veronica De La Garza, Director, State Government Affairs, on behalf of American Diabetes Association

COMMENT: I am writing on behalf of the American Diabetes Association (ADA), the nation's largest voluntary health organization concerned with the health of people with diabetes. An estimated 34 million Americans and 378,000 Arkansians 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.

Advances in treatments, including continuous glucose monitoring (CGM), have been shown to be effective tools in diabetes management and the prevention of complications associated with the disease. ADA's 2021 Standards of Medical Care in Diabetes (Standards), which is updated annually by a committee of U.S. experts in diabetes care, provides that the use of professional CGM and/or intermittent real-time or intermittently scanned CGM can be helpful in identifying and correcting patterns of hyper-and hypoglycemia and improving A1C levels in people with diabetes on noninsulin as well as basal insulin regimens.[1]

Unfortunately, there continue to be gaps in access to CGM and other technologies among under-served populations, including – and perhaps most acutely – in the Medicaid population. ADA applauds the Arkansas legislature for enacting legislation to address coverage of continuous glucose monitors to further broaden access for people with diabetes to these technologies that will enable them to better manage their diabetes, and which may result in fewer adverse health outcomes or even premature deaths.

ADA respectfully submits the recommendations below regarding the CGM proposed rule. These recommendations broadly reflect our support for measures that will expand access to CGM technology for Arkansas Medicaid beneficiaries with diabetes. Eliminating burdensome requirements for access to diabetes management technologies is vital to reducing disparities in utilization particularly among under-served people with diabetes.

- Eliminate prior authorization as a barrier

Prior authorization requirements can present barriers that delay timely access to devices, medications, or therapies. Such barriers, which include step therapy protocols, frequently override what a provider believes to be in his or her patient's best clinical interest. ADA recommends that Arkansas Medicaid ensure that coverage and formulary decisions be based on clinical evidence and the direction of health care providers. Additionally, there must be a clear and timely appeals process for denials of coverage.

- Broaden Channels of Access to CGM

[1] American Diabetes Association: Standards of Medical Care in Diabetes 2021, Diabetes Care 44: Supp. 1, p.S88 (January 2021).

ADA also recommends that CGM be made available through as many channels as possible including both mail-order and local pharmacies to increase access for the diverse population that can benefit from the devices.

- Ensure patient- and provider-centered choices for CGM devices

We respectfully urge that Arkansas Medicaid take extra care to avoid making choices that would limit access for people with diabetes to CGM or any technology that those individuals and their doctors believe is most appropriate to manage their diabetes. ADA's 2021 Standards provide that the choice of technology should be individualized based on patient's needs, desires, skill level, and availability of devices. These are determinations that should be made by a patient in conjunction with their health care provider.

Additionally, individuals who have been successfully using CGM should be able to continue to have access to that device across health care payers to avoid interruption in access that may result from the need for new training and education or lack of supplies and equipment. If coverage changes must occur, ADA recommends steps be taken to ensure a smooth transition process. At minimum, Arkansas Medicaid should adopt a transition period coupled with an exceptions process, enabling beneficiaries currently successfully using a CGM to continue to use that item and its associated supplies regardless of new limitations or exclusions.

The American Diabetes Association appreciates the opportunity to submit these recommendations for your consideration and looks forward to working with you to implement measures aimed at increasing access to CGMs to Arkansas Medicaid beneficiaries. Should you have any questions regarding these comments, please contact me at vdelagarza@diabetes.org.

RESPONSE: 1. PA process- The current PA process is streamlined and may be submitted via portal. If a provider has questions, we can have their provider representative do onsite education or education over the phone/zoom/teams meeting. The provider must complete the request and submit the required documents for the review to be completed.

2. Continuous Glucose Monitors are not a drug, rather a device, so they have been historically billed as a medical professional claim. Any changes to move them from a medical or DME type claim to a pharmacy claim would require large changes to both the medical and pharmacy systems.

3. AR Medicaid does not contract with one specific name brand. If a transition to a new product is required a provider may request a prior authorization with documented appropriate medical necessity.

Commenters' Names: Paul E. Valentin-Stone, M.D., Ann D. Layton, M.D., Ashley Poppy, APRN, CHI St. Vincent

COMMENT: Arkansas Department of Human Services, Division of Medical Services has issued a proposed rule for Medicaid coverage for Continuous Glucose Monitoring (CGM) systems, effective 1/1/2022. We are an Internal Medicine clinic that sees a high volume of patients with diabetes, so this bill will directly impact the ease of care for these patients to control their diabetes. It should keep them from utilizing the ER or hospitals by keeping their blood sugars regulated. The following are a few points that we hope you will consider with this new rule:

• The proposed rule provides coverage for the CGM if the client "has a presence of type 1 diabetes or any other type of diabetes with the use of insulin more than two times daily." We encourage DHS to explicitly include language for type 1 or type 2 patients on insulin and that also includes coverage for a client that is using an insulin pump.

• While it is common to require a prior authorization (PA) for CGM coverage in Medicaid programs, we encourage DHS to ensure that patient access is not compromised by a burdensome PA review process that could delay a patient receiving a CGM. This is especially important for reauthorization of CGM. A patient must remain on CGM to receive the full benefits of this technology.

• The most cost-effective channel for Medicaid patients to receive a CGM is through the pharmacy. Costs to the state for the CGM systems can be up to 50% lower if they choose to manage CGM as a pharmacy benefit and receive rebates. 21 state Medicaid programs manage CGM through the pharmacy channel and several more will be doing so, or are considering that products are readily available at the pharmacy. Additionally, CGM systems are now much easier to use so there is no need for a training visit to start a patient on CGM. A patient can receive his/her CGM supplies at the pharmacy while also picking up insulin.

Thank you for your consideration of these recommendations and we are very appreciative of the time and effort spent on this bill. We are excited to see our patients' care being a primary focus. We have seen the benefits of CGM use and are sure this will be a step forward in the care of these diabetic patients.

RESPONSE: 1. Requests for those who use an insulin pump would meet the more than 2 times per day criteria already. The use of an insulin pump indicates medical need for insulin more frequently than two times per day. We will add language to clarify that use of an insulin pump meets the qualifications.

2. PA process- The current PA process is streamlined and may be submitted via portal. If a provider has questions, we can have their provider representative do onsite education or education over the phone/zoom/teams meeting. The provider must complete the request and submit the required documents for the review to be completed.

3. Continuous Glucose Monitors are not a drug, rather a device, so they have been historically billed as a medical professional claim. Any changes to move them from a

medical or DME type claim to a pharmacy claim would require large changes to both the medical and pharmacy systems.

Commenters' Names: Lauren Fields, MBA, BSN, RN, Chief Nursing Officer, Anna Hall, MS, RDN, LD, CDCES, Clinical Director of Coordinated Care, Lydia Sartain, MS, RDN, LD, CDCES, Director of Diabetes and Nutrition, Shelby Roberson, MS, RDN, LD, CDCES, Registered Dietitian, ARcare

COMMENT: We are writing to you today as healthcare providers who are seeking the best possible outcomes and improved quality of life for our patients, family, and friends. Within ARcare, we are privileged to serve a wide variety of patients with more than fifty clinics across the state of Arkansas. We service rural areas, as well as the metro, but regardless of geographical location, one thing is consistent- we take care of many patients with Medicaid insurance. We are excited about the pending changes to come with Arkansas Medicaid providing coverage for continuous glucose monitor (CGM) use.

As diabetes educators, we can take numbers and information and provide the patient with the knowledge and skill set to better self-manage their diabetes diagnosis, but the use of CGM's and technology within the scope of diabetes care is incomparable. It takes numbers and information and converts it into a tangible and tactical tool that our patients are able to use. Per the Standards of Care, written by the American Diabetes Association, "major clinical trials of insulin-treated patients have included self-monitoring of blood glucose (SMBG) as part of multifactorial interventions to demonstrate the benefit of intensive glycemic control on diabetes complications. Glucose monitoring allows patients to evaluate their individual response to therapy and assess whether glycemic targets are being safely achieved. Integrating results into diabetes management can be a useful tool for guiding medical nutrition therapy and physical activity, preventing hypoglycemia, or adjusting medications ... " (7. Diabetes Technology: Standards of medical care in diabetes-2021. (2020). Diabetes Care, 44 (Supplement 1), S77-S97. https://doi.org/10.2337/dc21-s007).

In conclusion, there is proven research that continuous glucose monitoring is useful for reducing Hemoglobin A 1 c levels, as well as a decrease in hypoglycemic events, in both Type 1 and Type 2 children and adults, alike.

We are appreciative of the actions taken thus far to better meet the needs of our Medicaid patient population. We do ask that a few minor adjustments are made to the verbiage in the proposed rule to ensure ease and timeliness for our patients to obtain their CGM systems, such as follows:

We encourage DHS to explicitly include language for T1 or T2 patients on MDI or utilizing an insulin pump.

We encourage DHS to ensure that patient access is not compromised by a burdensome PA review process that could delay our patients receiving a CGM. This could be the

difference between life and death for a patient who is struggling with frequent hypoglycemic events or hypoglycemia unawareness.

Finally, we ask that DHS recognize the most cost-effective channel for Medicaid patients to receive a CGM is through the pharmacy. CGM systems can be up to 50% lower for the state, if CGM's are included as a pharmacy benefit. At ARcare, our team of clinical pharmacists, nurses, and dietitians are committed to ensuring our patients can utilize the device and take advantage of remote technology used to provide excellent patient care, even if patients are hesitant to come into the clinic for routine care and education, especially in these unprecedented times of COVID-19.

Again, we appreciate the action that has already taken place to improve the diabetes epidemic in Arkansas by use of CGM technology within our state and ask that you would consider these additional updates to the Arkansas Medicaid proposed rule for CGM coverage.

RESPONSE: 1. Requests for those who use an insulin pump would meet the more than 2 times per day criteria already. The use of an insulin pump indicates medical need for insulin more frequently than two times per day. We will add language to clarify that use of an insulin pump meets the qualifications.

2. PA process- The current PA process is streamlined and may be submitted via portal. If a provider has questions, we can have their provider representative do onsite education or education over the phone/zoom/teams meeting. The provider must complete the request and submit the required documents for the review to be completed.

3. Continuous Glucose Monitors are not a drug, rather a device, so they have been historically billed as a medical professional claim. Any changes to move them from a medical or DME type claim to a pharmacy claim would require large changes to both the medical and pharmacy systems.

The proposed effective date is January 1, 2022.

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

Per the agency, the total cost to implement this rule is $2,093,399 for the current fiscal year ($594,107 in general revenue and $1,499,293 in federal funds) and $4,186,799 for the next fiscal year ($1,188,213 in general revenue and $2,998,585 in federal funds). The total estimated cost by fiscal year to state, county, and municipal government as a result of this rule is $594,107 for the current fiscal year and $1,188,213 for the next fiscal year.

The agency indicated that there is a new or increased cost or obligation of at least $100,000 per year to a private individual, private entity, private business, state government, county government, municipal government, or to two or more of those entities combined. Accordingly, the agency provided the following written findings:

(1) a statement of the rule's basis and purpose;

The purpose of this Rule is to implement the requirements of Arkansas Act 643 of 2021.

(2) the problem the agency seeks to address with the proposed rule, including a statement of whether a rule is required by statute;

Act 643 of 2021 requires that Continuous Glucose Monitors (CGM) and related supplies be covered by Arkansas Medicaid. The Act defines a CGM, and the criteria for coverage.

(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;

Continuous Glucose Monitors provide safe and effective monitoring of glucose levels for those who require multiple measurements throughout the day and will help qualifying clients to control their diabetes in a manner that will prevent more costly treatments.

(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;

No less costly alternatives were identified.

(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;

No alternatives are proposed at this time.

(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

Not applicable

(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.

The Agency monitors State and Federal rules and regulations for opportunities to reduce and control cost.

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 643 of 2021. The Act, sponsored by Senator Breanne Davis, mandated that the Arkansas Medicaid Program cover a continuous glucose monitor for an individual with diabetes.

QUESTIONNAIRE FOR FILING PROPOSED RULES AND REGULATIONS WITH THE ARKANSAS LEGISLATIVE COUNCIL

DEPARTMENT/AGENCY Department of Human Services
DIVISION Division of Medical Services
DIVISION DIRECTOR Elizabeth Pitman
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INSTRUCTIONS

A. Please make copies of this form for future use.
B. Please answer each question completely using layman terms. You may use additional sheets, if necessary.
C. If you have a method of indexing your rules, please give the proposed citation after "Short Title of this Rule" below.
D. Submit two (2) copies of this questionnaire and financial impact statement attached to the front of two (2) copies of the proposed rule and required documents. Mail or deliver to:

Jessica C. Sutton
Administrative Rules Review Section
Arkansas Legislative Council
Bureau of Legislative Research
One Capitol Mall, 5th Floor
Little Rock, AR 72201

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1. What is the short title of this rule? Continuous Glucose Monitors

2. What is the subject of the proposed rule? See Attached.

3. Is this rule required to comply with a federal statute, rule, or regulation? Yes ☒ No ☐
   If yes, please provide the federal rule, regulation, and/or statute citation. Act 643 of 2021

4. Was this rule filed under the emergency provisions of the Administrative Procedure Act?
   Yes ☐ No ☒
   If yes, what is the effective date of the emergency rule? _____
   When does the emergency rule expire? _____
   Will this emergency rule be promulgated under the permanent provisions of the Administrative Procedure Act?
   Yes ☐ No ☐

5. Is this a new rule? Yes ☐ No ☒
If yes, please provide a brief summary explaining the regulation. _____

Does this repeal an existing rule? Yes ☐ No ☒
If yes, a copy of the repealed rule is to be included with your completed questionnaire. If it is being replaced with a new rule, please provide a summary of the rule giving an explanation of what the rule does. _____

Is this an amendment to an existing rule? Yes ☒ No ☐
If yes, please attach a mark-up showing the changes in the existing rule and a summary of the substantive changes. **Note: The summary should explain what the amendment does, and the mark-up copy should be clearly labeled "mark-up."**

See attached:

6. Cite the state law that grants the authority for this proposed rule? If codified, please give the Arkansas Code citation. Arkansas Code §§ 20-76-201, 20-77-107, and 25-10-129

7. What is the purpose of this proposed rule? Why is it necessary? See Attached.

8. Please provide the address where this rule is publicly accessible in electronic form via the Internet as required by Arkansas Code § 25-19-108(b).
https://humanservices.arkansas.gov/do-business-with-dhs/proposed-rules/

9. Will a public hearing be held on this proposed rule? Yes ☒ No ☐
If yes, please complete the following:

Date: October 20, 2021

Time: 1:00 p.m.

Place: **https://us02web.zoom.us/j/85292090330**
Webinar ID: 852 9209 0330

10. When does the public comment period expire for permanent promulgation? (Must provide a date.)
November 11, 2021

11. What is the proposed effective date of this proposed rule? (Must provide a date.)
January 1, 2022

12. Please provide a copy of the notice required under Ark. Code Ann. § 25-15-204(a), and proof of the publication of said notice. See Attached.

13. Please provide proof of filing the rule with the Secretary of State as required pursuant to Ark. Code Ann. § 25-15-204(e). See Attached.

14. Please give the names of persons, groups, or organizations that you expect to comment on these rules? Please provide their position (for or against) if known. DME Providers and Manufacturers

FINANCIAL IMPACT STATEMENT

PLEASE ANSWER ALL QUESTIONS COMPLETELY

DEPARTMENT Department of Human Services

DIVISION Division of Medical Services

PERSON COMPLETING THIS STATEMENT Jason Callan

TELEPHONE 501-320-6540 **FAX** _____ **EMAIL:** Jason.Callan@dhs.arkansas.gov

To comply with Ark. Code Ann. § 25-15-204(e), please complete the following Financial Impact Statement and file two copies with the questionnaire and proposed rules.

SHORT TITLE OF THIS RULE Continuous Glucose Monitors

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 an agency is proposing a more costly rule, please state the following:

   (a) How the additional benefits of the more costly rule justify its additional cost;
   N/A

   (b) The reason for adoption of the more costly rule;
   N/A

   (c) Whether the more costly rule is based on the interests of public health, safety, or welfare, and if so, please explain; and;
   N/A

   (d) Whether the reason is within the scope of the agency's statutory authority; and if so, please explain.
   N/A

4. If the purpose of this rule is to implement a federal rule or regulation, please state the following:

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

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	$

(b) What is the additional cost of the state rule?

Current Fiscal Year		**Next Fiscal Year**	
General Revenue	$594,107	General Revenue	$1,188,213
Federal Funds	$1,499,293	Federal Funds	$2,998,585
Cash Funds		Cash Funds	
Special Revenue		Special Revenue	
Other (Identify)		Other (Identify)	
Total	$2,093,399	Total	$4,186,799

5. What is the total estimated cost by fiscal year to any private individual, entity and business subject to the proposed, amended, or repealed rule? Identify the entity(ies) subject to the proposed rule and explain how they are affected.

Current Fiscal Year
$ _____

Next Fiscal Year
$ _____

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6. What is the total estimated cost by fiscal year to state, county, and municipal government to implement this rule? Is this the cost of the program or grant? Please explain how the government is affected.

Current Fiscal Year
$ 594,107

Next Fiscal Year
$ 1,188,213

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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;
The purpose of this Rule is to implement the requirements of Arkansas Act 643 of 2021.

(2) the problem the agency seeks to address with the proposed rule, including a statement of whether a rule is required by statute;
Act 643 of 2021 requires that Continuous Glucose Monitors (CGM) and related supplies be covered by Arkansas Medicaid. The Act defines a CGM, and the criteria for coverage.

(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;

Continuous Glucose Monitors provide safe and effective monitoring of glucose levels for those who require multiple measurements throughout the day and will help qualifying clients to control their diabetes in a manner that will prevent more costly treatments.

(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;
No less costly alternatives were identified.

(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;
No alternatives are proposed at this time.

(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
Not applicable

(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.

The Agency monitors State and Federal rules and regulations for opportunities to reduce and control cost.

Statement of Necessity and Rule Summary

Continuous Glucose Monitors

Statement of Necessity

The purpose of this Rule is to implement the requirements of Act 643 of 2021. Act 643 requires that Continuous Glucose Monitors (CGM) and related supplies be covered by Arkansas Medicaid. The Act defines a CGM, and the criteria for coverage. A Prior Authorization (PA) will be required.

Additionally, the procedure codes will be updated to the National procedure codes used by Medicare, and Medicaid will pay the Medicare rates, according to established State Plan reimbursement methodology. See the attached CGM Fact Sheet for additional information about the rates and procedure codes.

Rule Summary

Medicaid is updating a provider manual and amending the Medicaid State Plan coverage pages to comply with Act 643.

The Provider Manual is the Prosthetic/DME (Durable Medical Equipment) Provider Manual. Two (2) new sections will be added to the provider manual to include the information listed above. A link will allow providers to view or print the authorized procedure codes.

Finally, the SPA will be updated to include the coverage criteria (amount, duration, and scope).

NOTICE OF RULE MAKING

The Director of the Division of Medical Services of 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.

Effective January 1, 2022:

The Director of the Division of Medical Services (DMS) amends the Prosthetic/DME (Durable Medical Equipment) Provider Manual and the Medicaid State Plan to include coverage for Continuous Glucose Monitors (CGM). Act 643 of the 93rd General Assembly requires Arkansas Medicaid to cover the costs of CGMs and related supplies. Authorized procedure codes are updated and provided via an embedded hyperlink. The Medicaid State Plan is updated with the coverage criteria including amount, duration, and scope. Medicaid payments for the GCMs and related supplies are calculated using the Medicare rate methodology used by Medicaid. The projected annual cost of this change for state fiscal year (SFY) 2022 is $2,093,399 ($594,107 state portion with a federal match of $1,499,293) and for SFY 2023 is $4,186,799 ($1,188,213 state portion with a federal match of $2,998,585).

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 https://humanservices.arkansas.gov/do-business-with-dhs/proposed-rules/. Public comments must be submitted in writing at the above address or at the following email address: ORP@dhs.arkansas.gov. All public comments must be received by DHS no later than November 11, 2021. 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. 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.

A public hearing by remote access only through a Zoom webinar will be held on October 20, 2021, at 1:00 p.m. and public comments may be submitted at the hearing. Individuals can access this public hearing at **https://us02web.zoom.us/j/85292090330**. The webinar ID is **852 9209 0330**. If you would like the electronic link, "one-tap" mobile information, listening only dial-in phone numbers, or international phone numbers, please contact ORP at ORP@dhs.arkansas.gov.

If you need this material in a different format, such as large print, contact the Office of Rules Promulgation at 501-396-6428.

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. 4502035775

Elizabeth Pitman, Director
Division of Medical Services