ACTION: Final



Common Sense Initiative

Mike DeWine, Governor Jon Husted, Lt. Governor Carrie Kuruc, Director

Business Impact Analysis

Rule Contact Name and Contact Information:
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Regulation/Package Title (a general description of the rules' substantive content):
Electronic Visit Verification (EVV)
Rule Number(s): <u>5160-1-40</u>
Date of Submission for CSI Review: <u>8/13/2020</u>
Public Comment Period End Date: <u>8/20/2020</u>
Rule Type/Number of Rules:
New/rules No Change/rules (FYR?)
Amended/1_rules (FYR? No) Rescinded/rules (FYR?)

The Common Sense Initiative is established in R.C. 107.61 to eliminate excessive and duplicative rules and regulations that stand in the way of job creation. Under the Common Sense Initiative, agencies must balance the critical objectives of regulations that have an adverse impact on business with the costs of compliance by the regulated parties. Agencies should promote transparency, responsiveness, predictability, and flexibility while developing regulations that are fair and easy to follow. Agencies should prioritize compliance over punishment, and to that end, should utilize plain language in the development of regulations.

77 SOUTH HIGH STREET | 30TH FLOOR | COLUMBUS, OHIO 43215-6117

Reason for Submission

1. R.C. 106.03 and 106.031 require agencies, when reviewing a rule, to determine whether the rule has an adverse impact on businesses as defined by R.C. 107.52. If the agency determines that it does, it must complete a business impact analysis and submit the rule for CSI review.

Which adverse impact(s) to businesses has the agency determined the rule(s) create?

The rule(s):

- a. Requires a license, permit, or any other prior authorization to engage in or operate a line of business.
- **b.** \Box Imposes a criminal penalty, a civil penalty, or another sanction, or creates a cause of action for failure to comply with its terms.
- c. 🛛 Requires specific expenditures or the report of information as a condition of compliance.

Regulatory Intent

2. Please briefly describe the draft regulation in plain language.

The amended rule provides definitions of terminology unique to the Electronic Visit Verification (EVV) implementation, specifies services subject to EVV requirements, establishes operational requirements for providers of those services and outlines the regulatory foundation for using an alternate data collection component from what is provided by the Department. The changes to the rule provide additional flexibility for providers who are required to use EVV.

3. Please list the Ohio statute(s) that authorize the agency, board or commission to adopt the rule(s) and the statute(s) that amplify that authority.

Section 5164.02 of the Ohio Revised Code

4. Does the regulation implement a federal requirement? Is the proposed regulation being adopted or amended to enable the state to obtain or maintain approval to administer and enforce a federal law or to participate in a federal program?

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The rule implements federal requirements. Congress enacted the 21st Century Cures Act which requires Medicaid programs to implement EVV for home and community based services. The EVV system implemented must capture the type of service provided, the time the service is provided, the location of service delivery, and the person providing the service. Failure to implement a compliant EVV system will result in a reduction in the federal funding for Medicaid services.

5. If the regulation includes provisions not specifically required by the federal government, please explain the rationale for exceeding the federal requirement.

The amended rule is consistent with and does not exceed federal requirements.

6. What is the public purpose for this regulation (i.e., why does the Agency feel that there needs to be any regulation in this area at all)?

Home and community-based services are integral to the provision of long term services and supports.

The rule is a key component in compliance with the 21st Century Cures Act and provides transparence in service delivery and payment, ensuring that individuals receive the medically necessary services they need, and that the department reimburses providers appropriately for the services provided.

7. How will the Agency measure the success of this regulation in terms of outputs and/or outcomes?

ODM will measure the success of OAC 5160-1-40 through improved payment accuracy and a reduction in fraud, waste and abuse.

8. Are any of the proposed rules contained in this rule package being submitted pursuant to R.C. 101.352, 101.353, 106.032, 121.93, or 121.931?

No

Development of the Regulation

9. Please list the stakeholders included by the Agency in the development or initial review of the draft regulation.

The following entities, were invited, by email to participate in the EVV Stakeholder Advisory Group.

Almost Family Ohio Olmstead Task Force Leading Age Ohio Home Care Network Ohio Council for Home Care and Hospice

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Ohio Valley Home Health, Inc. Ohio Department of Aging Ohio Department of Developmental Disabilities Ohio Provider Resource Association Viaquest Inc. Ohio Council on Aging CareSource CareStar **Buckeye Health Plan** Aetna Better Health of Ohio Molina Healthcare United Healthcare Paramount Advantage Ohio Attorney General – Medicaid Fraud Control Unit Ohio Long Term Care Ombudsman HomeCare by Blackstone PCG Ohio Health Care Association **Disability Rights Ohio** ARC Ohio Ohio Association of County Boards Statewide Association of Centers for Independent Living

In addition, more than 150 individuals representing individuals using home and community based services, families of individuals using home and community based services and providers of home and community based services have joined the EVV Stakeholder Advisory Group.

Meetings began in October 2016 and have continued throughout the implementation. In addition, information is shared regularly with the EVV Stakeholder Advisory Group by email.

Information about the additional flexibility has been shared with the stakeholders by email and was reviewed during the virtual Stakeholder Advisory Group meeting held on July 22, 2020.

10. What input was provided by the stakeholders, and how did that input affect the draft regulation being proposed by the Agency?

The amendments reflect stakeholder input indicating that the additional flexibility is helpful.

11. What scientific data was used to develop the rule or the measurable outcomes of the rule? How does this data support the regulation being proposed?

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Medicaid provider claims data and a review of similar projects in other state medicaid programs were used to inform and develop the parameters surrounding the Ohio medicaid EVV project. Scientific data is not applicable to the amendments.

12. What alternative regulations (or specific provisions within the regulation) did the Agency consider, and why did it determine that these alternatives were not appropriate? If none, why didn't the Agency consider regulatory alternatives?

Alternative regulations were not considered by the department. The 21st Century Cures Act tasked the Department with developing and establishing standards for this program.

The amended rule reflects the structure of the EVV program implemented in the Ohio Medicaid program. The structure of the EVV program was determined prior to the procurement of an EVV vendor after considering information obtained through a Request for Information and researching methods used in other state programs. The amendments need to be documented in the Ohio Administrative Code to ensure consistent application for providers and to support efforts to ensure program integrity.

13. Did the Agency specifically consider a performance-based regulation? Please explain. Performance-based regulations define the required outcome, but don't dictate the process the regulated stakeholders must use to achieve compliance.

Prior to issuing an RFP and contracting with a vendor for the Ohio Medicaid EVV system, the department considered alternate approaches to EVV, including those where each provider would have to procure and utilize an EVV system meeting Department requirements. Those approaches were not selected because there was significant additional potential cost to providers while creating additional complexity to achieving agency objectives.

Instead ODM implemented a hybrid approach. A single system to collect and store visit data is integral to achieving the objectives regarding transparency in service utilization and improving payment accuracy. However, ODM recognizes the investment some agency providers may have made in EVV systems prior to the ODM initiative and in EVV systems that are integrated with business.

The amendments to the rule do not alter the structure of the EVV implementation. The amendments offer providers additional flexibility in achieving compliance.

14. What measures did the Agency take to ensure that this regulation does not duplicate an existing Ohio regulation?

ODM is the only entity authorized to enact the regulations contained in the amended rule. The amended rule was reviewed by Ohio Medicaid policy development staff, Office of Legal Services and the Office of Legislation to ensure there was no duplication.

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15. Please describe the Agency's plan for implementation of the regulation, including any measures to ensure that the regulation is applied consistently and predictably for the regulated community.

The Department is using email and the Department website to communicate rule updates to providers and other stakeholders. ODM has a strong partnership with stakeholder organizations to ensure providers are aware of the changes included in the amendment.

Adverse Impact to Business

16. Provide a summary of the estimated cost of compliance with the rule. Specifically, please do the following:

a. Identify the scope of the impacted business community; and

The business community impacted by the amended rule includes Medicaid fee-for-service and managed care providers of the following services:

- Home health nursing and aide services
- Private duty nursing
- RN assessments
- Ohio Home Care Waiver nursing services, Ohio Home Care Waiver personal care services and Ohio Home Care Waiver attendant services
- Level One Waiver Homemaker Personal Care (HPC) services
- Individual Options Waiver HPC services
- PASSPORT nursing, personal care and CHOICES home care attendant services.

b. Identify the nature of all adverse impact (e.g., fees, fines, employer time for compliance,); and

Providers impacted by the amended rule may have incurred administrative expenses associated with reporting information using EVV. The information reported includes demographic information about the individuals served and, for agency providers, for the direct care workers they employ. Impacted providers will use EVV to record the start and end of the visit, the individual receiving the service, and the service provided. Finally, providers are required to use the EVV system to clear data integrity errors (exceptions) in order to ensure that the EVV system accurately reflects the services provided through Medicaid programs operated by ODM, DODD and the Ohio Department of Aging (ODA). Providers are also required to notify Sandata when devices are no longer being used, triggering the Sandata device recovery process and to request replacement devices in the event of device failure. Providers must also report to ODM

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known or suspected tampering of devices or falsification of EVV data. If use of an alternate data collection component is requested by a provider, the provider must satisfy all the technical and business requirements of ODM. If an alternate data collection component is not approved by ODM, a provider may request an administrative reconsideration.

A provider who fails to comply with EVV requirements may be subject to termination of its provider agreement.

The amendments do not increase the adverse impacts and may, in some cases, reduce the adverse impacts.

c. Quantify the expected adverse impact from the regulation.

Administrative costs incurred by impacted provides pursuant to both the rescinded rule and the new rule will vary widely by provider. Demographic information related to individuals receiving services varies based on the number of Medicaid individuals served, business practices regarding client intake and discharge, the average duration of service for individuals served by the provider, and existing business practices regarding maintenance of demographic information regarding the individuals served. Demographic information related to direct care workers employed by the provider are only be recorded by agency providers and varies widely based on the number of individuals employed, current business practices regarding hiring and termination of employees and employee turnover rates. The capture of visit data and the effort to clear data integrity errors will vary based on the number of visits performed, the accuracy and compliance rates of providers and their staff when using EVV and current business practices used to document the care provided in home and community based setting. Reporting known or suspected tampering of devices or falsification of EVV data or requesting an administrative reconsideration will vary based on whether these situations apply to a provider and the circumstances.

Because the costs will vary significantly based on provider business choices, processes and volume, and because the department does not have access to information related to the costs incurred by impacted providers, we are unable to provide a reasonable estimate costs per provider.

The amendments do not increase the cost of compliance and may, in some cases, reduce the cost of compliance.

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17. Why did the Agency determine that the regulatory intent justifies the adverse impact to the regulated business community?

Home and community-based services are an increasingly important piece in the long term services and supports continuum and present unique challenges in terms of oversight and accountability. The amended rule implements EVV using technology to create transparency in a new and innovative way while allowing individuals who use HCBS to maintain their independence. In addition, ODM must implement EVV to maintain the current level of federal funding for the Medicaid program.

The additional flexibilities documented in the amendments are necessary to support providers of home and community-based services.

Regulatory Flexibility

18. Does the regulation provide any exemptions or alternative means of compliance for small businesses? Please explain.

No. The underlying federal requirement does not provide any exemptions or alternative means of compliance for small businesses. Reimbursement policies are applied uniformly, and no exceptions are made based on the provider's size.

19. How will the agency apply Ohio Revised Code section 119.14 (waiver of fines and penalties for paperwork violations and first-time offenders) into implementation of the regulation?

Not applicable

20. What resources are available to assist small businesses with compliance of the regulation?

The Department is providing an EVV system to all providers at no cost. Training regarding the use of EVV in Ohio Medicaid is being provided at no charge through self-paced on line training. In addition, the vendor will be providing support for EVV system users for the duration of contract.

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