

CSI - Ohio

The Common Sense Initiative

Business Impact Analysis

Agency Name: Ohio Department of Medicaid

Regulation/Package Title Long Term Care Home Health

Rule Number(s): 5160-1-40, 5160-12-08, 5160-45-10

Date: September 14, 2017

Rule Type:

- New
 Amended

- 5-Year Review
 Rescinded

The Common Sense Initiative was established by Executive Order 2011-01K and placed within the Office of the Lieutenant Governor. Under the CSI Initiative, agencies should balance the critical objectives of all regulations with the costs of compliance by the regulated parties. Agencies should promote transparency, consistency, predictability, and flexibility in regulatory activities. Agencies should prioritize compliance over punishment, and to that end, should utilize plain language in the development of regulations.

Regulatory Intent

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

Please include the key provisions regulation as well as any proposed amendments.

5160-1-40

The rule provides definitions of terminology unique to the 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. This rule also outlines provider training requirements as determined by the Department and reasons for provider termination for non-compliance.

5160-45-10

OAC rule 5160-45-10 will establish the core conditions of participation that a provider must meet in order to furnish Ohio Department of Medicaid (ODM)-administered waiver services. It replaces the current OAC rule 5160-45-10 which is being amended pursuant to five year review and is included in this package. OAC rule 5160-45-10 details that ODM-administered waiver service providers shall maintain a professional relationship with the individuals to whom they provide services. Services shall be provided in a person-centered manner that is in accordance with the individual's approved all services plan, is attentive to the individual's needs and maximizes the individual's independence. Providers shall refrain from any behavior that may detract from the goals, objectives and services outlined in the individual's approved all services plan and/or that may jeopardize the individual's health and welfare. This rule also establishes that ODM-administered waiver service providers shall never engage in behavior that causes or may cause abuse or distress or compromise the individual's health and welfare; engage in advantageous or manipulative behavior, or behavior that may pose a conflict of interest; falsify the individual's signature, or make fraudulent, deceptive or misleading statements in the advertising, solicitation, administration or billing of services; and submit claims for waiver services rendered while the individual is hospitalized, institutionalized or incarcerated. OAC rule 5160-45-10 is being amended to update Ohio Department of Medicaid (ODM) -administered waiver program provider conditions of participation. Rule changes serve to implement an Electronic Visit Verification (EVV) initiative for selected home and community based services as will be set forth in Chapter 5160-1 of the Administrative Code.

5160-12-08

Key Provisions - The RN Assessment service is a distinct Medicaid service performed only by an RN when making decisions and nursing diagnoses, planning nursing interventions and evaluating the need for other interventions, developing the plan of care, and/or assessing the need to communicate and consult with other health team members.

OAC rule 5160-12-08 is being updated to incorporate changes made accordance with rule 5160-1-40 of the Administrative Code to implement an ODM-approved electronic visit verification (EVV) system. This rule sets forth provisions for RN Assessment and the RN Consultation service. The amendment proposed to this rule adds paragraph (B)(7) to require that the RN assessment visit be verified using an ODM-approved electronic visit verification (EVV) system in accordance with rule 5160-1-40 of the Administrative Code.

2. Please list the Ohio statute authorizing the Agency to adopt this regulation.

5016-1-40

Ohio Revised Code Sections 5164.02

5160-45-10

Ohio Revised Code Section 5166.02.

5160-12-08

Ohio Revised Code Section 5164.02.

3. 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?

5160-1-40

Congress enacted the 21st Century Cures Act which requires Medicaid programs to implement electronic visit verification (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.

5160-45-10

Yes. In order for CMS to approve a 1915(c) home and community-based services waiver, a state must make certain assurances concerning the operation of the waiver. These assurances are spelled out in 42 C.F.R 441.302, and include (a) "necessary safeguards have been taken to protect the health and welfare of the beneficiaries of the services." CMS cites in its waiver applications that providers of waiver services must be qualified, i.e., only those agencies and workers meeting the state's qualification requirements can provide services to waiver participants. The state must establish qualification requirements for agency and non-agency providers, including licensure/certification standards, training and other requirements. It must also regularly monitor providers' compliance with those requirements. The proposed rule will assist the State in assuring the health and welfare of waiver participants by among other things, requiring the provision of services by qualified ODM-administered waiver service providers who adhere to the programs' provider requirements.

5160-12-08

Yes. The proposed amendments will enable Ohio to maintain approval to administer and enforce Ohio's State Plan services, which includes the RN assessment services.

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

5160-1-40

This rule is consistent with federal requirements.

5160-45-10

This rule is consistent with federal requirements.

5160-12-08

This rule is consistent with federal requirements.

5. 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)?

5160-1-40

Home and community based services are integral to the provision of long term services and supports. EVV will provide transparency 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.

5160-45-10

The public purpose of these regulations is to assure the health and welfare of waiver participants as required by 42 C.F.R 441.302(a) through the provision of services by qualified providers. The State is doing so by establishing core conditions of participation which providers must meet in order to be ODM-administered waiver service providers.

5160-12-08

Rule 5160-12-08 is necessary for the statewide administration of the EVV system. It will enable ODM to comply with federal requirements, and also to ensure the appropriate level of safety and statewide compliance for services. RNs must be qualified and maintain core standards when providing services.

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

5160-1-40

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

5160-45-10

Successful outcomes are measured through a finding of compliance with provider standards. The expectation is that adherence to the conditions of participation by providers will result in a reduced

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number of incidents that threaten the health and welfare of individuals participating in the waiver program.

5160-12-08

The success of this regulations will be measured by the safe and effective provision of RN assessment services furnished by qualified providers who can effectively meet the needs of Medicaid recipients.

Development of the Regulation

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

If applicable, please include the date and medium by which the stakeholders were initially contacted.

5160-1-40

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

EVV Stakeholder Advisory Group Meetings were held on the following dates:

October 14, 2016	March 1, 2017	July 19, 2017
October 25, 2016	April 4, 2017	August 22, 2017
November 8, 2016	June 20, 2017	

All meetings were held in person and by phone at The Ohio department of Medicaid. Agendas including rules for comment and consideration were sent via email prior to the meetings. Deadlines were given for returning rule comments to specified ODM staff.

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

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Ohio Attorney General – Medicaid Fraud Control Unit
Ohio Long Term Care Ombudsman
Robin Kyman, non-agency Medicaid provider
HomeCare by Blackstone
PCG

5160-45-10

ODM has been convening an external stakeholder group since May, 2013, for the purpose of reviewing OAC rules governing ODM-administered waivers. The workgroup generally meets every two weeks (in-person and by phone) and has been responsible for the adoption, rescission and amendment of a number of rules thus far. It consists of individuals enrolled on ODM-administered waivers, as well as members of the following organizations:

The Ohio Council for Home Care and Hospice
Midwest Care Alliance
CareSource (case management contractor)
CareStar (case management contractor)
Council on Aging (case management contractor)
Public Consulting Group (PCG) (provider oversight contractor) Ohio
Olmstead Task Force
Disability Rights Ohio
Ohio Department of Aging
Ohio Department of Developmental Disabilities

ODM also contacted seven non-agency providers (i.e., nurses and personal care aides) for the purpose of soliciting comments regarding the proposed rules. One non-agency personal care aide provided feedback.

5160-12-08

Proposed changes to the home health and PDN rules were discussed at high level on March 22nd and August 23rd, 2017. The meetings were held from 10:00 a.m. to Noon, at the Ohio Medicaid Lazarus Building. A call-in option is offered at each meeting.

The following organizations were invited to participate:

Academy of Senior Health Sciences
Disability Rights Ohio
Leading Age Ohio
Midwest Care Alliance
Ohio Association of Area Agencies on Aging
Ohio Association of Health Plans
Ohio Council for Home Care & Hospice
Ohio Department of Developmental Disabilities
Ohio Department of Health

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Ohio Department of Mental Health and Addiction Services
Ohio Department of Aging
Ohio Health Care Association
Ohio Department of Medicaid - Managed Care Plans
Ohio Nurses Association
Ohio Olmstead Task Force
Ohio Provider Resource Association

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

5160-1-40

The Department began meeting regularly with stakeholders in October 2016 to inform the implementation of the EVV system in Ohio Medicaid. In addition, a draft of the rules was provided to stakeholders on July 13, 2017 and the rule was reviewed with stakeholders during the Stakeholder Advisory Group meeting held on July 19, 2017. The department asked stakeholders to send any additional comments by the close of business on Tuesday, July 26, 2017. Stakeholder feedback was received and included in the formation of the rule specific to programmatic decisions and required data elements.

5160-45-10

ODM has an existing relationship with stakeholders for the purpose of reviewing OAC rules regarding ODM- administered waivers. As noted in the response to question 7, an external stakeholder group meets every two weeks and has been responsible for the adoption, rescission and amendment of a number of rules thus far. Stakeholder input will continue to play an intricate part during the roll out of the EVV system.

5160-12-08

The Ohio Department of Medicaid has an existing relationship with stakeholders affiliated with the provision of nursing services in the state. Ohio's State Plan Services Workgroup – which includes the organizations listed in response to question 7 – convened on multiple occasions to ensure stakeholder engagement in the process. Stakeholder input will continue to play an intricate part during the roll out of the EVV system.

9. 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?

5160-1-40

Medicaid provider claims data and a review of similar projects in other state Medicaid programs was used to inform and develop the parameters surrounding the Ohio Medicaid EVV project.

5160-45-10

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Scientific data was not applicable to the development of these rules.

5160-12-08

Scientific data was not applicable to the development of these rules.

10. 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?

5160-1-40

Alternative regulations were not considered by the department. The structure of the EVV project was determined prior to the procurement.

5160-45-10

ODM and the stakeholder workgroup considered alternative rule language as part of the rule development process and settled upon language that was mutually agreed upon and best suited to accomplish the purposes of the rules. Such language had to meet the federal and state guidelines under which ODM-administered waivers are permitted to operate.

5160-12-08

None. Alternative regulations were not considered by the Ohio Department of Medicaid as the requirements of these rules are dictated by federal and state laws and regulations.

11. 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.

5160-1-40

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 is implementing 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 investment some agency providers may have made in EVV systems prior to the ODM initiative and in EVV systems that are integrated with business processes within agencies. As a result, agency providers may choose to use alternate data collection components that meet technical requirements established by the department so long as they successfully integrate with the data aggregation component included in the EVV system established by the department's vendor, Sandata.

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5160-45-10

No. Performance-based regulations are not deemed appropriate and are not authorized by statute

5160-12-08

Performance-based regulations were not considered appropriate for this rule, as the rule is guided by federal law. Performance-based regulations is not authorized by statute for RN assessment services.

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

5160-1-40

The proposed rules were reviewed by policy development staff in consultation with the Ohio Department of Medicaid, Office of Legal Services and the Office of Legislation to ensure there was no duplication.

5160-45-10

All regulations regarding ODM-administered waivers are promulgated by ODM and implemented by ODM, its designees and providers, as appropriate. While other state agencies participated in the rule-writing process, they do not impose any requirements that are specific to this program. The regulations were reviewed by Medicaid's legal and legislative staff to ensure that there is no duplication within the rules.

5160-12-08

The proposed rule was reviewed by policy development staff in consultation with the Ohio Department of Medicaid, Office of Legal Services and the Office of Legislation to ensure there was no duplication.

13. 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.

5160-1-40

ODM initiated provider outreach in December 2016 using email communication to make providers aware of the EVV initiative. In addition, automated communication by phone and text has been used to share information with providers regarding the Ohio Medicaid EVV initiative. ODM plans to continue communication to providers in this fashion through the implementation period.

Mandatory provider training will be held prior to implementation. The training is being offered in three formats – in person classroom training, live webinar training and self-paced online training to meet the needs of individuals with different learning styles and scheduling needs. Classroom training will be offered at a variety of locations around the state over a two month period.

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In addition, ODM will initially implement EVV data collection on January 8, 2018. Claims for services subject to EVV will be paid regardless of the EVV visit data for the first 6 months of implementation. This will provide an opportunity for providers to become familiar with the EVV system before it impacts payment for services.

5160-45-10

Rule changes to implement an Electronic Visit Verification (EVV) initiative for selected home and community based services will include mandatory provider training held prior to the implementation of EVV. The training is being offered in three formats – in person classroom training, live webinar training and self-paced online training to meet the needs of individuals with different learning styles and scheduling needs. Classroom training will be offered at a variety of locations around the state over a two month period. These trainings will educate providers and guide them to successful EVV implementation to ensure the regulation is applied consistently and predictably for the regulated provider community.

5160-12-08

Written correspondence will be sent to providers and other stakeholders, including but not limited to all county departments of job and family services, explaining the changes that have been made to these rules. Additionally, the final rules will be made available to stakeholders and the general public on the Ohio Department of Medicaid's website.

Adverse Impact to Business

14. 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;

5160-1-40

The impacted business community includes State Plan Medicaid providers of home health nursing and aide services, private duty nursing, and RN assessments. The impacted community also includes Ohio Home Care Waiver nursing services, Ohio Home Care Waiver personal care services, and Ohio Home Care Waiver attendant services.

5160-45-10

The impacted community also includes Ohio Home Care Waiver nursing services, Ohio Home Care Waiver personal care services, and Ohio Home Care Waiver home care attendant services.

5160-12-08

There are over 3,500 providers who employ RNs eligible to bill for the RN assessment service. This includes Medicare Certified Home Health Agencies, other accredited agencies, and independent nurse providers.

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

5160-1-40

Providers may incur administrative expenses associated with training of administrative staff and service providers, initial data entry for system population, and ongoing system maintenance.

5160-45-10

Providers may incur administrative expenses associated with training of administrative staff and service providers, initial data entry for system population, and ongoing system maintenance.

5160-12-08

This rule requires providers to allocate time to execute provider agreements with ODM, imposes record keeping requirements on providers of RN assessment and RN consultation services, and requires providers to utilize EVV to verify visits.

c. Quantify the expected adverse impact from the regulation.

The adverse impact can be quantified in terms of dollars, hours to comply, or other factors; and may be estimated for the entire regulated population or for a “representative business.” Please include the source for your information/estimated impact.

5160-1-40, 5160-45-10

The Department provided opportunity for Leading Age Ohio and The Ohio Council for Home Care and Hospice to provide input into the cost to implement and maintain an **Electronic Visit Verification (EVV)** system provided by the department.

Below is an analysis of the annual cost for three representative home care providers in the state. The first is a medium provider with an average daily census of 1,100 Medicaid individuals for whom they are providing services, the next two are smaller providers with an average daily census of 90-100 Medicaid individuals in their care.

Table 1 – Summary of each agency’s total cost to implement and maintain EVV

Agency	Training + E-mail + EVV Manager + Auto reconciliation	Training + E-mail + EVV Manager + Manual reconciliation
Agency A	\$987, 182	\$1,298,922
Agency B	\$79,760	\$105,292
Agency C	\$98,892	\$125,256

The Department recognizes there is a cost of compliance for EVV, however, assumptions in the above analysis assume that employees of agencies and non-agency providers will require access to secure email accounts. Because email is only required for log-in to the device, which does not store data or

personal information, a secure email is not required. Email access can be obtained at no cost through providers such as Gmail and Yahoo. The associations' estimate includes a \$25/ employee/month increased cost to allow for the secure email, which is not a required cost of program compliance. If a provider chooses to obtain secure email access for employees, this is beyond the requirements for EVV implementation.

5160-12-08

This rule requires agency and non-agency skilled nurses who engage in the provision of in-person RN assessment and/or RN consultation service to ensure compliance with individual plans of care, to maintain documentation of services provided and to enter into provider agreements with Medicare certified agencies. An RN assessment would be approximately \$46.59 total per nurse, or equivalent to the salary of a registered nurse (RN) plus his or her administrative costs, e.g., average \$37.70 salary, plus \$3.19 overhead and \$5.70 mileage more or less depending where the agency is located. SOURCE: *Midwest Care Alliance* (MCA). An additional 5 hours per individual is initially projected to ensure the compliance with individual plans of care, to collaborate and consult amongst nurses, and to maintain copious documentation of service. It is reported that the daily cost to keep records for one patient is \$3.56 (e.g., 90 patients at \$320.00).

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

5160-1-40, 5160-45-10

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. EVV uses 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 in order to maintain the current level of federal funding for the Medicaid program.

5160-12-08

RN assessments are offered as part of the Ohio's state plan services and as are subject to certain requirements. Provider participation is optional, although compliance with program requirements is required for providers who choose to participate. Providers understand that compliance with program requirements may include various operating costs including administrative costs (e.g., training, monitoring and oversight, etc.)

Regulatory Flexibility

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

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5160-1-40

No. The underlying federal requirement does not provide any exemptions or alternative means of compliance for small businesses.

5160-45-10

Not Applicable for this program

5160-12-08

No. The provisions in this rule is mandatory for all RN assessment service providers.

17. 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?

5160-1-40

ODM recognizes that this is a significant change in business process for impacted providers and will NOT deny claims for non-compliance for the first 6 months that EVV is operational in the Medicaid program. Instead an informational message regarding EVV compliance will be recorded when claims are processed.

5160-45-10

Not Applicable for this program

5160-12-08

ORC section 119.14 is not applicable to this rule.

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

5160-1-40

The Department is providing an EVV system to all providers at no cost. Training regarding the use of EVV in Ohio Medicaid will be provided at no charge in locations around the state, through moderated webinars and through self-paced on-line training. In addition, the vendor will be providing support for EVV system users 24/7 for the duration of the contract.

5160-45-10

The Department is providing an EVV system to all providers at no cost. Training regarding the use of EVV in Ohio Medicaid will be provided at no charge in locations around the state, through moderated webinars and through self-paced on-line training. In addition, the vendor will be providing support for EVV system users 24/7 for the duration of the contract.

5160-12-08

Providers in need of assistance may contact the Bureau of Long Term Services and Supports, through the Provider Relations Hotline at (800) 686-1516.

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