CSI - Ohio
The Common Sense Initiative

Business Impact Analysis

Agency Name:	OHIO DEPARTMENT OF AGING
Package Title:	ODA PROVIDER CERTIFICATION: HOME MEDICAL EQUIPMENT + SUPPLIES
Rule Number:	173-39-02.7
Date:	March 28, 2017, Revised April25, 2017
Rule Types:	☑ 5-Year Review ☐ Rescinded ☐ New ☑ Amended ☐ No change

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 regulations in plain language.
Please include the key provisions of the regulation as well as any proposed amendments.

OVERVIEW

OAC173-39-02.7 regulates providers when they provide home medical equipment and supplies to individuals enrolled in the PASSPORT Program.

ODA has conducted a 5-year review of the rule. ODA's proposed amendments would add clarity to the rule and update its terminology, but not add any requirements for ODA-certified providers of home medical equipment and supplies.

SPECIFIC AMENDMENTS

ODA proposes to delete part of the definition stating the purpose of home medical equipment and supplies is to "help prevent the consumer's placement in a nursing facility." That is a purpose for the PASSPORT Program and applies to every good or service provided to individuals enrolled in the program. Preventing placement in a nursing facility does not need to be part of this definition or any definition of a good or service.

ODA proposes to insert a paragraph that would function like a sub-heading to indicate where in the rule requirements for the provider begin. This merely adds clarity to the rule. All paragraphs occurring after this sub-heading would be indented underneath.

ODA proposes to insert a general requirement to comply with the requirements for every ODA-certified provider in OAC173-39-02. Without this amendment, ODA-certified providers would still be required to comply, but may not be aware of the need to do so.

ODA proposes to delete 2 requirements which unnecessarily duplicate requirements in OAC173-39-02.

ODA also proposes to make basic terminology amendments, including the following:

- Adding *ODA provider certification* to the beginning of the rule's title.
- Using a simplified definition.
- Replacing uses of *consumers* with *individuals*.
- Consistently referring to *individuals* in the plural throughout the definition of *home medical equipment*
- Consistently using *equipment and supplies*, not *products, etc.*
- Replacing uses of *must* and *will* with *shall* and uses of *may not* with *shall not*.
- Replacing uses of *furnish* with *provide.*
- Replacing *reimburse* with *pay.*
- Replacing *prior to* with *before*.
- Replacing *preauthorized amount* with *item rate authorized by the case manager*.

2. Please list the Ohio statute authorizing the Agency to adopt these regulations.

ORC§§ 173.01, 173.02, 173.391, 173.52, and 173.522.

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?
If yes, please briefly explain the source and substance of the federal requirement.

In Ohio's application to the Centers for Medicare and Medicaid Services (CMS) for a waiver to authorize the Medicaid-funded component of the PASSPORT Program, Ohio indicated it adopted a rule on home medical equipment and supplies and cited OAC173-39-02.7. Because CMS authorized a waiver that included the home medical equipment and supplies, as regulated by OAC173-39-02.7, the state is responsible for maintaining OAC173-39-02.7.

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

ODA is not exceeding any 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)?

The rule exists to comply with the state laws ODA listed in its response to BIA question #2, especially ORC§173.391 to ensure continued implementation of the PASSPORT Program's approved Medicaid waiver application, as authorized by CMS. (*cf.*, ODA's response to #3.)

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

ODA (and its designees) will monitor the providers for compliance.

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.

On March 29, 2016, ODA asked Senior Resource Connection, Ohio Association of Senior Centers, Ohio Association of Area Agencies on Aging (O4A), Catholic Social Services of the Miami Valley, and the Ohio Association of Medical Equipment Services (OAMES) if they would share any issues they have with OAC173-39-02.7.

On April 5, 2016, ODA emailed the following question to a sample of 13 providers[1] who provided email contact information to ODA in their provider profile:

> Dear _____:
>
> ODA is in the process of reviewing OAC173-39-02.7 to see if the rule requires amendments. To help with the review, we're asking a sample of providers the following questions:
>
> - When working with individuals enrolled in the PASSPORT Program, do you (1) only sell, (2) only rent, or (3) both sell and rent home medical equipment?
> - If you sell (*vs.* rent) home medical equipment, does the equipment typically come with a warranty? If so, how long does the warranty period last?
>
> Thank you for responding to our questions. Please let us know if you have any concerns with the current rule that ODA should seek to resolve.

On October 26, 2016, ODA offered the Ohio Association of Medical Equipment Services (OAMES) an opportunity to share any issues they have with the rule.

From March 28 to April 16, 2017, ODA conduced an online public-comment period of the rule and this BIA.

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

In response to the March 29, 2016 email, Senior Resource Connection indicated they provide home medical equipment and supplies, but had no issues to raise with the rule at this time. Catholic Social Services also indicated that they had no issues to raise with the rule. No other party responded. O4A, on behalf of AAA6, asked for the rule to clarify when the monthly payment covered maintenance costs for equipment (e.g. when still under warranty) and when it did not (e.g. after warranty expires). ODA will provide this clarity directly to AAA6 outside of the rule development process.

6 providers (46% of the sample) responded to ODA's April 5, 2016 email. The results are below:

- No provider raised concerns about the rule.
- Overall, renting *vs.* selling appears to be a non-issue for amending the rule. Senior Resource Connection and Target Microsystems said they only rented home medical equipment to individuals. Staker's Service Drugs (Stakers) said it only sold home medical equipment to individuals. Columbus Medical Equipment (CME), Schwieterman Pharmacy, and Valued Relationships, Inc. (VRI) said they both rented and sold equipment. VRI said the vast majority of its equipment was rented.
- At the present time, warranty periods do not seem to be an issue affecting the drafting of rule amendments Stakers said warranty periods vary by manufacturer, but are in force for at least a year. CME and VRI said

[1] The original sample had 17, but 1 provider claimed to not provide home medical equipment for the PASSPORT Program, and the emails to 3 other providers were undeliverable.

equipment (e.g., medication dispensers) typically comes with a manufacturer's warranty, but the manufacturer establishes the length of time the warranty remains in force. Schwieterman Pharmacy and VRI said warranties typically last at least 1 year. VRI also said manufacturers of supplies (e.g., bed pad sensors, chair pad sensors, etc.) typically do not give warranties for their supplies.

On October 28, 2016, OAMES said it didn't have any formal comments to offer at that time, although individual providers who are members of OAMES may comment later in the rule-development process.

During the March 28 to April 16, 2017 online public-comment period, ODA received the following:

- 1 comment from the OAMES.
- 1 comment from a medical equipment provider.
- 4 comments from 3 PASSPORT administrative agencies (PAAs), which are ODA's designees.

ODA lists the comments from the online public-comment period and ODA's responses to those comments in the table below.

	COMMENTS	ODA's RESPONSES
1.	(C) [now (B)] Requirements for ODA-certified providers of minor home medical equipment and supplies" We believe that the word minor should be removed. *Emily Trulo, Fiscal Manager* *Ohio District 5 Area Agency on Aging (PAA5)*	The name of this service mirrors the name of the federally-approved PASSPORT waiver service. For more information, please review ODA's response to question #3 on this BIA.
2.	(C)(1) We believe the reference to non-agency providers should be removed as we know of no such non-agency providers being certified as Home Medical Equipment providers. *Emily Trulo, Fiscal Manager* *Ohio District 5 Area Agency on Aging (PAA5)*	The federally-approved PASSPORT waiver permits agency and non-agency providers to provide this service. For more information, please review ODA's response to question #3 on this BIA.

	COMMENTS	ODA's RESPONSES
3.	(C)(7) [now (B)(7)] Thank you for the opportunity to provide comments. I am addressing the proposed Ohio Administrative rule 173-30-02.7, "***Home medical equipment and supplies***" filed by the Ohio Department of Aging on March 28, 2017. The association is providing input on two issues relative to section (C)(7) of the proposed rule: 1) "proof of delivery", and 2) defining "ship date". OAMES believes that ODA should follow Medicare and Medicaid requirements for proof of delivery to create consistencies for providers, especially given the focus on dual eligible beneficiaries. CMS and the Ohio Department of Medicaid allow for electronic verification of delivery by providing the tracking information for the Medicare and Medicaid programs respectively and we believe this practice should be codified by ODA as well. The specific language we support in the Ohio Medicaid program can be found in rule 5160-10-05 "*Reimbursement for covered services*", section (A)(1)(a)(b)(c)(d). Please note that we are currently working with ODM to review this and many other DME rules. This specific rule will be combined with several other DME rules and include formatting changes and minor editing. We don't expect any substantive change in this particular language and would be able to provide you the draft language that we've agreed to with ODM if you'd like. Or given the rule is in-progress and about to be revised and refiled, we would be happy to connect you to our ODM contacts to ensure we coordinate a consistent policy with the ODM rule and the ODA rule. Additionally, we believe the "ship date" definition should be consistent in all of these government-funded programs. Both Medicare and Medicaid define the shipping date as the date of service for the claim. We recommend the following language for this policy: "*For an item that is shipped directly to a recipient, the shipping date is the dispensing date."* Consistent practices in billing and documentation processes allow providers to be more efficient in their business operations. Thank you for the opportunity to comment on this rule. Please let me know if you have any questions. Kam Yuricich, Executive Director *Ohio Association of Medical Equipment Suppliers*	Thank you for your comments. ODA will take this into consideration in ongoing conversations with ODM as we continue to align our service specifications.

	COMMENTS	ODA's RESPONSES
4.	(C)(7) [now (B)(7)] Is it okay for a provider to have UPS/USPS deliver an item without obtaining a signature as long as proof of delivery from the carrier exists via an electronic verification? *Kathy Peck, General Manager* *Duraline Medical Products, Inc.*	Provided all requirements under this rule are followed, this scenario may be an acceptable method of documenting delivery.
5.	(C)(7) [now (B)(7)] Could ODA please clarify the term "electronic verification" of service delivery? UPS tracking records currently provide delivery date, time, address and package location, if left without obtaining a signature. USPS tracking records record similar information. A previous directive from ODA: NOTICE 0513546 (dated May 17, 2013) requires a provider of HME to obtain the name of the person accepting the delivery and their signature in electronic or paper format. Providers have reported there is an additional cost to obtain signatures, when using UPS, for example. *Teresa H Shane, Provider Relations Supervisor* *Central Ohio Area Agency on Aging (PAA6)*	ODA will work with AAAs to clarify expectations regarding provider oversight of this rule.
6.	(C)(7) [now (B)(7)] Electronic verification needs to be clarified, is the UPS or Fed Ex deriver able to drop the item off on the porch. Does the bill date and delivery date need to match. These are areas that need clarification as I have been completing reviews ad I have been informed that the PASSPORT rules and the Medicaid rules do not match. *Kathleen M. Geise, Quality Assurance Manager* *Catholic Social Services of the Miami Valley (a PAA)*	Please review ODA's response to comment #5.

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?

ODA is not proposing to amend the rules based upon scientific data.

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?

ODA is not proposing to add any new requirements to the rule. Instead, ODA is proposing to delete duplicate requirements in the rule and amend the remainder of the rule to make it more clear. ODA did not consider any alternatives to these rule-improving initiatives.

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.***

ODA did not consider performance-based regulations when considering whether to amend this rule.

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

ORC§173.391 only authorizes ODA (*i.e.*, not any other state agency) to develop requirements for ODA-certified providers of goods and services to individuals who are enrolled in ODA-administered programs.

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.

Before the rules would take effect, ODA will post them on ODA's website. ODA also sends an email to subscribers of our rule-notification service to feature the rules.

Through its regular monitoring activities, ODA and its designees will monitor providers for compliance. OAC173-39-02 requires all providers to allow ODA (and its designees) to monitor.

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;

100% of states surveyed use Medicaid waiver programs, like the PASSPORT Program, to pay for "equipment, technology, and supplies."[2] ODA has certified 169 providers to provide home medical equipment and supplies. 91% of these providers are Ohio-based businesses. 6 of these are non-agency providers.

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

The PASSPORT Program's payment of Medicaid funds for home medical equipment and supplies is an all-inclusive payment that includes the following aspects:

1. Purchasing, delivering, and installing home medical equipment or purchasing and delivering supplies.

2. Retaining records to show Medicare, Medicaid, or any other third-party payer did not (in full or in part) the home medical equipment or supplies and recouping third-party payments before billing the PASSPORT Program.

3. The following ongoing responsibilities: (1) evaluating, maintaining, and adjusting (*e.g.*, refitting to individual); (2) repairing or replacing defective equipment (including assuming liability liability for equipment warranties); and (3) assisting the individual with equipment adjustments and education/instruction on using the equipment.

4. Retaining records that verify the delivery of, installation of, or education/instruction on using the home medical equipment and supplies.

[2] Victoria Peebles and Alex Bohl. *The HCBS Taxonomy: A New Language for Classifying Home- and Community-Based Services.* (MATHEMATICA POLICY RESEARCH. DOI: http://dx.doi.org/10.5600/mmrr.004.03b01) E8.

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.

The appendix to OAC5160-1-06.1 establishes the maximum-possible payment of Medicaid funds the PASSPORT Program would make for medical equipment or supplies. In the table below, ODA compares the maximum-possible payment to the amount billed by providers.

TYPES OF HOME MEDICAL EQUIPMENT AND SUPPLIES	MAXIMUM-POSSIBLE PAYMENT PER ITEM 2015	TOTAL ITEMS BILLED 2015	TOTAL PAID 2015	AVERAGE PAID PER ITEM 2015
Ambulatory Equipment	$5,224.93	6,728	$2,081,169.88	$309.33
Non-Ambulatory Equipment	$5,224.93	19,055	$1,214,137.87	$63.72
Hygiene & Disposable Supplies	$5,224.93	29,897	$1,333,811.98	$44.61
Equipment Repair	$5,224.93	1,517	$259,541.39	$171.09
Nutritional Supplements	$5,224.93	4,053	$405,120.80	$99.96

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

ODA is not making any burdens upon providers that the provider would not face in the normal course of doing business. Providers also charge much less than the maximum-possible amount for a unit. Thus, the regulatory burden of (1) providing the home medical equipment or supplies, (2) replacing defective home medical equipment or supplies (*i.e.*, a warranty), and (3) retaining records of that verify the delivery of, installation of, or education about home medical equipment and supplies is reasonable compared to the health and safety of individuals who receive long-term care.

Regulatory Flexibility

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

The rules treat providers the same, regardless of their size.

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?

ORC§119.14 establishes the exemption for small businesses from penalties for first-time paperwork violations if the business timely corrects the violation, but not if the violation is ineligible for such an exemption according to ORC§119.14(C).

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

ODA does not discriminate between providers based upon the size of their business or organization. Providers regulated by this rule are typically small businesses according to ORC§119.14. ODA (and its designees) are available to help providers of all sizes with their questions. Any person may contact Tom Simmons, ODA's policy development manager, with questions about the rule.

Additionally, ODA maintains an online rules library to help providers find rules regulating them. Providers may access the online library 24 hours per day, 365 days per year.

173-39-02.7 **ODA provider certification: ~~Home~~ home medical equipment and supplies.**

(A) Home medical equipment and supplies (HME) is a service ~~designed to promote functional independence and safe, effective, in-home care through the provision of health-related equipment and supplies. The equipment items and/or supplies eligible to be purchased, installed and/or rented through this service are those items that~~ providing rented or purchased home medical equipment and supplies to individuals to enable ~~the~~ those ~~consumer~~ individuals to function safely in their homes with greater independence ~~in the home and help prevent~~ thereby eliminating the ~~consumer's~~ need for placement in a nursing facility.

HME is limited to equipment and supplies allowed under Chapter 5160-10 of the Administrative Code, miscellaneous equipment and supplies, equipment repairs, and equipment and supplies not paid (in full or in part) by medicare, state plan medicaid, or another third-party payer.

ODA is consolidating this language and moving it to (A), so the definition says what HME is *and* what HME is not.

~~(B) HME items are limited to only those medicaid items in rule 5101:3-10-03 of the Administrative Code, other items and repairs as applicable in rules 5101:3-10-02 to 5101:3-10-26 of the Administrative Code, and miscellaneous items that include, but are not limited to: walker baskets or trays; room monitors; eating, dressing and vision assistive devices; incontinent bath wipes; and medication dispensers. HME items are also limited to those items that and are not covered by other payers (third-party payers, medicare, state plan medicaid, etc.). A HME provider must have documentation that items to be purchased cannot be paid for by medicare, state plan medicaid, or other sources prior to authorization by ODA's designee.~~

ODA is removing this provider requirement from the definition and moving it to (C)(2).

~~(C) HME items must be approved and authorized by the case manager and must be included in the consumer's service plan.~~

This requirement duplicates requirements for every ODA-certified provider in OAC173-39-02.

~~(D)~~(B) A unit of HME ~~service~~ is the item purchased or rented, and the unit rate is the purchase, installation, and/or rental price authorized for the item by ODA's designee.

(C) Requirements for ODA-certified providers of minor home medical equipment and supplies:

(1) General requirements: The agency provider shall comply with the requirements for every ODA-certified agency provider in rule 173-39-02 of the Administrative Code and the non-agency provider shall comply with the requirements for every ODA-certified agency provider in rule 173-39-02 of the Administrative Code.

(2) Before ODA's designee may authorize equipment or supplies, the provider shall document the equipment and supplies to be purchased were not covered (in full or in part) by medicare, state plan medicaid, and any other third-party payer.

Post-Comment Period Note: When ODA files this rule with JCARR, it will move the unit language to the end of the rule (to become (C). This would make (C) in this draft become (B). Additionally, ODA will add the standard unit and rate paragraphs informing readers that ODM established the maximum-possible rates in OAC5160-1-06.1 and rate-setting methodology in OAC5160-31-07.

~~(1)~~(3) The provider ~~must~~ shall ~~furnish~~ provide professional, ongoing assistance when needed to evaluate and adjust ~~products~~ equipment and supplies delivered, and/or to instruct the ~~consumer~~ individual or the ~~consumer's~~ individual's caregiver in the use of ~~an item furnished~~ equipment and supplies.

ODA is removing this provider requirement from the definition and moving it to (C)(2).

~~(2) The provider must have the prior approval of the case manager for any HME item(s) purchased and delivered.~~

~~(E)~~(4) The provider ~~must~~ shall assume liability for equipment warranties and ~~must~~ shall install, maintain, and/or replace any defective parts or items specified in those warranties. Replacement items or parts for HME are not ~~reimbursable~~ payable as rental equipment.

~~(F)~~(5) The provider ~~must~~ shall, in collaboration with the case manager, ascertain and recoup any third-party resource(s) available to the ~~consumer~~ individual ~~prior to~~ before billing ODA or its designee. ODA or its designee ~~will~~ may then pay ~~any~~ the unpaid balance up to the lesser of the provider's billed charge or the maximum allowable ~~reimbursement set forth in division level designation 5101:3~~ payment established in Appendix A to rule 5160-1-06.1 of the Administrative Code.

~~(G)~~(6) The provider ~~must~~ shall submit the price for an item to be purchased or rented ~~within~~ no more than two business days ~~of~~ after the case manager's request. The provider ~~must~~ shall purchase, deliver, and install (as appropriate) the authorized item(s) ~~prior to~~ before submitting a bill to ODA's designee. The billed amount for each item ~~may~~ shall not exceed the ~~preauthorized amount~~ item rate authorized by the case manager.

~~(H)~~(7) The provider ~~must~~ shall maintain a record for each ~~consumer~~ individual. The record ~~must~~ shall document the delivery, installation of the item(s) purchased or rented, any education, and/or instructions for the use of equipment and/or supplies provided to the ~~consumer~~ individual, and ~~must~~ shall include documentation of delivery of item(s) to the ~~consumer~~ individual. The documentation ~~must~~ shall consist of both of the following:

~~(1)~~(a) The ~~consumer's~~ individual's signature, the signature of the ~~consumer's~~ individual's caregiver, or electronic verification of delivery~~; and,~~.

~~(2)~~(b) The date ~~on which~~ the provider delivered the equipment and/or supplies ~~were delivered~~.