

Business Impact Analysis

Agency Name: Ohio Department of Mental Health and Addiction Services Regulation/Package Title: Health Home Service Rule Number(s): 5122-29-33			
Date: 3 June 2013, Amended 15 July 2013, Refiled March 10, 2014			
Rule Type:			
New	□ 5-Year Review		
X Amended	□ Rescinded		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 of the regulation as well as any proposed amendments.

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Ohio is moving forward with expanding access to the health home service for adults and children with Severe and Persistent Mental Illness (SPMI) and Severe Emotional Disturbance (SED) consistent with the Governor's Office of Health Transformation priorities to rebalance Medicaid long-term care spending while coordinating care for individuals with the most costly, chronic and complex health conditions. The health home initiative aims to reduce emergency room visits, hospital admissions and readmissions, reduce reliance on long-term care facilities and reward outcomes for care that is person-centered, value-added and sustainable for Ohio's publicly funded health care system. The initiative is a pilot project that is being implemented in at least two phases in a limited number of counties. Phase one of the project began in 2013 and covered five counties and phase two is being rolled out to an additional six counties in 2014. Certification as a service provider is necessary for a provider to receive payment under Medicaid regulations.

Rule 5122-29-33 contains the certification standards for health home service for persons with severe and persistent mental illness, a benefit for beneficiaries who meet the State's definition of serious and persistent mental illness (which includes adults with serious mental illness [SMI] and children with serious emotional disturbance [SED]), initially using a regional approach. A health home is not a building; it is a coordinated, person-centered system of care. An individual who is eligible for health home services can obtain comprehensive medical, mental health and drug and/or alcohol addiction treatment, and social services that are coordinated by a team of health care professionals. Ohio's Community Behavioral Health Centers (CBHCs) will be eligible to apply to become Medicaid health homes for Medicaid beneficiaries with SPMI. The goals of Ohio's CBHC health homes for Medicaid beneficiaries with SPMI are aligned with those of CMS. They are as follows; improve the integration of physical and behavioral health care; lower the rates of hospital emergency department (ED) use; reduce hospital admissions and re-admissions; reduce healthcare costs; decrease reliance on long-term care facilities; improve the experience of care, quality of life and consumer satisfaction and improve health outcomes. Moreover, we fully expect to achieve better care coordination and management of health conditions as well as increase the use of preventive and wellness management services.

UPDATED March 2014:

This rule was pulled from the electronic rule filing system on August 21, 2013, and has been revised based on stakeholder input. The changes are in the following areas:

Paragraph (E) – A health home provider must demonstrate integration of physical and behavioral health care for a minimum of six months prior to the date of application.

Health home providers may co-locate with a primary care provider and the primary care setting is subject to the provisions of the rule and must be reported to the department..

Paragraph (G) – An electronic health record must be implemented and actively used prior to certification. There is no longer a twelve month grace period after certification in which to implement an electronic health record system.

Paragraph (J) – The health home provider shall use a team to deliver health home service, which must include at least one nurse care manager.

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

Sections 5119.61; 5119.611 and 5119.612 of the O.R.C.

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.

The Centers for Medicaid and Medicare Services (CMS) offers states the option to implement health home service as a Medicaid reimbursable service. The State of Ohio previously received approval to implement health home service in five Ohio counties. ODMH/OhioMHAS and Ohio Medicaid will next submit a Medicaid State Plan Amendment to the Centers for Medicaid and Medicaid Services requesting approval to cover the Health Home service for persons with SPMI statewide beginning October 1, 2013 and to receive an enhanced (90%) federal medical assistance percentage for the first eight quarters that the state health home service state plan is in effect.

ODMH/OhioMHAS is required by CMS under the State Plan Amendment to have a process for assuring agency compliance with the standards.

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

The health home service includes State selected quality measures that exceed the CMS required core set of quality measures. CMS lists a minimum of seven required core quality measures (outcomes), and also asks states to identify measurable goals of their health home model and intervention. Once a State has identified their measurable goals, CMS asks the state to identify quality measures that operationalize as well as map to the goals articulated by the State for the health home. Following CMS' above mentioned guidance, ODMH/OhioMHAS has identified nine core measurable goals and additional quality measures based on the input of diverse stakeholders and content

experts, and the scientific data. To the extent possible, ODMH/OhioMHAS has aligned the additional quality measures with other State and Federal requirements and selected quality measures that can be drawn from claims data in order to minimize potential burden and cost on the providers and the state. ODMH/OhioMHAS has strived to propose a health home model and the quality measures that were necessary to meet the state's goals for achieving good health outcomes and savings as well as meeting the federal requirements and eliciting a favorable response from CMS. The state will collect, aggregate and analyze the data and make it available to providers to be able to respond to the health needs of the defined population as a whole.

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 Centers for Medicare and Medicaid Services requires ODMH/OhioMHAS implement regulatory standards in order to approve adding a service to the State of Ohio Medicaid Plan as a covered service under the community mental health Medicaid program. O.R.C. 340.09 requires a service to be Certified by ODMH/OhioMHAS if a Board wants to pay for a service using non-Medicaid (local) public funds. Providers of health home service that do not wish to either bill the federal community mental health Medicaid program, or enter into a contract with the local community mental health board are not required to follow the standards established by ODMH/OhioMHAS.

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

The State will report core measures to CMS based on information submitted by health home providers and monitor the additional state measures to assess overall health home goals and objectives. Additionally, the State will calculate cost savings that resulted from improved care coordination and managements achieved through the health home service. ODMH/OhioMHAS will also monitor success by tracking the number of agencies which obtain certification to provide health home service.

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.

ODMH/OhioMHAS meets weekly with the Ohio Department of Jobs and Family Services/Ohio Medicaid, which is the state agency responsible for obtaining CMS

approval of the state plan amendment and the state agency responsible for administering the Medicaid program, i.e. providers wanting to bill Medicaid will need to obtain a contract with Ohio Medicaid in able to do so. In addition, ODMH/OhioMHAS and Ohio Medicaid held a Kaizen event the week of May 20, which included a representative from the Ohio Council of Behavioral Health & Family Service Providers, which represents several of ODMH/OhioMHAS's certified provider agencies. In addition, ODMH/OhioMHAS met with the Ohio Council May 31 and incorporated suggestions.

The initial rule was developed with the following input: In 2011, the Ohio Department of Mental Health invited a wide variety of stakeholders, including providers, consumers, advocates, and Medicaid Managed Care Plans, using a variety of mediums - e-mail, other committee meetings, face-to-face, etc to develop the initial standards for the new service. The following organizations actively participated in discussions regarding this proposal: Ohio Departments of: Mental Health, Job and Family Services, and Alcohol and Drug Addition Services, Office of Health Transformation, Ohio Association of County Behavioral health Authorities, The Ohio Council of Behavioral Health & Family Services Providers, The Ohio Empowerment Coalition for Mental Health Recovery, the National Alliance on Mental Illness Ohio, Ohio Association of Child Caring Agencies, Inc., Ohio Hospital Association, Ohio Association of Health Plans, Public Children Services Association of Ohio, and National Association of Social Workers. In addition, the draft rules for the original (new) health home rule were made available for comment on the ODMH/OhioMHAS website from June 15 – June 20, and ODMH/OhioMHAS certified agency executive directors, stakeholders, and subscribers to an agency listsery were notified by e-mail of this opportunity to provide input.

UPDATED MARCH 2014

This rule had been filed in the electronic rule filing system with LSC and JCARR but was placed in a "to-be-refiled" status on August 21, 2013. The rule was halted to coordinate changes with a companion rule administered by Ohio Medicaid.

In order to engage stakeholders and arrive at a fiscal sustainability strategy for the health home initiative, OhioMHAS and ODM co-chaired a series of meetings from August 2013 through February 2014. The stakeholders who participated in these meetings included behavioral health providers and trade associations, community behavioral health advocates, and state agency leadership and policy staff. A total of nine meetings were held during which alternatives to the previously proposed

reimbursement methodology were openly explored and discussed. The amendments to the rule are the result of those meetings.

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

In addition to feedback during the Kaizen which was incorporated into the overall health home certification process (application & rule, certification, data exchange, etc.) the Ohio Council made a post Kaizen request to 1) clarify language regarding health home's responsibility regarding the delivery of physical health care, i.e. the language identifies the health home is responsible to ensure the consumer receives the right primary care services, but is not responsible for the quality, and 2) to ensure that the rule is not misinterpreted to require expanded enrollment.

UPDATED MARCH 2014

During the period between when the rule was placed in "To Be Refiled" status in August of 2013 and March, 2014, stakeholder input led to three changes that served to limit the pool of potential service providers. This narrowing of the field was felt as being necessary in order to insure that providers in the pilot program were those best suited to carrying out the principles of health home integration and giving the pilot program the best opportunity to have successful outcomes. The changes that were made are:

- \bullet Paragraph (E) A health home provider must demonstrate integration of physical and behavioral health care for a minimum of six months prior to the date of application. Health home providers may co-locate with a primary care provider and the primary care setting must meet the provisions of this rule and be reported to the department.
- Paragraph (G)(3) An electronic health record must be implemented and actively used prior to certification.
- Paragraph (J) The health home provider shall use a team to deliver health home service, which must include at least one nurse care manager.
- 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?

The measurable outcomes selected for health home service are standardized measures from the nationally recognized sources such as National Committee for Quality Assurance, National Quality Forum, Agency for Healthcare Research and Quality, and Substance Abuse and Mental Health Services Administration. The measurable outcomes of the rule were developed based on information and scientific data obtained

through a review of the scientific literature and the following Ohio-specific research studies:

The Ohio Department of Mental Health (ODMH/OhioMHAS), in conjunction with Case Western Reserve University, investigated the causes of deaths of seriously mentally ill consumers who died between 2004 and 2007 and who were served by the Ohio state-operated psychiatric hospitals and/or community-based mental health programs (pending publication). When compared to decedents in Ohio's general population over the study's time frame, only 32% of the seriously mentally ill consumers were 65 years or older at the time of their deaths, compared to 75% of the general Ohio population.

An earlier Ohio study examined mortality and medical comorbidity among patients with serious mental illness admitted to an Ohio public mental health hospital between 1998 and 2002. Heart disease (21%) was the leading cause of death. The mean age at death for decedents with Ohio public mental health hospital admission was 47.7 years, corresponding to an average of 32 years of potential life lost per patient (Miller et al., 2006).

In a recent study funded by the Northeast Ohio Medical University's BeST Center and the Health Foundation of Greater Cincinnati and conducted by Health Management Associates and the Ohio Colleges of Medicine Government Resource Center it was found that in Ohio:

- Adults with serious mental illness (SMI) represented about 10% of the Medicaid population and 26% of total Medicaid expenditures.
- The rate of co-occurring chronic physical health conditions is higher among individuals with SMI and particularly among individuals with schizophrenia and psychosis.
- Adults with SMI have approximately twice the rate of hospitalization and ED visits for many ambulatory care sensitive conditions including diabetes, COPD, pneumonia and asthma.
- Adults with schizophrenia have over twice the rate of hospital emergency department (ED) visits for hypertension and diabetes.

In addition to the Ohio specific statistics above, the numerous national studies in clinical settings support behavioral health treatment approaches can contribute to high risk health conditions: second generation anti-psychotic medications are highly

associated with weight gain, diabetes, abnormal cholesterol levels and metabolic syndrome.

The scientific data were used to support all components of the health home including the development of the program goals and design, the provider standards, and the selection of the outcome measures. The data will also be used to evaluate the effectiveness and impact of the regulation in the future.

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?

None. The health home service delivery model is a new approach and at this point, no alternatives to regulate this service exist.

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.

The Ohio Department of Mental health and addiction services will be requiring the performance measures as described in response to question 6 to measure the performance of rule requirements.

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

The Ohio Department of Jobs and Family Services/Ohio Medicaid, which administers the Ohio Medicaid Program, is revising the rules which authorize billing Medicaid for the Health Home service. Provider agencies which want to render health home service as a Medicaid reimbursable service will need to enter into a contract with ODJFS/Ohio Medicaid. ODMH/OhioMHAS worked in tandem with the ODJFS/Ohio Medicaid to develop rules which are complementary rather than duplicative.

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.

Chapters 5122-25 to 5122-29-30 of the Administrative Code define that certification process that is the same for all providers. ODMH/OhioMHAS has conducted multiple webinars and regional forums. ODMH/OhioMHAS will conduct additional training/forums for providers of the service, including an application training scheduled for June 14, 2013, and weekly Technical Assistance webinars beginning June

24, 2013 for at least five weeks, after which time ODMH/OhioMHAS will request input from providers on the need to continue the webinars.

UPDATED MARCH 2014

OhioMHAS will be conducting training during the summer of 2014 to coincide with the phase two rollout of the program. Details are still be worked out and will be finalized once phase two providers are identified and training needs are established.

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;
 Any currently certified community mental health providers which voluntarily chooses to add health home service to its existing ODMH/OhioMHAS
 Certification, or any new provider which want to become certified by
 ODMH/OhioMHAS and provide health home service. A provider can choose to be ODMH/OhioMHAS certified to provide some, but not all Medicaid billable services, including health home service.

It should be noted that this service is a pilot project and is only open to a specific set of counties. Phase one was limited to Adams, Butler, Lawrence, Lucas and Scioto counties. Phase two will be limited to Cuyahoga, Erie, Franklin, Hamilton, Portage and Summit counties.

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

ODMH/OhioMHAS Certification is required in order to bill Community Mental Health Medicaid or receive a contract with the local community mental health board to receive local public funds to pay for health home service. There is no fee for ODMH/OhioMHAS certification. The Health Home service rule does require providers to be certified by ODMH/OhioMHAS for four other Medicaid billable services. Certification for those four services requires an agency to first obtain appropriate behavioral health accreditation by one of three national accrediting bodies, which do charge an accreditation fee, or undergo a state certification survey. In addition, agencies will have a limited time (up to 4 years depending on accrediting body and accreditation cycle) after obtaining ODMH/OhioMHAS Certification to add accreditation/recognition/certification

in integrated behavioral health/physical health care. Agencies will also need to dedicate staff time to implement the standards.

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.

If a provider chooses a state agency survey to meet the requirements for certification for behavioral health therapy and counseling, mental health assessment, pharmacologic management and community psychiatric supportive treatment services, then the provider must pay a fee based upon the amount of agency services funded by public dollars. By rule, certification fees range from \$180 to \$5000, although a health home provider would likely pay a fee of \$1800 or higher. Although a provider may choose the state certification option for other services, it is still required by the health home service rule to obtain behavioral health/primary care accreditation/recognition or certification. For this reason, it is thought that most providers of health home service will maintain accreditation. Accreditation or National Committee on Quality Assurance fees vary based upon the accreditation/certification/recognition body; agency size including budget, number of locations, consumers served and staff; number of services accredited, etc. Average fees range from \$6895 to \$20,000 for a 3 or 4 year accreditation, although fees can be higher or lower. This is based upon fee schedules provided by the accrediting bodies or available on-line. Agencies may or may not incur an additional accreditation fee when adding when adding accreditation for integrated behavioral health/physical health. This is dependent upon the accrediting body standards, and agency size, and ODMH/OhioMHAS is unable to estimate the cost of an increase, if applicable. The amount of additional staff time to implement the standards is difficult to estimate, based upon the expertise of employees within the agency. An agency with a history of providing integrated care will require less staff time than an agency implementing these services for the first time. For the physical health component, some mental providers already provide physical health services. Some may be adding this as a service, while others will contract with a provider of physical health services.

UPDATED MARCH 2014:

If a provider voluntarily obtains certification for health home service, the provider will need to acquire an electronic health record system. The actual

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costs of implementing or expanding an electronic health record will vary by provider for a variety of reasons, including whether the provider currently has any form of an electronic health record, the size of provider and number of staff and records, electronic health record system chosen, etc. Costs of an electronic system include hardware, software, implementation assistance, training, and ongoing fees and maintenance. Internet research shows costs of hardware and software often average between \$20,000 to \$50,000. Some of the expenditures may be offset over time by the efficiency of an electronic system, and decrease in costs related to a paper system.

Prior to March 2014 this rule allowed the implementation of the electronic health record system within twelve months of becoming certified to provide this service. The change was made through work with Medicaid and stakeholders after the rule was placed in the "To Be Refiled" status in August of 2013. The requirement is being changed to narrow the field of potential providers for the pilot program. By requiring the electronic health record system at certification, the pool of potential providers has been narrowed to those best situated to produce successful outcomes under the pilot program. Other changes to the rule during the August 2013 to March 2014 timeframe were made to assist with this narrowing of the potential provider pool; this includes the tightening of integration between behavioral and physical health care in paragraph (E) and the requirement of at least one nurse care manager for every health home provider in paragraph (J). The Department estimates the cost associated with addition of the nurse care manager would vary from \$0.00 if the agency already has a nurse on staff that can fill the nurse care manger role up to approximately \$61,750 annually, the mean annual wage in 2013 for a Registered Nurse employed in Ohio (Source: Bureau of Labor Statistics. Retrieved from http://www.bls.gov/oes/current/oes291141.htm#st) if a Registered Nurse is newly hired and one hundred per cent of their time was devoted to the health home program.

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

ODMH/OhioMHAS is not able to add a service as a community mental health Medicaid covered service without implementing standards and the ability to assure compliance.

The Health Home service is being piloted by OhioMHAS and Medicaid to lower the overall health care costs of those served by the clients of the service. By providing integrated behavioral and physical health care, cost savings are expected in such areas

as primary medical care and emergency room visits. In order to provide this service as a covered Medicaid service, OhioMHAS must certify providers and set standards is it is doing in this rule.

Regulatory Flexibility

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

No, the regulation does not provide exemptions or alternative means of compliance for small businesses. An agency may request a waiver or a variance pursuant to OAC 5122-25-06.

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?

ODMH/OhioMHAS's general practice is to require a written plan of correction, whereby a provider identifies how it will correct a violation that cannot be immediately corrected. If a provider is non-compliant with the certification application process, ODMH/OhioMHAS will notify the provider of such, and allow the provider to correct the issue, e.g. submit missing documentation, correct paperwork, etc. The OAC rules do not authorize assessing a fine. ODMH/OhioMHAS does have the authority to issue a probationary Certificate in place of a full certificate when (a) Serious deficiencies are found during the department's determination of an agency's compliance with the certification standards; or (b) The agency's documented corrective action(s) is not approved by the department. There is no penalty associated with issuing a probationary certificate, i.e. the agency may still provide and bill for the service as long as the service is medically necessary and documented. ODMH/OhioMHAS does not have the authority to allow expenditure of public funds for services which are not medically necessary and documented.

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

ODMH/OhioMHAS has staff available to provide technical assistance in explaining the standards. ODMH/OhioMHAS also conducted webinars and regional state-wide forums to discuss health home service. ODMH/OhioMHAS and/or ODJFS plan to establish learning communities for providers of health home service. ODMH/OhioMHAS sponsors yearly CARF and Joint Commission training for providers to assist with maintaining conformance to accrediting body standards. By

contracting directly with the accrediting bodies, ODMH/OhioMHAS is able to offer the training at fees of approximately \$200 - \$400 less per person, and eliminate out-of-state travel costs.

ODMH/OhioMHAS will conduct additional training/forums for providers of the service, including an application training scheduled for June 14, and weekly Technical Assistance webinars beginning June 24 for at least five weeks, after which time ODMH/OhioMHAS will request input from providers on the need to continue the webinars.