CSI - Ohio

The Common Sense Initiative

Business Impact Analysis

Agency Name: Ohio Department of Medicaid

Regulation/Package Title: BHPP General Hospital Rules

Rule Number(s): 5160-2-01, 5160-2-04

Date:

Rule Type:

- ☐ **New**
- ☐ **Amended**
- **X 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- ☐ **Rescinded**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 of the regulation as well as any proposed amendments.

   Rule 5160-2-01, entitled Eligible Providers, sets forth the policies to determine which hospitals may be enrolled in the Medicaid (Title XIX) program. Hospitals are required to meet the conditions of participation for the Medicare (Title XVIII) program as described in 42 C.F.R. Part 482 effective as of October 1, 2013. The rule is being proposed for five-year rule review. The proposed changes are updates to Ohio Administrative Code and agency references

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throughout the rule, adding date references to Code of Federal Regulations references, and updating the rule structure to improve readability.

Rule 5160-2-04, entitled Coverage of hospital provided pharmaceutical, dental, vision care, medical supply and equipment, and medically-related transportation services, sets forth coverage of pharmaceutical, dental, vision care, medical supply and equipment and medically-related transportation services provided by hospitals. The proposed changes to the rule include updates to Ohio Administrative and Revised Code references and updating language regarding transportation services. The provision that "ODJFS may periodically require hospitals to produce evidence of invoice costs supporting amounts billed for take-home drugs" was moved to 5160-2-07.13 Utilization Control.

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

   5164.02

3. **Does the regulation implement a federal requirement?** Yes. **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?** Yes.
   If yes, please briefly explain the source and substance of the federal requirement.

   As the state Medicaid agency, the Department is required under 42 C.F.R. Part 482 to ensure all hospitals enrolled in Medicare are eligible to participate in the Ohio Medicaid program upon execution of a provider agreement. In addition, it is Medicaid's responsibility to ensure that an eligible hospital that is currently determined to meet the requirements for Medicare participation has in effect a hospital utilization review plan applicable to all patients who receive medical assistance under through Medicaid. Rule 5160-2-01 implements this requirement.

   Rule 5160-2-04 does not implement a federal requirement.

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

   Rule 5160-2-01, entitled Eligible Providers, sets forth the policies to determine which hospitals may be enrolled in the Medicaid program. All hospitals that meet Medicare conditions of participation as described in 42 C.F.R. Part 482 effective as of October 1, 2013, are eligible to participate in the Ohio Medicaid program upon execution of a provider agreement. Meeting the conditions of participation is a standard business practice for all hospitals, including those owned by Counties, Townships, and Municipal Corporations. The Department recognizes that there is a cost to all hospitals including those owned by Counties, Townships, and Municipal Corporations when they enroll to participate in the Medicare program and psychiatric hospitals and psychiatric units of hospitals when they obtain their licensure from the Department of Mental Health and Addiction Services, however there is no additional cost of compliance for hospitals and psychiatric hospitals to be eligible to participate in the Ohio Medicaid program.

Rule 5160-2-04 is a not a federal requirement.

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 public purpose for rule 5160-2-01 is to set forth the policies to determine which hospitals may be enrolled in Medicaid and to comply with federal regulations.

   The purpose of rule 5160-2-04 sets forth coverage of pharmaceutical, dental, vision care, medical supply and equipment and medically-related transportation services provided by hospitals.

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

   Rule 5160-2-01, entitled Eligible Providers, sets forth the policies to determine which hospitals may be enrolled in the Medicaid program. CMS has long-standing conditions of participation for hospitals which are described in 42 C.F.R. Part 482 to ensure all hospitals be enrolled in Medicare. It has been the Department's policy that hospitals that meet the conditions as described in 42 C.F.R. Part 482 and are enrolled by Medicare as a hospital may also be enrolled to participate in the Ohio Medicaid program upon execution of a provider agreement. Without the policy that allows Medicaid to adhere to Medicare's conditions and limitations, the Department would have to hire additional staff to ensure each hospital was in compliance with current regulations, adding additional cost to hospitals (i.e., fees for licensure). A secondary complication is an increased likelihood of patients not having access to care, as individual hospitals would not be able to accept patients until compliance was satisfied for both Medicare and Medicaid. The measureable outcome of this regulation is speedy access to hospital services by Medicaid beneficiaries and the non-imposition of double licensure and certification costs on hospitals.

   Success for Rule 5160-2-04 will be measured by the reduction of inquiries from providers inquiring how to bill for hospital-provided pharmaceutical, dental, vision care, medical supply and equipment, and medically-related transportation services. The following sentence, "ODJFS may periodically require hospitals to produce evidence of invoice costs supporting amounts billed for take-home drugs," was relocated to rule 5160-2-07.13, Utilization Control. The BIA for 5160-2-07.13 addresses the utilization review requirement as it relates to the submission of information for claim validation purposes, meeting federal utilization review requirements, etc.

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.

Summary statements about the proposed revisions in these rules have been shared and discussed at monthly meetings between the Department and the Ohio Hospital Association (OHA). In addition, the draft rules were publicized via the Department's clearance process and no additional comments were received.

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

   No comments were received during the clearance review process.

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?**

   Not applicable for either rule.

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. Rule 5160-2-01 is the result of a federal mandate and Rule 5160-2-04 describes coverage of pharmaceutical, dental, vision care, medical supply and equipment and medically-related transportation services provided by hospitals.

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.***

    No.

    Rule 5160-2-01 is the result of a federal mandate.

    Rule 5160-2-04 describes coverage of pharmaceutical, dental, vision care, medical supply and equipment and medically-related transportation services provided by hospitals and does not dictate the process the regulated stakeholders must use to achieve compliance.

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

    Ohio Administrative Code rule 5160-2-01 is the only regulation that defines which hospitals can participate in the Ohio Medicaid program. OAC rule 5160-2-04 is the only regulation that describes Medicaid coverage of pharmaceutical, dental, vision care, medical supply and equipment and medically-related transportation services provided by hospitals. The agency reviewed the regulations cited within the rules and reduced duplication when possible by referring readers to other existing rules.

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.**

Rule 5160-2-01, entitled Eligible Providers, sets forth the policies to determine which hospitals may be enrolled in the Medicaid (Title XIX) program. To be eligible to participate in the Ohio Medicaid (Title XIX) program, hospitals must be enrolled in the Medicare (Title XVIII) program and meet the conditions of participation as described in 42 C.F.R. Part 482. See, e.g., 42 C.F.R. 440.10 and 42 C.F.R. 440.20.

The proposed changes to Rule 5160-2-04 do not require implementation. The existing policies for coverage of hospital-provided pharmaceutical, dental, vision care, medical supply end equipment, and medically-related transportation services are already coded in the claims payment system and are working appropriately.

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;**

Both rules impact all hospitals enrolled as Ohio Medicaid providers.

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

As the state Medicaid agency, the Department is required under 42 C.F.R. Part 482, 42 C.F.R. 440.10, and 42 C.F.R. 440.20 to ensure all hospitals enrolled in Medicare are eligible to participate in the Ohio Medicaid program upon execution of a provider agreement. To become an eligible provider in the Ohio Medicaid (Title XIX) program, the hospital will incur the fees associated with enrollment in the Medicare (Title XVIII) program.

    b. **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.

No additional adverse impact is anticipated as result of rule 5160-2-01, as any hospital providing inpatient psychiatric services would already have their licensure.

No additional adverse impact is anticipated as result of rule 5160-2-04. Language that required a reporting of information (and thus would have been an adverse impact) in the prior version (5160-2-04(A)(2)) has been removed in this updated version.

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

The Department recognizes that there is a cost to all hospitals when they enroll to participate in the Medicare program, including psychiatric hospitals and psychiatric units of hospitals when they obtain their licensure from the Department of Mental Health and Addiction Services. However, there are no additional adverse impact from this rule is expected for hospitals and psychiatric hospitals to be eligible to participate in the Ohio Medicaid program.

Regulatory Flexibility

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

No.

Rule 5160-2-01 is the result of a federal mandate.

Rule 5160-2-04 simply describes Medicaid coverage of pharmaceutical, dental, vision care, medical supply and equipment and medically-related transportation services provided by hospitals.

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?**

There are no fines or penalties associated with rule 5160-2-01.

There are no fines or penalties associated with rule 5160-2-04.

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

Providers needing enrollment assistance may contact ODM provider services at http://medicaid.ohio.gov/PROVIDERS/EnrollmentandSupport/ProviderEnrollment.aspx or hospital services at Hospital_policy@medicaid.ohio.gov.

Hospitals may email questions regarding rule 5160-2-04 to Hospital_policy@medicaid.ohio.gov.

5160-2-01 **Eligible providers.**

(A) ~~To participate in the medicaid program, a hospital must have a valid, current provider agreement. A "provider agreement" is a contractual agreement whereby the provider agrees to adhere to conditions of participation with the Ohio department of job and family services as described in rule 5101:3-1-17.2 of the Administrative Code~~.

All hospitals, except those excluded in paragraphs (A)(1) and (A)(2) of this rule, that meet medicare (Title XVIII) conditions of participation as described in 42 C.F.R 482 effective as of October 1, 2013, are eligible to participate in the Ohio medicaid (Title XIX) program upon execution of a provider agreement. Also considered to be eligible is a hospital that is currently determined to meet the requirements for Title XVIII participation and has in effect a hospital utilization review plan applicable to all patients who receive medical assistance under Title XIX. The following hospitals are excluded from participation:

(1) Tuberculosis facilities, and

(2) Facilities that have fifty per cent or more of their beds registered pursuant to Chapter 3701-59 of the Administrative Code as alcohol and/or drug abuse rehabilitation beds, and have no beds licensed as psychiatric beds pursuant to Chapter 5122-14 of the Administrative Code.

(B) The following facilities with more than sixteen beds shall be eligible to participate in Title XIX only for the provision of inpatient psychiatric services to recipients age sixty-five or older in accordance with paragraph (C) of this rule and to recipients under age twenty-one in accordance with paragraph (D) of this rule:

(1) A hospital with fifty per cent or more of its beds registered as alcohol and/or drug abuse rehabilitation beds that also has beds licensed as psychiatric beds pursuant to Chapter 5122-14 of the Administrative Code;

(2) Hospitals that have at least half of their beds licensed as psychiatric beds pursuant to Chapter 5122-14 of the Administrative Code or operated under the authority of the state mental health authority in accordance with section 5119.01 of the Revised Code; and

(3) Hospitals that have half or more of their discharges in any six-month time period reviewed by the ~~Ohio department of job and family services~~ the department and determined to be for psychiatric and/or substance abuse treatment.

(C) Hospitals that are eligible to participate only for the provision of inpatient psychiatric

services in accordance with paragraph (B) of this rule and are rendering inpatient psychiatric services to recipients age sixty-five or older must be licensed by the ~~Ohio department of mental health~~ Ohio department of mental health and addiction services in accordance with Chapter 5122-14 of the Administrative Code or operated under the authority of the state mental health authority in accordance with section 5119.01 of the Revised Code, and must provide services in accordance with Chapter 5122-14 of the Administrative Code. Hospitals shall operate pursuant to the provisions of 42 C.F.R. 441 subpart C effective as of October 1, 2013.

(D) Hospitals that are eligible to participate only for the provision of inpatient psychiatric services in accordance with paragraph (B) of this rule and are rendering inpatient psychiatric services for recipients under age twenty-one must:

(1) Provide services under the direction of a physician;

(2) Operate pursuant to the provisions of 42 C.F.R. 441 subpart D effective as of October 1, 2013;

(3) Be a psychiatric hospital or an inpatient program in a psychiatric hospital, either of which is accredited by the "Joint Commission on Accreditation of Hospitals," and must be licensed by the ~~Ohio department of mental health~~Ohio department of mental health and addiction services in accordance with Chapter 5122-14 of the Administrative Code or operated under the authority of the state mental health authority in accordance with section 5119.01 of the Revised Code, and must provide services in accordance with Chapter 5122-14 of the Administrative Code; and

(4) Provide services before the recipient reaches age twenty-one or, if the recipient was receiving services immediately before ~~he/she~~he or she reached age twenty-one, before the earlier of the following:

(a) The date ~~he/she~~he or she no longer requires the services; or

(b) The date ~~he/she~~he or she reaches age twenty-two.

(E) The following facilities with sixteen or fewer beds shall be eligible to participate in Title XIX only for the provision of inpatient psychiatric services to recipients in accordance with paragraph (F) of this rule:

(1) A hospital with fifty per cent or more of its beds registered as alcohol and/or drug abuse rehabilitation beds that also has beds licensed as psychiatric beds

pursuant to Chapter 5122-14 of the Administrative Code;

(2) Hospitals that have at least half of their beds licensed as psychiatric beds pursuant to Chapter 5122-14 of the Administrative Code or operated under the authority of the state mental health authority in accordance with section 5119.01 of the Revised Code; and

(3) Hospitals that have half or more of their discharges in any six-month time period reviewed by the ~~Ohio department of job and family services~~ the department and determined to be for psychiatric and/or substance abuse treatment.

(F) Hospitals that are eligible to participate only for the provision of inpatient psychiatric services in accordance with paragraph (E) of this rule and are rendering inpatient psychiatric services to recipients must be licensed by the ~~Ohio department of mental health~~Ohio department of mental health and addiction services in accordance with Chapter 5122-14 of the Administrative Code or operated under the authority of the state mental health authority in accordance with section 5119.01 of the Revised Code, and must provide services in accordance with Chapter 5122-14 of the Administrative Code. Hospitals shall operate pursuant to the provisions of 42 C.F.R. 482 subpart E effective as of October 1, 2013.

5160-2-04 **Coverage of hospital-provided pharmaceutical, dental, vision care, medical supply and equipment, and ~~ambulance or ambulette~~medically-related transportation services.**

(A) Drugs.

(1) Drugs are classified as: administered inpatient (drugs administered to a patient while an inpatient); administered outpatient (drugs administered to a patient at the hospital in connection with outpatient services); take-home (drugs dispensed on an outpatient basis for use away from the hospital).

(2) Administered inpatient drugs are considered inpatient services and are reimbursed as an inpatient service. Administered outpatient drugs are considered outpatient services and are reimbursed as an outpatient hospital service in accordance with rule ~~5101:3-2-21~~5160-2-21 of the Administrative Code. Take-home drugs must be billed in accordance with provisions in Chapter ~~5101:3-9~~5160-9 of the Administrative Code. Payment to hospitals for take-home drugs will be reimbursed according to the provisions of Chapter ~~5101:3-9~~5160-9 of the Administrative Code. ~~ODJFS may periodically require hospitals to produce evidence of invoice costs supporting amounts billed for take-home drugs.~~

(B) Medical supplies and equipment.

(1) Inpatient coverage: ~~Supplies and equipment for the care and treatment of the recipient during an inpatient stay, including implants and devices that are part of a surgical, immediate post surgical, or early fitting procedure (e.g., pacemakers, halos, and prosthetic devices), appliances that are generally applied prior to discharge (e.g., initial prostheses), and other items that are medically necessary as described in rule 5101:3-2-02 of the Administrative Code to permit or facilitate the patient's discharge from the hospital until such time as the recipient can obtain a permanent item or supply are covered inpatient hospital services and, as such, must be included in the hospital's inpatient billing. In order to be reimbursed for supplies and equipment furnished to an inpatient for use solely outside the hospital, the hospital must be approved under the medicaid program as a medical supplies provider. See Chapter 5101:3-10 of the Administrative Code for coverage, limitation, billing, and reimbursement provisions relative to medical supplies providers.~~

(a) Supplies and equipment are covered for the care and treatment of the recipient during an inpatient stay and include:

(i) implants and devices that are part of a surgical, immediate post surgical, or early fitting procedure (e.g., pacemakers, halos, and prosthetic devices);

(ii) appliances that are generally applied prior to discharge (e.g., initial prostheses); and

(iii) other items that are medically necessary as described in rule 5160-1-01 of the Administrative Code to permit or facilitate the patient's discharge from the hospital until such time as the recipient can obtain a permanent item or supply.

(b) Covered items must be included in the hospital's inpatient billing.

(c) Medical supplies and equipment provided to medicaid recipient for use outside the hospital are reimbursed accordance with Chapter 5160-10 of the Administrative Code.

(2) Outpatient coverage: ~~In order to be reimbursed for medical supplies and equipment on an outpatient basis, a hospital must be approved under the medicaid program as a medical supplies provider. Hospital outpatient departments that so desire may make application to provider enrollment. See Chapter 5101:3-10 of the Administrative Code for coverage, limitation, billing, and reimbursement provisions relative to medical supplies providers.~~

(a) Rule 5160-10 the Administrative Code describes the coverage and reimbursement of medical supplies provided during the provision of an outpatient visit.

(b) Medical supplies and equipment provided to the medicaid recipient for use outside the hospital are reimbursed in accordance with Chapter 5160-10 of the Administrative Code.

(C) Dental services: Except for dental services described in rule ~~5101:3-2-03~~5160-2-03 of the Administrative Code and emergency dental services provided in the emergency room, all dental services are covered and reimbursed as dental services under the provisions set forth in Chapter ~~5101:3-5~~5160-5 of the Administrative Code.

(D) Vision care services: All vision care services are covered and reimbursed as inpatient or outpatient hospital services. All vision care materials are covered and reimbursed in accordance with the provisions of Chapter ~~5101:3-6~~5160-6 of the Administrative Code.

(E) ~~Ambulance and ambulette~~Medically-related transportation services: The services of hospital staff as ~~attendents~~attendants during transportation are covered and reimbursed as an inpatient or outpatient hospital service. Transportation to or from a hospital, including inter hospital transfer, that is provided in accordance with Chapter 5160-15 of the Administrative Code is not a hospital service and is

reimbursed as described in Chapter 5160-15 of the Administrative Code. ~~Services related to the use and operation of the transport vehicle, including standard equipment and driver, are reimbursed as an ambulance or ambulette service. The provisions of this paragraph apply to ambulance and ambulette services provided to or from the hospital, including interhospital ambulance or ambulette services. See Chapter 5101:3-15 of the Administrative Code for coverage, limitation, billing, and reimbursement provisions relative to ambulance and ambulette services providers~~.