CSI - Ohio

The Common Sense Initiative

Business Impact Analysis

Agency Name: Ohio Department of Medicaid

Regulation/Package Title: Provider-administered injections and pharmaceuticals; adding existing coverage for provider administered skin substitutes.

Rule Number(s):

To be amended: 5160-4-12

To be rescinded: 5160-4-35

Date: March 3, 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- ☑ Rescinded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 of the regulation as well as any proposed amendments.

   Rule 5160-4-35, "Skin substitutes for wound treatment and healing," sets forth coverage and payment provisions for the professional application of skin substitute grafts performed by wound care specialists in different settings for the standard wound care treatment of burns and ulcers. This rule is being proposed for rescission.

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Rule 5160-4-12, "Immunizations, injections and infusions (including trigger-point injections), and provider-administered pharmaceuticals," sets forth coverage and payment provisions for injections and other pharmaceuticals administered by professional practitioners. This rule is being proposed for amendment.

The proposed changes move the coverage and payment policy for covered skin substitute grafts from rule 5160-4-35 to rule 5160-4-12 which will be re-titled, "Immunizations, injections and infusions (including trigger-point injections), skin substitutes, and provider administered pharmaceuticals." The amendment to rule 5160-4-12 references a payment table/fee schedule on the department's web site, http://medicaid.ohio.gov, which houses codes for all covered skin substitutes. Adding the skin substitute coverage and payment provisions to rule 5160-4-12 directs a reader to one rule that combines all coverage and payment provisions for these professional services. Coverage and payment for skin substitute grafts will be unchanged by these rule amendments.

Additionally, references to a discontinued limited family planning benefit have been removed. Am. Sub. H.B. 64 of the 131st General Assembly terminated this optional limited eligibility benefit effective December 31, 2015. Individuals that were eligible for this limited benefit were instructed to apply for either the full Medicaid benefit through Ohio Benefits or for medical insurance through the Federally Facilitated Marketplace.

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

   The Ohio Department of Medicaid (ODM) is promulgating these rules under section 5164.02 of the Ohio Revised Code.

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.

   No.

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

   These payment policies are not required by federal law, but they do fall within the federal authority granted to states in administering the Medicaid program.

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)?**

   This rule establishes coverage and payment policies for professional provider administered pharmaceuticals.

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

   The success of these rules will be measured by the extent to which the Medicaid Information Technology System (MITS) results in correct payment of claims for services and supplies rendered.

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 September 16, 2016, an email was sent to the Ohio State Medical Association, the Ohio Association of Advanced Practice Nurses (OAAPN), and the Ohio Association of Physician Assistants sharing the proposed changes to Rule 5160-4-12 and inviting their review and comment prior to the public-comment process known as Clearance.

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

   The OAAPN asked that the Department provide additional detail in rule 5160-4-12 to describe Medicaid payments for wound treatment services performed by professional wound care specialists in facility and non-facility settings. OAAPN's recommendations were welcomed and incorporated into the rule amendment, which adds clarity to payment policies in various settings. The association is pleased with the changes made to the draft amendment of this rule.

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 use of scientific data does not apply to the development of this 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?**

    No alternative was apparent.

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 concept of performance-based regulation does not apply to these services.

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

    These rules have been reviewed by legal and policy staff for duplication within the Medicaid agency division 5160 of the Ohio Administrative Code.

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.**

    The policies set forth in these rules will be incorporated into the Medicaid Information Technology System (MITS) as of the effective dates of these rules. They therefore will be applied by the Department's electronic claim-payment system automatically and consistently whenever an appropriate provider submits a claim for an applicable service.

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

    a. The scope of the impacted business community consists of providers of professional services, mainly physicians, advance practice nurses, and physician assistants, that administer vaccines, toxoids, therapeutic injections, and apply skin substitutes for professional wound treatment.

    b. These rules imposes no license fees or fines. The nature of the adverse impact is the maintenance of required documentation in the individual's medical record. Maintaining accurate medical records is considered industry standard and is required under other state and federal regulations for purposes of program integrity. Rule 5160-4-12 requires providers of trigger-point injections to document the following information in the individual's medical record: (1) a proper evaluation including a patient history and physical examination leading to diagnosis of the trigger point, (2) the reason or reasons

for selecting this therapeutic option, (3) the affected muscle or muscles, (4) the muscle or muscles injected and the number of injections, (5) the frequency of injections required, (6) the name of the medication used in the injection, (7) the results of any prior treatment, and (8) corroborating evidence that the injection is medically necessary. Also, for skin substitutes, it must be documented in the individual's medical record that the application of skin substitute grafts must result in 50% or greater improvement to a wound in order for continued use (re-applications). If the skin substitute grafts are not resulting in a 50% or greater improvement in the wound healing process, then the practitioner shall not continue applying the skin substitutes and must seek another form of wound treatment to promote healing.

c. The costs of updating an individual's medical record can and do vary from practitioner to practitioner depending on a variety of factors. For example, the technology used by a practitioner to dictate in the medical record could significantly decrease the amount of time spent in documentation, as could the use of an employee to enter documentation that could simply be reviewed and signed by the practitioner. This cost also depends on who performed the task. The median statewide hourly wage for a billing clerk, according to Labor Market information (LMI) data published by the Ohio Department of Job and Family Services, is $16.10; for a physician, it is $58.03. Adding 30% for fringe benefits brings these figures to $20.96 and $75.43 generating a necessary documentation cost between $1.76 (five minutes at $20.96 per hour) and $37.71 (thirty minutes at $75.43 per hour).

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

The documentation requirements in this rule are an effective tool for preventing fraud, waste, and abuse. Documentation also promotes quality and cost-effectiveness to help ensure that the Ohio Medicaid program pays for wound care services that are medically necessary and most appropriate to the needs of the persons who receive them. Furthermore, these requirements are consistent with professional standards and are imposed for program integrity purposes.

Regulatory Flexibility

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

These rules outline actions all providers must take in order to receive Medicaid payment. The requirements are applied uniformly and no exception is made based on an entity's 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?**

    These rules impose no sanctions on providers.

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

    Providers that submit claims through an electronic clearinghouse (a "trading partner") can generally rely on the clearinghouse to know current Medicaid claim submission procedures.

    Information sheets and instruction manuals on various claim-related topics are readily available on the Medicaid website.

    The Bureau of Provider Services renders technical assistance to providers through its hotline, (800) 686-1516.

    Policy questions may be directed via e-mail to the Non-Institutional Benefit Management section of ODM's policy bureau, at noninstitutional_policy@medicaid.ohio.gov.

TO BE RESCINDED

5160-4-35 **Skin substitutes for wound treatment and healing.**

(A) The following skin substitutes are covered in an office setting in conjunction with standard wound care regimens for the treatment of burns or ulcers:

(1) Q4101, skin substitute, apligraf, per square centimeter; and

(2) Q4102, skin substitute, oasis wound matrix, per square centimeter; and

(3) Q4103, skin substitute, oasis burn matrix, per square centimeter; and

(4) Q4106, skin substitute dermagraft, per square centimeter; and

(5) Q4110, skin substitute, primatrix, per square centimeter.

(B) Skin substitutes may be used on burns when skin grafting is not the appropriate option. These covered bioengineered skin substitutes are expected to function as a permanent replacement for lost or damaged skin. They may be used for temporary wound coverage or wound closure as appropriate and medically necessary.

(C) Skin substitutes are not separately reimbursable in any institutional setting, including long-term care facility, hospital inpatient, outpatient, or emergency room place of service.

(D) If skin substitute applications and re-applications show no significant improvement after three separate treatments, additional re-applications are inappropriate and other treatment modalities should be considered. Skin substitute treatments should not last more than twelve weeks. Improvement of fifty per cent or greater must be documented in the medical records for the reimbursement of additional re-applications after twelve weeks of treatment. If after twelve weeks the medical records do not support the significant improvement of the wound using the skin substitute treatments, the Ohio department of job and family services may recoup any inappropriate reimbursement.

(E) Wound preparation is considered part of the procedure. All products, including dressings, are included in the evaluation and management service and are not separately reimbursable.

Effective:

Five Year Review (FYR) Dates: Exempt

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Certification

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Date

Promulgated Under:	119.03
Statutory Authority:	5111.02
Rule Amplifies:	5111.02
Prior Effective Dates:	8/2/2011

5160-4-12 **Immunizations, injections and infusions (including trigger-point injections), skin substitutes, and provider-administered pharmaceuticals.**

(A) General provisions.

(1) "Current procedural terminology (CPT)" is a comprehensive listing of medical terms and codes published by the American medical association, www.ama-assn.org, for the uniform designation of diagnostic and therapeutic procedures in surgery, medicine, and the medical specialties. "Healthcare common procedure coding system (HCPCS)" is a numeric and alphanumeric code set maintained and distributed by the centers for medicare and medicaid services (CMS), http://www.cms.gov, for the uniform designation of certain medical procedures and services.

(2) A "not otherwise specified," "unlisted," or "miscellaneous" procedure code should be reported on a claim only if no procedure code is available that identifies the particular service or item provided.

(3) No separate payment is made for an immunization, injection, infusion, vaccine, toxoid, or provider-administered pharmaceutical as a medical service if it is provided in a hospital setting (inpatient hospital, outpatient hospital, or hospital emergency department).

(4) A provider-administered pharmaceutical reported on a claim submitted in accordance with Chapter 5160-9 of the Administrative Code is regarded as a pharmacy service rather than a physician service, and payment of the claim is governed by the provisions of that chapter. For example, a vaccine, toxoid, or other provider-administered pharmaceutical prescribed for a resident of a long-term care facility (LTCF) and subsequently administered by a LTCF staff member is a pharmacy service.

(5) Payment for an immunization, injection, or infusion includes payment for related supplies (e.g., alcohol wipes, needles, syringes, and tubing).

(B) Coverage of immunizations. An immunization has two components: the administration of the vaccine or toxoid and the vaccine or toxoid itself.

(1) Payment for administration may take one of two forms:

(a) Payment for the most appropriate administration procedure; or

(b) Payment for the least complex evaluation and management service rendered to an established patient.

(2) Separate payment may be made for the vaccine or toxoid. No payment, however, will be made for vaccines that can be obtained at no cost through the federal vaccines for children (VFC) program, which is administered by the Ohio department of health (ODH).

(3) Limitations based on age or gender apply to certain vaccines.

(a) Regardless of the formulation, payment for hepatitis B vaccine (HBV) administered to individuals younger than nineteen years of age may be made only under the VFC program. Different procedure codes must be reported on claims to distinguish HBV administered to individuals younger than nineteen from HBV administered to individuals older than eighteen.

(b) Both the quadrivalent vaccine and the nine-valent vaccine for the human papilloma virus (HPV) are covered for both males and females from nine through twenty-one years of age. ~~For both males and females who are eligible for medicaid only through the family planning services benefit, coverage extends through twenty-six years of age.~~

(c) The bivalent vaccine for HPV is covered for females from nine through twenty-one years of age. ~~For females who are eligible for medicaid only through the family planning services benefit, coverage extends through twenty-six years of age.~~ This vaccine is not covered for males.

(C) Coverage of therapeutic, prophylactic, or diagnostic injections or infusions (excluding chemotherapy and other complex procedures).

(1) An injection or infusion has two components: the administration of a fluid medium and, except in the case of hydration, the pharmaceutical itself. No separate payment is made for the administration service if an injection or infusion is given during the course of an office visit or in conjunction with another medical service that includes an evaluation and management element.

(2) Payment may be made for an injection or infusion or a provider-administered pharmaceutical only if at least one of the following criteria is met:

(a) Its use for a particular indication has been approved by the U.S. food and

drug administration; or

(b) According to accepted standards of medical practice, it is a specific or effective treatment for the particular condition for which it is given.

(3) No separate payment is made for an injection or infusion or a provider-administered pharmaceutical that meets either of the following criteria:

(a) The frequency or duration of its administration exceeds accepted standards of medical practice for the particular condition; or

(b) It is provided for or in association with noncovered medicaid services, which are defined in rule 5160-4-28 of the Administrative Code.

(4) Immune globulin is covered when it is used to provide passive immunity to an individual who is immunosuppressed; has an acquired or congenital immunodeficiency; is at risk of Rho(D) isoimmunization; or is in immediate danger of contracting a communicable disease through direct contact with blood, saliva, or other body fluids through an open wound, bite, puncture, or mucous membrane.

(5) Epoetin alfa (EPO) for the treatment of anemia, either associated with or not related to chronic renal failure, is covered as a medical service when a provider incurs the cost of the drug and the service is provided in a clinic (e.g., a renal dialysis facility) or office setting.

(6) Certain procedure codes represent a specific number of dosage units. On a claim, the fewest number of procedure codes must be reported together to represent the administered dosage.

(D) Coverage of trigger-point injections.

(1) A trigger point is a hyperexcitable area of the body, where the application of a stimulus will provoke pain to a greater degree than in the surrounding area. The purpose of a trigger-point injection is to treat not only the symptom but also the cause through the injection of a single substance (e.g., a local anesthetic) or a mixture of substances (e.g., a corticosteroid with a local anesthetic) directly into the affected body part in order to alleviate inflammation and pain. Payment may be made for a trigger-point injection only if the following criteria are met:

(a) The patient must have a diagnosis for which the trigger-point injection is an appropriate treatment; and

(b) The following information must be documented in the patient's medical record:

(i) A proper evaluation including a patient history and physical examination leading to diagnosis of the trigger point;

(ii) The reason or reasons for selecting this therapeutic option;

(iii) The affected muscle or muscles;

(iv) The muscle or muscles injected and the number of injections;

(v) The frequency of injections required;

(vi) The name of the medication used in the injection;

(vii) The results of any prior treatment; and

(viii) Corroborating evidence that the injection is medically necessary.

(2) A trigger-point injection is normally considered to be a stand-alone service. No additional payment will be made for an office visit on the same date of service unless there is an indication on the claim (e.g., in the form of a modifier appended to the evaluation and management procedure code) that a separate evaluation and management service was performed.

(3) Certain trigger-point injection procedure codes specify the number of injection sites. For these codes, the unit of service is different from the number of injections given. Payment may be made for one unit of service of the appropriate procedure code reported on a claim for service rendered to a particular patient on a particular date.

(4) Trigger-point injections should be repeated only if doing so is reasonable and medically necessary. For trigger-point injections of a local anesthetic or a steroid, payment will be made for no more than eight dates of service per calendar year per patient.

(E) Coverage of skin substitutes.

(1) Skin substitutes for wound treatment and healing are covered in an office setting in conjunction with standard wound care regimens for the treatment of burns or ulcers. Payment may be made to the practitioner when the practitioner utilizes a skin substitute product along with the performance of a valid skin application procedure. Skin substitutes are covered for the treatment of ulcers when a professional practitioner determines a skin substitute will benefit the type of ulcer. Applications and re-applications must show improvement in accordance with paragraph (E)(6) of this rule.

(2) Skin substitutes may be used on burns when skin grafting is not the appropriate option. These covered bioengineered skin substitutes are expected to function as a permanent replacement for lost or damaged skin. They may be used for temporary wound coverage or wound closure as appropriate and medically necessary.

(3) No separate payment is made to a hospital for the supply of skin substitute grafts provided in hospital settings (inpatient hospital, outpatient hospital or hospital emergency department). Payment for the products is included in the hospital's facility payment. When a practitioner applies the skin substitute grafts in a hospital setting, only the professional application procedure is reimbursable to the practitioner.

(4) No separate payment is made to a LTCF for the supply of skin substitute grafts provided by a LTCF for residents of a LTCF. Payment for these products is included in the LTCF payment. Except as provided in paragraph (E)(5) of this rule, when a practitioner applies skin substitute grafts in a LTCF setting, only the professional application procedure is reimbursable to the practitioner.

(5) The supply of skin substitute grafts may be separately reimbursable to a professional practitioner administering wound treatment in a LTCF only when the product is supplied by the practitioner in conjunction with the application of the skin substitute grafting procedure as described in the integumentary system section of the CPT. Payment may be made to the practitioner when the practitioner utilizes a skin substitute product along with the performance of a valid skin application procedure.

(6) If skin substitute applications and re-applications show no significant improvement after three separate treatments, additional re-applications are inappropriate and other treatment modalities should be considered. Skin substitute treatments should not last more than twelve weeks. A decrease of fifty per cent or greater in wound volume must be documented in the medical records for the reimbursement of additional re-applications after twelve weeks of treatment. If after twelve weeks the medical records do not support

the significant improvement of the wound using the skin substitute treatments, the Ohio department of medicaid may recoup any inappropriate reimbursement.

~~(E)~~(F) Claim payment.

(1) On the department's web site, http://medicaid.ohio.gov, is a list of vaccines, toxoids, and other provider-administered pharmaceuticals each of which is covered by medicaid either as a medical service or as a VFC-designated vaccine. Payment for a covered non-VFC vaccine, toxoid, skin substitutes, or other provider-administered pharmaceutical is the lesser of two figures:

(a) The provider's submitted charge; or

(b) The maximum allowable amount, which is the first applicable item from the following ordered list:

(i) An amount specified in or determined in accordance with the Administrative Code;

(ii) The maximum allowable cost (MAC), which is defined in Chapter 5160-9 of the Administrative Code;

(iii) The payment limit shown in the current medicare part B drug pricing file, which is available at http://www.cms.gov;

(iv) One hundred seven per cent of the wholesale acquisition cost (WAC); or

(v) Eighty-five and six-tenths per cent of the average wholesale price (AWP).

(2) The payment amount for any other covered administration service or evaluation and management service is the lesser of the provider's submitted charge or the maximum amount listed in appendix DD to rule 5160-1-60 of the Administrative Code.

Replaces: 5160-4-35, 5160-4-12

Effective:

Five Year Review (FYR) Dates:

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Certification

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Date

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