Ohio | Common Sense Initiative

Mike DeWine, Governor
Jon Husted, Lt. Governor

Joseph Baker, Director

Business Impact Analysis

Agency, Board, or Commission Name: Ohio Department of Medicaid

Rule Contact Name and Contact Information:

Tommi Potter, Rules Administrator, Rules@medicaid.ohio.gov, 614.752.3877

Regulation/Package Title (a general description of the rules' substantive content):

OAC 5160-9 ODM Pharmacy Program

Rule Number(s): OAC 5160-9-01 (rescind/new), 5160-9-02 (rescind/new), 5160-9-05 (rescind/new), 5160-9-06 (amend), and 5160-9-07 (no change)

Date of Submission for CSI Review: 7/28/2023

Public Comment Period End Date: 8/4/2023

Rule Type/Number of Rules:

New/3 rules — **No Change/1 rules (FYR Y)**

Amended/1 rules (FYR Y) — **Rescinded/3 rules (FYR Y)**

The Common Sense Initiative is established in R.C. 107.61 to eliminate excessive and duplicative rules and regulations that stand in the way of job creation. Under the Common Sense Initiative, agencies must balance the critical objectives of regulations that have an adverse impact on business with the costs of compliance by the regulated parties. Agencies should promote transparency, responsiveness, predictability, and flexibility while developing regulations that are fair and easy to follow. Agencies should prioritize compliance over punishment, and to that end, should utilize plain language in the development of regulations.

Reason for Submission

1. **R.C. 106.03 and 106.031 require agencies, when reviewing a rule, to determine whether the rule has an adverse impact on businesses as defined by R.C. 107.52. If the agency determines that it does, it must complete a business impact analysis and submit the rule for CSI review.**

   Which adverse impact(s) to businesses has the agency determined the rule(s) create?

   The rule(s):

   a. ☒ **Requires a license, permit, or any other prior authorization to engage in or operate a line of business.**

   b. ☒ **Imposes a criminal penalty, a civil penalty, or another sanction, or creates a cause of action for failure to comply with its terms.**

   c. ☒ **Requires specific expenditures or the report of information as a condition of compliance.**

   d. ☒ **Is likely to directly reduce the revenue or increase the expenses of the lines of business to which it will apply or applies.**

Regulatory Intent

2. **Please briefly describe the draft regulation in plain language.**

The Ohio Department of Medicaid (ODM) is proposing changes to the OAC rules concerning coverage of pharmacy services. The rules in Chapter 5160-9 outline the Ohio Medicaid pharmacy program benefits and coverage, conditions for participation as a prescriber or pharmacy provider, billing and payment for providers, and cost sharing for Medicaid Fee-For-Service (FFS) members.

Updates to the rules in this chapter include:

• OAC 5160-9-01 is rescinded and made new to create a singular definitions rule for the Chapter in OAC 5160-9-01 which consolidates definitions which were previously located throughout individual rules in Chapter 5160-9. The rule describes the provider types eligible for payment of pharmacy services for pharmacy providers which requires a valid Drug Enforcement Agency (DEA) registration and signed provider agreement with the Ohio Department of Medicaid (ODM). Specialty designation is required for clinic providers, who are not eligible to become "pharmacy providers," but who have valid Medicaid provider agreements and meet criteria under the Ohio.

Revised Code to personally furnish pharmaceuticals and bill for self-administered take-home drugs. Language regarding the cost of dispensing survey requirement was relocated to OAC 5160-9-06.

• OAC 5160-9-02 is rescinded and made new to remove, revise, and relocate the existing appendix of durable medical equipment and medical supplies to be online among the library of pharmacy reference documents, including the unified preferred drug list, quantity limits, etc. to make access easier for providers in a single site and permit inclusion of real-time updates in pricing and coverage. The rule includes a description of the processes for medical supplies and durable medical equipment claims submission and billing, exceptions to the pharmacy billing requirement, and preferred medical supplies. Eligible providers must apply to, and be approved by, the Ohio Department of Medicaid (ODM) to be eligible to dispense medical supplies/durable medical equipment and be licensed, registered, or exempt from licensure or registration under Chapter 4761 of the Revised code to bill for home medical equipment that is subject to regulation under Chapter 4752 of the Revised Code.

• OAC 5160-9-05 is rescinded and made new to include updates for the payment of prescribed drugs. The rule language describes payment for prescribed drugs, including ingredient cost, administration fee, professional dispensing fee, professional dispensing fee for compounded drugs, vaccines, and application of coordination of benefits. Professional dispensing fees are based on the claims volume submitted by a provider through the biannual cost of dispensing survey.

• OAC 5160-9-06 is proposed for amendment. Updates to the rule include renaming the rule from "Pharmacy services: billing and recordkeeping requirements" to "Pharmacy services: billing, record keeping, and cost of dispensing survey requirements," as the rule now includes language describing the cost of dispensing survey requirements which was relocated from OAC 5160-9-01. The rule requires the report of information as a condition of compliance through participation in the cost of dispensing survey. It also imposes a cause of action for failure to comply with its terms with respect to the cost of dispensing survey. Failure to complete the survey may result in a lower payment amount for the professional dispensing fee a provider receives. Failure to participate in the survey could result in reduced revenue for a provider.

• OAC 5160-9-07 is proposed without change to language in the rule body.

• Language was updated throughout the rules to consistently identify people who receive Medicaid services as "recipients" rather than "patient," "member," "consumer," and "individual."

• Language was also updated to active tense and to remove restrictive language wherever possible.

3. **Please list the Ohio statute(s) that authorize the agency, board or commission to adopt the rule(s) and the statute(s) that amplify that authority.**

   The Ohio Department of Medicaid (ODM) is promulgating these rules under sections 5160.34, 5162.03, 5164.02, 5164.7, 5164.752, 5160.34, 5162.031, 5162.20, 5162.30, 5164.02, 5164.03, 5164.70, 5164.7510, 5164.7511, 5164.752, 5164.753, 5164.754, 5164.7570, 5164.79, 5165.01, and 5165.47 of the Revised Code.

4. **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?**
   Yes, the rule changes are necessary to allow ODM to continue receiving Federal Financial Participation as part of the medicaid program. The regulation does not exceed the federal requirements.

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

   These rules do not include any provisions that exceed federal requirements.

6. **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)?**

   These rules involve the coverage of and payment for pharmacy services. ODM is required to adopt such rules under R.C. 5164.02.

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

   The success of these rules is measured by the extent to which providers can submit claims and receive correct payment.

8. **Are any of the proposed rules contained in this rule package being submitted pursuant to R.C. 101.352, 101.353, 106.032, 121.93, or 121.931?**
   No.

Development of the Regulation

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

- Ohio Association of Community Health Centers
- Ohio Hospital Association
- Ohio State Medical Association
- Ohio Pharmacists Association
- Ohio Council of Retail Merchants
- National Association of Chain Drug Stores
- National Community Pharmacist Association
- Medicaid Managed Care Entities

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

Any changes and needed modifications that came to light through the clearance process were accepted by ODM and incorporated into the rules.

11. 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 these rule.

12. 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?

ODM is required to adopt rules to establish coverage of and payment for Medicaid services. Whatever the policy may be, the form of the rule is the same; no alternative is readily apparent.

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

In the process of revising the rules, ODM staff members took great care not to duplicate provisions. Any provision of another rule applying specifically to these services is incorporated by reference.

14. 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.

Changes resulting from the rules will be implemented through the pharmacy pricing and audit consultant (PPAC) and the single pharmacy benefit manager (SPBM) with oversight from ODM.

Adverse Impact to Business

15. Provide a summary of the estimated cost of compliance with the rule(s). Specifically, please do the following:

a. Identify the scope of the impacted business community, and

b. Quantify and identify the nature of all adverse impact (e.g., fees, fines, employer time for compliance, etc.).

All fees associated with licensing in the state of Ohio, as a pharmacy provider, as defined in section 4729.15 of the Revised Code are required for a provider to practice in Ohio regardless of their participation with the Ohio Medicaid program. Providers are additionally required to have a valid Drug Enforcement Agency (DEA) registration and signed provider agreement with the Ohio Department of Medicaid (ODM).

Adverse impacts to providers include time spent to complete a biannual cost of dispensing survey required in section 5164.752 of the Revised Code which is estimated to take less than two hours for completion. Failure to complete the survey results in assignment to the lowest rate for the professional dispensing fee.

16. Are there any proposed changes to the rules that will reduce a regulatory burden imposed on the business community? Please identify.

Many of the changes made to OAC Chapter 5160-9 rules were made to provide clarity to processes for coverage, billing, and payment and to centralize information available for providers and other stakeholders and partners.

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

Completion of a cost of dispensing survey by terminal distributors of dangerous drugs is required by section 5164.752 of the Revised Code and time spent to complete the survey is less than two hours. Professional dispensing fees are based on the claims volume submitted by a provider through the biannual cost of dispensing survey and higherclaims volumes could cause a provider to be moved to a lower tier of dispensing fee. Any costs associated with licensing in the state of Ohio, as a pharmacy provider, as defined in section 4729.15 of the Revised Code would be required for a provider to practice in Ohio regardless of their participation with the Ohio Medicaid program. Providers are additionally required to have a valid Drug Enforcement Agency (DEA) registration and signed provider agreement with the Ohio Department of Medicaid (ODM).

Regulatory Flexibility

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

Medicaid rules outline all actions providers must take to receive Medicaid payment. They do not set forth requirements for engaging in business and no exception is made based on the size of an entity or organization.

19. 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?

Not applicable. Ohio Administrative Code 5160-9-06 requires the report of information as a condition of Compliance through participation in the cost of dispensing survey. It also imposes a cause of action for failure to comply with its terms with respect to the cost of dispensing survey. Failure to complete the survey may result in a lower payment amount for the professional dispensing fee a provider receives. Failure to participate in the survey could result in reduced revenue for a provider.

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

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

Policy questions may be directed via e-mail to the ODM's pharmacy section: Medicaid_pharmacy@medicaid.ohio.gov .

5160-9-01 **Pharmacy services: definitions.**

(A) Covered drugs.

(1) "Compounded prescriptions" are prescription drugs made by combining two or more drugs. Active pharmaceutical ingredients (API) and excipients are listed on the ODM pharmacy program website at https://pharmacy.medicaid.ohio.gov.

(2) "Covered prescribed drug" means a drug covered by the Ohio department of medicaid (ODM) pharmacy program, or a managed care plan entity as defined in rule 5160-26-01 of the Administrative Code. Covered prescribed drugs are prescribed drugs that are dispensed to an eligible recipient for use in the recipient's residence, including a nursing facility (NF), as defined in section 5165.01 of the Revised Code, or intermediate care facility for individuals with intellectual disabilities (ICF/IID), as defined in section 5124.01 of the Revised Code, and fall into one of the following categories:

(a) "Dangerous drugs" as defined in section 4729.01 of the Revised Code that meet the definition of a "covered outpatient drug (COD)" as defined in 42 C.F.R. 447.502 (November 19, 2021) that are not non-covered drugs.

(b) Over-the-counter (OTC) drugs listed on the "OH PBM OTC List" located on the ODM pharmacy website at https://pharmacy.medicaid.ohio.gov. The list is updated regularly and is recorded with the effective date included in each new version.

(B) "Noncovered drugs" are drugs that fall into one of the following categories for which coverage is not available through the Ohio medicaid pharmacy program as described in Rule 5160-9-03 of the Administrative Code.

(C) Pricing.

(1) "340B ceiling price" means the highest price allowed to be charged by a manufacturer to a 340B covered entity as described in section 340B(a)(4) of the "Public Health Service Act," 42 U.S.C. 256b(a)(4) (in effect as of June 25, 2020).

(2) "Actual acquisition cost (AAC) means the best determination by the Ohio department of medicaid (ODM) of the actual amount the provider paid to purchase the prescribed drug. ODM acquires AAC data through one or more of the following: national survey of retail pharmacy providers, e.g., national average drug acquisition cost (NADAC) rate process, states' surveys of retail pharmacy providers e.g.,Ohio average acquisition cost (OAAC), and published compendia prices, e.g., wholesale acquisition cost (WAC).

(3) "Administration fee" means the maximum amount payable to a provider to administer a vaccine or injectable drug that is payable under this chapter and authorized to be administered by a pharmacist or pharmacy intern in accordance with sections 4729.41 and 4729.45 of the Revised Code and the rules promulgated thereunder.

(4) "Equivalent drug product" means drug products with the same active ingredient, strength, and dosage form.

(5) "Equivalent generic drug products" means equivalent drug products that are identified by the medicaid drug rebate program (MDRP) drug product data files as non-innovator products. MDRP files are available on the federal centers for medicare and medicaid services (CMS) website at https://www.medicaid.gov.

(6) "Ingredient cost" means the portion of the total medicaid payment amount attributable to the cost of the drug product, or in the case of a compound drug, the sum of the cost of the ingredients that are covered in accordance with rule 5160-9-03 of the Administrative Code.

(7) "Long-term care facility (LTCF)" means a nursing facility as defined in section 5165.01 of the Revised Code or intermediate care facility for individuals with intellectual disabilities as defined in section 5124.01 of the Revised Code.

(8) "NADAC" means the rate determined by the CMS to be the average AAC for retail community pharmacies. NADAC rates are on the CMS website at https://www.medicaid.gov.

(9) "Ohio average acquistion cost (OAAC)" means pricing that more accurately reflects the actual acquisition cost for drugs for pharmacy providers in Ohio and is based on actual costs for the provider to purchase a drug.

(10) "Prescribed drug" has the same meaning as in section 5164.01 of the Revised Code.

(11) "Professional dispensing fee (PDF)" means the fee or fees determined pursuant to section 5164.753 of the Revised Code and set forth in this rule.

(12) "State maximum allowable cost (SMAC)" means the maximum amount determined by ODM, based upon an estimate of the statewide average acquisition cost (AAC) for a particular equivalent generic drug group, to be paid to Ohio medicaid providers for an equivalent generic drug group.

(13) "WAC" means the amount reported by a pharmaceutical manufacturer to pharmacy pricing compendia as the list price for a drug and may not represent the actual price of a particular transaction.

(D) Provider types eligible for payment for pharmacy services.

(1) "Clinic" providers with valid medicaid provider agreements and meet the criteria under the Revised Code to personally furnish pharmaceuticals, but are not eligible to become a "pharmacy provider" are eligible to apply for a "pharmacy" specialty designation and bill for self-administered take-home drugs.

(2) A "pharmacy provider" designation and provider number can be obtained by a "terminal distributor of dangerous drugs," as defined in section 4729.01 of the Revised Code, who:

(a) Has a valid drug enforcement agency (DEA) registration; and,

(b) Has a pharmacist as the "responsible person," as defined in rule 4729:5-2-01 of the Administrative Code; and,

(c) Complies with eligible provider rules 5160-1-17 to 5160-1-17.9 of the Administrative Code and signs a provider agreement with the Ohio department of medicaid (ODM).

(3) A "hospital" provider acting as a pharmacy can obtain a "pharmacy" specialty designation and bill for self-administered take-home drugs.

TO BE RESCINDED

5160-9-01 **Eligible providers of pharmacy services and cost of dispensing survey.**

(A) Provider types eligible for payment for pharmacy services:

(1) A "pharmacy provider" designation and provider number can be obtained by a "terminal distributor of dangerous drugs," as defined in section 4729.01 of the Revised Code, who also:

(a) Has a valid drug enforcement agency (DEA) registration; and

(b) Has a pharmacist as the "responsible person," as defined in rule 4729-5-11 of the Administrative Code; and

(c) Complies with eligible provider rules 5160-1-17 to 5160-1-17.11 of the Administrative Code and signs a provider agreement with the Ohio department of medicaid (ODM).

(2) A "hospital" provider acting as a pharmacy in accordance with paragraphs (A)(1)(a) to (A)(1)(c) of this rule can obtain a "pharmacy" specialty designation and bill for self-administered take-home drugs.

(3) "Clinic" providers that have a valid medicaid provider agreement and have met the criteria under the Revised Code to personally furnish pharmaceuticals but are not eligible to become a "pharmacy provider" as defined in paragraph (A)(1) of this rule, are eligible to apply for a "pharmacy" specialty designation and bill for self-administered take-home drugs.

(B) Provider types described in paragaph (A) of this rule are required to submit a complete response to the cost of dispensing survey conducted according to section 5164.752 of the Revised Code.

(1) A complete response to the cost of dispensing survey includes supplying complete information about the terminal distributor for, at the least, all of the following categories:

(a) Demographics;

(b) Number of prescriptions dispensed annually, broken out by medicaid fee-for-service and other payers and including a total volume for the location;

(c) Sales and cost of goods sold;

(d) Direct expenses;

(e) Overhead expenses; and

(f) Certification that the person who submits the survey believes the information to be true, correct, and complete.

(2) Providers that do not submit a complete response to the cost of dispensing survey may be paid a lower professional dispensing fee (PDF) in accordance with paragraph (E)(1) of rule 5160-9-05 of the Administrative Code.

(3) Newly-enrolled providers shall be assigned to the dispensing fee described in paragraph (E)(1)(b)(vi) of rule 5160-9-05 of the Administrative Code, unless the provider received the new provider number due to a change in ownership. In that situation, the department shall use the number of prescriptions reported by the previous owner to determine the PDF. In a situation other than a change of ownership, a provider is newly-enrolled if the date of approval of an application to enroll as a provider, or the date of approval of a pharmacy specialty designation, is less than ninety days prior to the distribution of the most recently-conducted cost of dispensing survey. The date of approval is not the effective date of the provider agreement or specialty designation when the effective date is made retroactive by ODM.

(4) If a provider experiences a change in prescription volume during the first nine months following the implementation of a PDF category significant enough that it would result in the provider falling into a different PDF category, the provider may submit a written request with supporting documentation to ODM, no later than the thirtieth day of April of the first year, requesting assignment to a different category. If the supporting documentation justifies an adjustment, ODM will assign a new PDF category effective the first day of July for the second year.

(5) Providers that did not submit a complete response to the cost of dispensing survey conducted in 2016 may submit an attestation of the number of prescriptions filled in the provider's most recently completed fiscal year or other twelve-month period beginning no earlier than January 1, 2015. The attestation shall follow the format posted on the ODM website at http://pharmacy.medicaid.ohio.gov.

Effective:

Five Year Review (FYR) Dates:

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Certification

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Date

Promulgated Under:	119.03
Statutory Authority:	5164.02
Rule Amplifies:	5164.02, 5164.03, 5164.752
Prior Effective Dates:	04/07/1977, 09/19/1977, 12/21/1977, 12/30/1977, 07/08/1978, 10/01/1978, 05/09/1986, 11/01/1986, 10/01/1987, 02/01/1988, 01/13/1989 (Emer.), 04/13/1989, 06/01/1989, 07/01/1994, 10/01/1997, 02/03/2000 (Emer.), 05/01/2000, 04/14/2005, 08/02/2011, 04/01/2017

5160-9-02 **Pharmacy services: medical supplies and durable medical equipment.**

(A) Eligible pharmacies in the Ohio medicaid program may bill for medical supplies and durable medical equipment in accordance with Chapter 5160-10 of the Administrative Code, with the following stipulations:

(1) The provider must:

(a) apply to, and be approved by, the Ohio department of medicaid (ODM) to be eligible to dispense medical supplies/durable medical equipment; and

(b) use the same medicaid provider number as when billing for pharmaceuticals; and

(c) be licensed, registered, or exempt from licensure or registration under Chapter 4761. of the Revised Code to bill for home medical equipment that is subject to regulation under Chapter 4752. of the Revised Code.

(2) All products require a prescription written by a practitioner authorized to prescribe. The prescription must be obtained by and kept on file at the pharmacy.

(B) Claims submission and billing.

(1) Medical supplies/durable medical equipment is billed in the appropriate claim format designated by ODM for those services.

(2) Medical supplies, durable medical equipment, prosthetic, and orthotic devices are billed by pharmacy providers in accordance with Chapter 5160-10 of the Administrative Code.

(3) Medical supplies are billed by eligible providers of pharmacy services only, except as specified in paragraph (C) of this rule. Eligible providers of pharmacy services may bill for these items without applying to ODM for eligibility for dispensation of medical supplies/durable equipment as described in Chapter 5160-10 of the Administrative Code. The list of supplies is located on the ODM pharmacy website at https://pharmacy.medicaid.ohio.gov.

(4) Quantities billed should equal the number of items dispensed (e.g., the quantity of test strips billed should equal the number of individual test strips, not the number of boxes).

(5) The medical supplies document "Pharmacy benefits: medical supplies and durable medical equipment products" is located on the ODM pharmacy website and includes five columns indicating supply item coverage and

payments. The supplies in the document are billed through the pharmacy point of sale claims system using the national drug code (NDC) on the container from which the product was dispensed.

(a) Payment is the lesser of the submitted charge or the calculated allowable. The calculated allowable is the medicaid maximum payment.

(b) The calculated allowable is the medicaid maximum payment plus the professional dispensing fee applicable to the provider as described in paragraph (E)(1)(b) of rule 5160-9-05 of the Administrative Code.

(C) Exceptions to pharmacy billing requirement.

(1) Contraceptive supplies listed in the appendix to this rule may be billed by both pharmacy providers and providers eligible to bill in accordance with rule 5160-10-01 of the Administrative Code. Pharmacy provider should bill through the pharmacy point of sale claims system using the NDC on the container from which the product was dispensed.

(2) Supplies billed to medicare as the primary payer and crossed over to medicaid using the medicare crossover process described in paragraph (B) of rule 5160-1-05 of the Administrative Code may be billed by any provider eligible for the medicare crossover process.

(D) Preferred medical supplies.

(1) Selected products from the medical supply categories included in the appendix of this rule are designated as preferred brands, as specified on the ODM website at https://pharmacy.medicaid.ohio.gov.

(2) Products that are not designated as preferred supplies require prior authorization.

(a) Only the prescribing provider or a member of the prescribing provider's staff may request prior authorization.

(b) The prescriber should document medical necessity for the non-preferred brand and provide the reason why preferred brand cannot be used.

(c) When a request for prior authorization is denied, the recipient is informed in writing of the denial as well as informed of the right to appeal the denial.

TO BE RESCINDED

5160-9-02 **Pharmacy services: medical supplies and durable medical equipment.**

(A) Eligible pharmacies in the Ohio medicaid program may bill for medical supplies and durable medical equipment in accordance with Chapter 5160-10 of the Administrative Code, with the following stipulations:

(1) The provider must apply to, and be approved by, the Ohio department of medicaid (ODM) to be eligible to dispense medical supplies/durable medical equipment.

(2) All products require a prescription written by a practitioner authorized to prescribe. The prescription must be obtained by and kept on file at the pharmacy.

(3) The provider must use the same medicaid provider number as when billing for pharmaceuticals.

(4) The provider must be licensed, registered, or exempt from licensure or registration under Chapter 4761. of the Revised Code to bill for home medical equipment that is subject to regulation under Chapter 4752. of the Revised Code.

(B) Claims submitted for medical supplies/durable medical equipment must be billed in the appropriate claim format designated by ODM for those services.

(C) Medical supplies, durable medical equipment, prosthetic, and orthotic devices may be billed by pharmacy providers in accordance with Chapter 5160-10 of the Administrative Code.

(D) Only eligible providers of pharmacy services as described in rule 5160-9-01 of the Administrative Code are eligible to bill for the medical supplies listed in the appendix to this rule, except as specified in paragraph (G) of this rule. Eligible providers of pharmacy services may bill for these items without applying to ODM to be eligible to dispense medical supplies/durable medical equipment as described in Chapter 5160-10 of the Administrative Code.

(E) The quantity billed should be equal to the number of items dispensed (e.g., the quantity of test strips billed should be the number of individual test strips, not the number of boxes). The table in the appendix to this rule includes five columns to indicate supply item coverage and payment.

(1) Item description. This column describes the supply item.

(2) Medicaid coverage status. This column has one of two possible indicators for each item. "Y" indicates the item is covered by medicaid for all individuals eligible for medicaid and may be billed directly to ODM by the provider. "H" indicates that the item may be billed directly to ODM only if the item is intended for use by the individual in their personal residence, with the exception of individuals who reside in a nursing facility (NF), as defined in section 5165.01 of the Revised Code, or intermediate care facility for individuals with intellectual disabilities (ICF/IID), as defined in section 5124.01 of the Revised Code. For individuals residing in a NF or ICF/IID, the supply is the responsibility of the NF or ICF/IID and is included in the NF or ICF/IID facility per diem payment.

(3) Covered for dual eligible. This column indicates whether the supply is covered under the medicaid program for an individual who is a dual eligible as defined in rule 5160-1-05 of the Administrative Code. "Y" indicates the supply is covered for a dual eligible. "N" indicates the supply is not covered for a dual eligible.

(4) Maximum units. This column indicates the largest number of units of the supply that may be dispensed within the time period indicated. Claims submitted that exceed the maximum units shall be denied. Denials may be overridden by ODM or its designee in cases where medical necessity has been determined through prior authorization obtained by the prescriber from the ODM point-of-sale vendor.

(5) Maximum payment. This column indicates the medicaid maximum payment per item as defined in rule 5160-1-60 of the Administrative Code. Supplies with "*" in this column indicate that maximum payment will be calculated based on the wholesale acquisition cost (WAC) as defined in rule 5160-9-05 of the Administrative Code.

(a) For dates of service before the effective date of this rule, the maximum payment shall be one hundred seven per cent of WAC.

(b) For dates of service on or after the effective date of this rule, the maximum payment shall be one hundred per cent of WAC.

(F) The supplies listed in the appendix to this rule should be billed through the pharmacy point of sale claims system using the national drug code (NDC) on the container from which the product was dispensed. Payment shall be the lesser of the submitted charge or the calculated allowable. The calculated allowable is the medicaid maximum payment as described in paragraph (E)(5)(a) of this rule. For dates of service on or after the effective date of this rule, the calculated allowable is the medicaid maximum

payment as described in paragraph (E)(5)(b) of this rule plus the professional dispensing fee applicable to the provider as described in paragraph (E)(1)(b) of rule 5160-9-05 of the Administrative Code.

(G) Exceptions to pharmacy billing requirement.

(1) Contraceptive supplies listed in the appendix to this rule may be billed by both pharmacy providers and providers eligible to bill in accordance with rule 5160-10-01 of the Administrative Code. Pharmacy providers shall bill these supplies in accordance with paragraph (F) of this rule.

(2) Supplies billed to medicare as the primary payer and crossed over to medicaid using the medicare crossover process described in paragraph (B) of rule 5160-1-05 of the Administrative Code may be billed by any provider eligible for the medicare crossover process.

(H) Preferred medical supplies

(1) Selected products from the medical supply categories included in the appendix to this rule have been designated as preferred brands, as specified on the ODM web site at http://pharmacy.medicaid.ohio.gov.

(2) Products that have not been designated as preferred require prior authorization.

(a) Only the prescribing provider or a member of the prescribing provider's staff may request prior authorization.

(b) The prescriber shall document medical necessity for the non-preferred brand and why a preferred brand cannot be used.

(c) When a request for prior authorization is denied, the consumer will be informed in writing of the denial and the right to a state hearing.

Effective:

Five Year Review (FYR) Dates:

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Certification

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Date

Promulgated Under:	119.03
Statutory Authority:	5164.02
Rule Amplifies:	5162.03, 5164.02, 5164.70
Prior Effective Dates:	04/07/1977, 12/21/1977, 05/09/1986, 10/01/1997, 08/30/2001, 07/01/2006, 02/01/2010, 10/01/2011, 07/01/2013, 04/01/2017

Pharmacy Benefit: Medical Supplies and Durable Medical Equipment Products
Effective November 1, 2023

Item Description	Residence	Frequency Limit	Prior Authorization	Maximum Payment Amount
Alcohol wipe or swab	Non-LTCF	1020 per 102 days	Limit-based	$0.02
Blood glucose monitor for home use	Non-LTCF	1 per 720 days	Limit-based	Lesser of WAC or OAAC
Blood glucose test strip or reagent strip for home blood glucose monitor	Non-LTCF	714 per 102 days	Limit-based	Lesser of WAC or OAAC
Blood ketone test strip or reagent strip	Non-LTCF	340 per 102 days	Limit-based	Lesser of WAC or OAAC
Continuous glucose monitor (CGM) receiver	Non-LTCF	1 per three years	Limit-based	Lesser of WAC or OAAC
CGM sensor	Non-LTCF	3 per month	Limit-based	Lesser of WAC or OAAC
CGM transmitter	Non-LTCF	1 per three months	Limit-based	Lesser of WAC or OAAC
Contraceptive supply, condom, female	Non-LTCF	36 per month	Limit-based	$2.10
Contraceptive supply, condom, male	Non-LTCF	36 per month	Limit-based	$0.40
Insulin delivery device, reusable pen; 1.5 ml	Non-LTCF	1 per year	Limit-based	$40.00
Insulin delivery device, reusable pen; 3.0 ml	Non-LTCF	1 per year	Limit-based	$40.00
Lancet	Non-LTCF	714 per 102 days	Limit-based	Lesser of WAC or OAAC
Lancing device	LTCF / Non-LTCF	1 per year	Limit-based	Lesser of WAC or OAAC
Needle, sterile, any size (including pen needle)	Non-LTCF	714 per 102 days	Limit-based	Lesser of WAC or OAAC
Normal-low-high calibration solution/chips (for blood glucose monitor)	Non-LTCF	1 bottle per three months	Limit-based	Lesser of WAC or OAAC

Peak expiratory flow rate meter	Non-LTCF	1 per three years	Limit-based	$22.00
Spacer, bag, or reservoir, with or without mask, for use with metered dose inhaler	Non-LTCF	1 per year	Limit-based	$23.00
Syringe with needle, sterile, ≤ 1 cc	Non-LTCF	714 per 102 days	Limit-based	Lesser of WAC or OAAC
Urine test strip or reagent strip or tablet	Non-LTCF	340 per 102 days	Limit-based	$0.26

WAC – wholesale acquisition cost
OAAC- Ohio average acquisition cost

Supplies Billed by Ohio Medicaid Pharmacy Providers

Item Description	Medicaid Coverage Status	Covered for Dual Eligible	Maximum Units	Maximum Payment
Alcohol wipes or swabs	H	Y	200 per month	$0.02
Blood glucose monitor for home use	H	N	1 per four years	*
Blood glucose test or reagent strips for home blood glucose monitor	H	N	100 per month	*
Blood ketone test or reagent strips	H	Y	20 per month	*
Continuous Glucose Monitoring (CGM): Transmitter **	H	N	1 per three months	*
CGM: Receiver **	H	N	1 per four years	*
CGM: Sensors **	H	N	4 per month	*
Contraceptive supply, condom, female	H	Y	36 per month	$2.10
Contraceptive supply, condom, male	H	Y	36 per month	$0.40
Insulin delivery device, reusable pen; 1.5ml size	H	N	1 per year	$40.00
Insulin delivery device, reusable pen; 3ml size	H	N	1 per year	$40.00
Lancets	H	N	200 per month	*
Lancing Device	Y	N	1 per year	*
Needles only, sterile, any size, including pen needles	H	N	100 per month	*
Normal, low high calibration solution/chips (for blood glucose monitor)	H	Y	1 bottle per three months	*
Peak Expiratory Flow Rate Meter	H	Y	1 per three years	$22.00
Spacer, bag, or reservoir, with or without mask, for use with metered dose inhaler	H	Y	1 per year	$23.00
Syringe with needle, sterile less than or equal to 1 cc	H	Y	200 per month	*
Urine test or reagent strips or tablets	H	Y	200 per month	$0.26

* Maximum payment calculated as 100% of wholesale acquisition cost

** Prior authorization Required for CGM supplies

Effective April 1, 2017

5160-9-05 **Pharmacy services: payment for prescribed drugs.**

(A) Payment for prescribed drugs is the lesser of the provider's billed charges or the calculated allowable, after any coordination of benefits is applied as described in paragraph (E) of this rule. For prescribed drugs that are subject to a co-payment, the amount paid by the Ohio department of medicaid (ODM) is decreased by the amount equal to the co-payment billed to the recipient in accordance with rules 5160-1-09 and 5160-9-09 of the Administrative Code.

(B) The ingredient cost portion of the calculated allowable is determined in accordance with the following criteria:

(1) No ingredient cost is allowed for a pandemic vaccine or any other medication, provided by the Ohio department of health or other government entity at no cost to the provider.

(2) For any drug purchased under the 340B program, the ingredient cost is the lesser of submitted ingredient cost or the 340B ceiling price. If the 340B ceiling price is not available, the ingredient cost is the lesser of the submitted ingredient cost or fifty per cent of wholesale acquisition cost (WAC) If WAC is not available, the ingredient cost is the lesser of submitted ingredient cost or Ohio average acquisition cost (OAAC).

(3) For a clotting factor, the ingredient cost is the lesser of submitted ingredient cost or the payment limit shown in the current medicare part B drug pricing file, minus the furnishing fee assigned by medicare part B. The medicare part B pricing file is available at https://www.cms.gov.

(4) For all other ingredients not captured in paragraphs (B)(1) to (B)(3) of this rule the ingredient cost is the lesser of submitted ingredient cost or national average drug acquisition cost (NADAC). If the centers for medicare and medicaid services (CMS) has not published a NADAC for the ingredient for the date of service, the ingredient cost is the lesser of submitted ingredient cost or WAC.

(C) The administration fee portion of the calculated allowable for a vaccine, except for a vaccine for COVID-19, or other injectable drug administered at the pharmacy is nineteen dollars thirty-five cents. The administration fee for a vaccine for COVID-19 equals the medicare rate.

(D) The professional dispensing fee (PDF) portion of the calculated allowable is determined in accordance with the following criteria:

(1) The PDF to a provider for dispensing a non-compounded drug is assigned on the total number of prescriptions filled by the provider during the provider's last completed fiscal year prior to completing the required cost of dispensing survey and reported on the survey. The PDF is assigned in accordance with the following criteria:

(a) For provider reporting fewer than fifty thousand prescriptions, thirteen dollars and sixty-four cents.

(b) For providers reporting between fifty thousand and seventy-four thousand nine hundred ninety-nine prescriptions, ten dollars and eighty cents.

(c) For providers reporting between seventy-five thousand and ninety-nine thousand nine hundred ninety-nine prescriptions, nine dollars and fifty-one cents.

(d) For providers reporting one hundred thousand or more prescriptions, eight dollars and thirty cents.

(e) For a provider who failed to complete response to the required cost of dispensing fee survey for the previous reporting period, eight dollars and thirty cents.

(f) For providers newly enrolled as medicaid providers as described in rule 5160-9-06 of the Administrative Code, the PDF is as follows:

(i) For a new provider located in Ohio, the provider is assigned a PDF of thirteen dollars and sixty-four cents.

(ii) For a new provider located outside of Ohio, the provider is assigned a PDF of eight dollars and thirty cents.

(2) The PDF paid to a provider for dispensing compounded drugs is paid in accordance with the following criteria:

(a) The PDF for claims for dispensing total parenteral nutrition (TPN) is fifteen dollars per one-day supply on the claim, with a maximum total PDF of one hundred fifty dollars for the claim. To qualify for the TPN PDF, the TPN compound must be mixed by the pharmacy to the final form under sterile conditions. If the products are mixed or activated at the point of administration by connecting components or breaking seals without the need for sterile conditions, the dispensing does not qualify for payment of the compounded PDF.

(b) The PDF for dispensing sterile compounds, other than TPN, that are required to be sterile for a route of administration including inhaled, infused, instilled, implanted or injected, is ten dollars per days' supply,a maximum of seventy dollars for the claim. To qualify for payment of the sterile compound PDF, the sterile compound must be mixed by the pharmacy to the final form under sterile conditions. Products mixed or activated at the point of administration by connecting components or breaking seals without the need for sterile conditions are not eligible for

a sterile compound PDF.

(c) Compounded drugs that are not eligible for the TPN or sterile compound PDF will receive the PDF determined under paragraph (D) of this rule.

(3) Vaccine or injectable drug dispensing that qualifies for payment of an administration fee does not qualify for medicaid payment of a PDF.

(4) Notwithstanding paragraph (D)(1) of this rule, prescribed drugs, other than compounded drugs, dispensed to recipients residing in long term care facilities (LTCFs) are limited to one PDF per patient, per equivalent product, per month . If multiple supplies of an equivalent product are dispensed within the same month, only the ingredient cost will be paid. Exceptions to the one PDF per recipient, per product rule are:

(a) The prescriber ordered a second round of medication for an acute condition within the month.

(b) The prescriber changed the dosage.

(c) The drug was compromised by accident, including but not limited to being contaminated or destroyed.

(E) Coordination of benefits.

(1) Claims for medicare part B cost sharing as described in rule 5160-1-05 of the Administrative Code are submitted using the medical claim format and are not payable under this chapter.

(2) No payment will be made under this chapter for any drug that may be covered by medicare part D for an recipient who is eligible for coverage by medicare part D, regardless of whether the recipient is actually enrolled in a part D plan or the particular drug is covered by the recipient's part D plan.

(3) Cost-sharing for claims involving neither medicare part B nor medicare part D is determined in accordance with rule 5160-1-08 of the Administrative Code.

TO BE RESCINDED

5160-9-05 **Pharmacy services: payment for prescribed drugs.**

(A) Definitions.

(1) "340B ceiling price" means the highest price allowed to be charged by a manufacturer to a 340B covered entity as described in section 340B(a)(4) of the "Public Health Service Act," 42 U.S.C. 256b(a)(4) (in effect as of January 7, 2011).

(2) "Actual acquisition cost (AAC)" means the best determination by the Ohio department of medicaid (ODM) of the actual amount the provider paid to purchase the prescribed drug. ODM acquires AAC data through one or more of the following: national survey of retail pharmacy providers, e.g., national average drug acquisition cost (NADAC) rate process, states' surveys of ~~retail~~ pharmacy providers e.g.,Ohio average acquisition cost (OAAC), and published compendia prices, e.g., wholesale acquisition cost (WAC).

(3) "Administration fee" means the maximum amount payable to a provider to administer a vaccine or injectable drug that is payable under this chapter and authorized to be administered by a pharmacist or pharmacy intern in accordance with sections 4729.41 and 4729.45 of the Revised Code and the rules promulgated thereunder.

(4) "Calculated allowable" means the sum of the ingredient cost plus any applicable administration fee or professional dispensing fee.

(5) "Equivalent drug product" means drug products with the same active ingredient, strength, and dosage form.

(6) "Equivalent generic drug products" means equivalent drug products that are identified by the medicaid drug rebate program (MDRP) drug product data files as non-innovator products. MDRP files are available on the federal centers for medicare and medicaid services (CMS) web site at https://www.medicaid.gov.

(7) "Ingredient cost" means the portion of the total medicaid payment amount attributable to the cost of the drug product, or in the case of a compound drug, the sum of the cost of the ingredients that are covered in accordance with rule 5160-9-03 of the Administrative Code.

(8) "Long-term care facility (LTCF)" means a nursing facility as defined in section 5165.01 of the Revised Code or intermediate care facility for individuals with intellectual disabilities as defined in section 5124.01 of the Revised Code.

(9) "NADAC" means the rate determined by the CMS to be the average AAC for retail community pharmacies. NADAC rates are on the CMS website at https://www.medicaid.gov.

(10) "Prescribed drug" has the same meaning as in section 5164.01 of the Revised Code.

(11) "Professional dispensing fee (PDF)" means the fee or fees determined pursuant to section 5164.753 of the Revised Code and set forth in this rule.

(12) "State maximum allowable cost (SMAC)" means the maximum amount determined by ODM, based upon an estimate of the statewide AAC for a particular equivalent generic drug group, to be paid to Ohio medicaid providers for an equivalent generic drug group.

(13) "WAC" means the amount reported by a pharmaceutical manufacturer to pharmacy pricing compendia as the list price for a drug and may not represent the actual price of a particular transaction.

(B) Payment for prescribed drugs is the lesser of the provider's billed charges or the calculated allowable, after any coordination of benefits is applied as described in paragraph (F) of this rule. For prescribed drugs that are subject to a co-payment, the amount paid by ODM ~~will be~~ is decreased by the amount equal to the co-payment ~~that is to be~~ billed to the ~~individual~~ recipient in accordance with rules 5160-1-09 and 5160-9-09 of the Administrative Code.

(C) The ingredient cost portion of the calculated allowable ~~shall be~~ is determined in accordance with the following criteria:

(1) No ingredient cost ~~shall be~~ is allowed for a pandemic vaccine or any other medication, ~~that is~~ provided by the Ohio department of health or other government entity at no cost to the provider.

(2) For ~~dates of service on or after April 1, 2017, for~~ any drug purchased under the 340B program, the ingredient cost is the lesser of submitted ingredient cost or the 340B ceiling price. If the 340B ceiling price is not available, the ingredient cost ~~shall be~~ is the lesser of the submitted ingredient cost or fifty per cent of WAC.

(3) For ~~dates of service on or after April 1, 2017, for~~ a clotting factor, the ingredient cost ~~shall be~~ is the lesser of submitted ingredient cost or the payment limit shown in the current medicare part B drug pricing file, minus the furnishing fee assigned by medicare part B. The medicare part B pricing file is available at https://www.cms.gov.

(4) For all other ingredients not captured in paragraphs (C)(1) to (C)(3) of this rule~~:~~ the ingredient cost is the lesser of submitted ingredient cost or NADAC. If CMS has not published a NADAC for the ingredient for the date of service, the ingredient cost is the lesser of submitted ingredient cost or WAC.

(a) ~~For dates of service prior to April 1, 2017, including drugs purchased under the 340B program and clotting factors:~~

~~(i) Maximum allowable cost (MAC) pharmaceuticals.~~

~~*(a)* Maximum allowable costs have been determined by the federal department of health and human services for selected drugs. ODM shall not make payment for these products, in the aggregate, at a rate higher than the federal upper limit prices.~~

~~*(b)* ODM established a SMAC for additional selected drugs where either bio-equivalency of the drugs has been established or bio-inequivalency of the drugs has not been established. Payment for SMAC drugs shall be based on the sixty-fifth percentile of the estimated acquisition cost of all readily available equivalent generic drug products.~~

~~(ii) Estimated acquisition cost (EAC) pharmaceuticals. All products, other than those designated as MAC drugs, will be considered EAC drugs. Reimbursement will be based on the estimate of WAC determined by periodic review of pricing information from Ohio drug wholesalers, pharmaceutical manufacturers and a pharmacy pricing update service. Maximum reimbursement for these drugs will be WAC plus seven per cent.~~

(b) ~~For dates of service on or after April 1, 2017, the ingredient cost shall be the NADAC. If CMS has not published a NADAC for the ingredient for the date of service, the ingredient cost shall be the lesser of WAC or SMAC.~~

(D) ~~For dates of service on or after April 1, 2017, the~~ The administration fee portion of the calculated allowable for a vaccine, except for a vaccine for COVID-19, or other injectable drug administered at the pharmacy ~~shall be~~ is nineteen dollars thirty-five

cents. The administration fee for a vaccine for COVID-19 equals the medicare rate. ~~For dates of service prior to April 1, 2017, the administration fee shall be ten dollars. A vaccine, except for a vaccine for COVID-19, or other drug that is dispensed by a pharmacy to be administered outside the pharmacy, for example at a LTCF, is not eligible for a pharmacy administration fee but may be eligible for a professional dispensing fee.~~

(E) The PDF portion of the calculated allowable ~~shall be~~ is determined in accordance with the following criteria:

(1) ~~Non-compounded drugs.~~The PDF to a provider for dispensing a non-compounded drug is assigned based on the total number of prescriptions filled by the provider during the provider's last completed fiscal year prior to completing the survey required by rule 5160-9-01 of the Administrative Code and reported on the survey. The PDF is assigned in accordance with the following criteria:

(a) For provider reporting fewer than fify thousand prescriptions, thirteen dollars and sixty-four cents.

(b) For providers reporting between fifty thousand and seventy-four thousand nine hundred ninety-nine prescriptions, ten dollars and eighty cents.

(c) For providers reporting between seventy-five thousand and ninety-nine thousand nine hundred ninety-nine prescriptions,nine dollars and fifty-one cents.

(d) For providers reporting one hundred thousand or more prescriptions, eight dollars and thirty cents.

(e) For a provider who failed to submit a complete response to the cost of dispensing survey required by rule 5160-9-01 of the Administrative Code for the previous reporting period, eight dollars and thirty cents.

(f) For providers newly enrolled as medicaid providers as described in rule 5160-9-01 of the Administrative Code, the PDF is as follows:

~~(i)~~ For a new provider located in Ohio, the provider is assigned a PDF of thirteen dollars and sixty-four cents.

~~(ii)~~ For a new provider located outside of Ohio, the provider is assigned a PDF of eight dollars and thirty cents.

~~(a) For dates of service prior to April 1, 2017, only pharmacy and hospital providers as defined in rule 5160-9-01 of the Administrative Code are~~

~~eligible to receive a dispensing or administration fee. The dispensing fee shall be one dollar eighty cents.~~

~~(b) For dates of service on or after April 1, 2017, the PDF paid to a provider for dispensing a non-compounded drug shall be assigned based on the total number of prescriptions filled by the provider during the provider's last completed fiscal year prior to completing the survey required by rule 5160-9-01 of the Administrative Code and reported on the survey. The PDF shall be assigned in accordance with the following criteria:~~

~~(i) For providers reporting fewer than fifty thousand prescriptions, thirteen dollars and sixty-four cents.~~

~~(ii) For providers reporting between fifty thousand and seventy-four thousand nine hundred ninety-nine prescriptions, ten dollars and eighty cents.~~

~~(iii) For providers reporting between seventy-five thousand and ninety-nine thousand nine hundred ninety-nine prescriptions, nine dollars and fifty-one cents.~~

~~(iv) For providers reporting one hundred thousand or more prescriptions, eight dollars and thirty cents.~~

~~(v) For a provider that failed to submit a complete response to the cost of dispensing survey required by rule 5160-9-01 of the Administrative Code for the previous reporting period, eight dollars and thirty cents.~~

~~(vi) For providers newly enrolled as medicaid providers as described in rule 5160-9-01 of the Administrative Code, the PDF shall be as follows:~~

~~*(a)* For a new provider located in Ohio, the provider shall be assigned a PDF of thirteen dollars and sixty-four cents.~~

~~*(b)* For a new provider located outside of Ohio, the provider shall be assigned a PDF of eight dollars and thirty cents.~~

(2) ~~Compounded drugs.~~ The PDF paid to a provider for dispensing compounded drugs ~~shall be~~ is paid in accordance with the following criteria:

(a) The PDF for claims for dispensing total parenteral nutrition (TPN) ~~shall be~~ is fifteen dollars per one-day supply on the claim, with a maximum total

PDF of one hundred fifty dollars for the claim. To qualify for the TPN PDF, the TPN compound must be mixed by the pharmacy to the final form under sterile conditions. If the products are mixed or activated at the point of administration by connecting components or breaking seals without the need for sterile conditions, the dispensing does not qualify for payment of the compounded PDF.

(b) ~~For dates of service prior to April 1, 2017, claims submitted for infusion compounds will receive a dispensing fee of ten dollars per day, with a maximum dispensing fee of seventy dollars. Infusion compounds include intravenous (IV) therapy for chemotherapy, pain management and antibiotics.~~

~~(c)~~(b) ~~For dates of service on or after April 1, 2017, the~~ The PDF for dispensing sterile compounds, other than TPN, that are required to be sterile for a route of administration including inhaled, infused, instilled, implanted or injected, ~~shall be~~ is ten dollars per days' supply, ~~with a minimum PDF of twenty dollars and~~ a maximum of seventy dollars for the claim. To qualify for payment of the sterile compound PDF, the sterile compound must be mixed by the pharmacy to the final form under sterile conditions. Products ~~that are~~ mixed or activated at the point of administration by connecting components or breaking seals without the need for sterile conditions are not eligible for a sterile compound PDF.

~~(d)~~(c) ~~Compounded drugs other than TPN or sterile compounds.~~Compounded drugs that are not eligible for the TPN or sterile compound PDF will receive the PDF determined under paragraph (E) of this rule.

~~(i) For dates of service prior to April 1, 2017, compounded drugs that are not infusion compounds or TPN claims will receive a single six dollar dispensing fee per prescription.~~

~~(ii) For dates of service on or after April 1, 2017, compounded drugs that are not eligible for the TPN or sterile compound PDF will receive the PDF determined under paragraph (E)(1)(b) of this rule.~~

(3) Vaccine or injectable drug dispensing that qualifies for payment of an administration fee ~~shall~~ does not qualify for medicaid payment of a PDF.

(4) Notwithstanding paragraph (E)~~(1)~~ of this rule, prescribed drugs, other than compounded drugs, dispensed to ~~patients~~ recipients residing in LTCFs ~~shall be~~ are limited to one PDF per patient, per equivalent product, per month ~~rolling twenty-five days~~. ~~In the event that~~ If multiple supplies of an equivalent product

are dispensed within ~~twenty-five days~~the same month, only the ingredient cost ~~shall~~ will be paid. Exceptions to the one PDF per ~~patient~~recipient, per product rule are:

(a) ~~Situations where the~~ The prescriber ~~has~~ ordered a second round of medication for an acute condition within the ~~twenty-five day period~~month..

(b) ~~Situations where the~~ The prescriber ~~has~~ changed the dosage.

(c) ~~Situations where the~~ The drug ~~has been~~ was compromised by accident, ~~for example~~ including but not limited to being contaminated or destroyed.

(d) ~~Dispensing of controlled substances, which is limited to two PDFs per twenty-five days.~~

(F) Coordination of benefits.

(1) Claims for medicare part B cost sharing as described in rule 5160-1-05 of the Administrative Code ~~shall be~~ are submitted using the medical claim format and ~~shall not be~~ are not payable under this chapter.

(2) No payment ~~shall~~ will be made under this chapter for any drug that may be covered by medicare part D for an ~~individual~~ recipient who is eligible for coverage by medicare part D, regardless of whether the ~~individual~~ recipient is actually enrolled in a part D plan or the particular drug is covered by the ~~individual's~~ recipient's part D plan.

(3) Cost-sharing for claims involving neither medicare part B nor medicare part D is determined in accordance with rule 5160-1-08 of the Administrative Code.

Effective:

Five Year Review (FYR) Dates:

_____

Certification

_____

Date

Promulgated Under:	119.03
Statutory Authority:	5164.02
Rule Amplifies:	5162.03, 5164.20, 5164.752, 5164.753
Prior Effective Dates:	04/07/1977, 09/19/1977, 12/21/1977 (Emer.), 12/30/1977, 10/01/1978, 05/09/1986, 11/01/1986, 10/01/1987, 02/01/1988, 01/13/1989 (Emer.), 04/13/1989, 06/01/1989, 07/01/1994, 10/01/1997, 02/03/2000 (Emer.), 05/01/2000, 05/01/2002, 03/31/2003 (Emer.), 06/12/2003, 10/16/2003 (Emer.), 01/01/2004, 10/01/2005, 12/31/2007, 10/01/2009 (Emer.), 12/29/2009, 01/02/2010, 10/01/2010, 07/01/2011, 01/01/2016, 04/01/2017, 12/23/2020 (Emer.), 04/24/2021

5160-9-06 **Pharmacy services: billing requirements, ~~and recordkeeping~~record keeping requirements, and cost of dispensing survey.**

(A) The pharmacy claims submitted to the Ohio department of medicaid (ODM) or its designee, the pharmacy point-of-sale vendor, must reflect the actual national drug code (NDC) on the container from which the product was dispensed.

(B) All records of prescriptions must comply with federal and state regulations and ~~shall~~ be retained by the provider for a period of six years from the date of payment of the claim and if an audit is initiated during this time, records must be retained until the audit is resolved.

(C) For a pharmacy claim to be eligible for payment by ODM, any prescription executed in written (and non-electronic) format must be executed on a tamper-resistant form.

(1) To be considered tamper resistant, a prescription form must contain all of the following three characteristics:

(a) One or more features designed to prevent unauthorized copying of a completed or blank prescription form;

(b) One or more features designed to prevent the erasure or modification of information written on the prescription by the prescriber; and

(c) One or more features designed to prevent the use of counterfeit prescription forms.

(2) The tamper-resistant requirement applies to all written prescriptions presented at the pharmacy when ODM pays any part of the claim, including when ODM is not the primary payer, in accordance with paragraphs (F) and (G) of this rule.

(3) The tamper-resistant requirement does not apply in the following situations:

(a) Prescriptions transmitted to the pharmacy via an electronic prescription transmission system, facsimile device, or telephone, in accordance with rules promulgated by the state board of pharmacy in agency 4729 of the Administrative Code;

(b) Orders for medications administered in a provider setting and billed by the administering provider in accordance with paragraph (H) of rule 5160-9-03 of the Administrative Code; or

(c) Orders for medications administered in a nursing facility (NF) or intermediate care facility for individuals with intellectual disabilities (ICF/IID), if the order is written in the ~~patient's~~ recipient's medical record and given by medical staff directly to the pharmacy. The prescription is considered tamper resistant if the ~~patient~~ recipient does not have opportunity to handle the written order.

(4) If a written prescription that is not tamper resistant is presented at the pharmacy, the pharmacy may fill the prescription on an emergency basis and obtain a compliant tamper-resistant replacement from the prescriber within seventy-two hours of dispensing.

(a) A tamper-resistant replacement may be obtained via any of the following methods:

(i) Telephone verification from the prescriber or prescriber's staff, documented on the prescription with the name of the person at the prescriber's office verifying the prescription, date of verification, and identification of the pharmacist or pharmacy staff member requesting verification;

(ii) Obtaining a copy of the prescription from the prescriber via facsimile device;

(iii) Obtaining an electronic prescription from the prescriber; or

(iv) Obtaining a replacement written prescription from the prescriber on a tamper-resistant form.

(b) The replacement tamper-resistant prescription shall be filed with the original, non-tamper-resistant prescription.

(c) The dispensing pharmacist shall use professional judgment to define an emergency situation.

(5) When it is determined that a ~~consumer~~ recipient is retroactively eligible, and the ~~consumer's~~ recipient's original or refill prescription was filled during a period when the ~~consumer~~ recipient is retroactively eligible, the pharmacy must ensure that the original prescription was tamper resistant before billing the pharmacy claim to ODM.

(a) If the prescription meets the provisions of paragraph (C)(3) of this rule, the tamper-resistant requirement does not apply.

(b) If the original prescription was not tamper resistant, the pharmacy may obtain a tamper-resistant replacement as described in paragraphs (C)(4)(a) and (C)(4)(b) of this rule.

(D) Claims for drugs purchased through the 340B drug discount program as defined in ~~rule 5160-1-17.11 of the Administrative Code shall be~~ section 340B(a)(4) of the "Public Health Service Act," 42 U.S.C. 256b(a)(4) (as in effect as of January 7, 2011) are submitted with the provider's actual acquisition cost plus cost of dispensing, and ~~shall~~ use the codes described in billing instructions issued by ODM or its designee.

(E) Voids and reversals

(1) Return to stock

(a) When ~~patients~~ recipients fail to pick up their prescriptions, pharmacies must reverse the claim submitted to ODM as soon as possible and not later than fourteen days after preparation.

(b) When prescriptions ~~have been~~ were dispensed to a resident of a NF or ICF/IID and there is an unutilized portion of a legally redispensable drug remaining, the drug must either be:

(i) Destroyed; or

(ii) Returned to the pharmacy to be redispensed and the product cost, not including the dispensing fee, must be credited to ODM~~. This shall be done~~ by voiding or reversing the original claim and submitting a new claim for the utilized amount plus dispensing fee.

(2) Voids, reversals, and replacement claims for other reasons

(a) Original claims ~~shall~~ should be submitted within three hundred sixty-five days of the date of service. Claims may be reversed, voided, or replaced (i.e., re-billed) at any time within the first three hundred sixty-five days after the date of service.

(b) Claims may be reversed, voided, or replaced beyond three hundred sixty-five days after the date of service in the following circumstances:

(i) Adjudicated paid claims may be reversed and replaced (i.e., re-billed) beyond three hundred sixty-five days after the date of service if the adjudication date of the replacement claim is within ninety days after the date of original claim payment.

(ii) Adjudicated denied claims may be replaced (i.e., re-billed) beyond three hundred sixty-five days after the date of service if the adjudication date of the replacement claim is within ninety days after the date of adjudication of an original denied claim.

(iii) Adjudicated paid claims may be reversed or voided beyond three hundred sixty-five days after the date of service if the adjudication date of the reversal or void is within five hundred forty-five days after the date of original claim payment.

(F) Third party liability

(1) In accordance with rules 5160-1-17.2 and 5160-1-08 of the Administrative Code, ODM is the payer of last resort.

(2) The provider's claim shall include the following indicators for each third-party payer as described in billing instructions issued by ODM or its designee.

(a) A payer identification code;

(b) Whether the claim was approved or denied, and if denied the reason for the denial;

(c) All amounts paid by third-party payers; and

(d) The ~~patient~~ recipient 's responsibility amount assigned by each payer.

(G) Medicare part B-covered services

Drugs covered by medicare part B for dually eligible ~~consumers~~ recipients ~~shall~~ will first be billed by the provider to medicare. When appropriate, ODM ~~shall~~ pays the medicare part B cost sharing in accordance with rules 5160-1-05 to 5160-1-05.3 of the Administrative Code. Cost sharing for medicare part B services ~~shall~~ should

not be billed in a pharmacy claim format and ~~shall~~ should be billed in accordance with the billing instructions issued by ODM for professional claims billed secondary to medicare part B or medicare part C.

(H) Medicare part D-covered services

Drugs that are covered or are eligible to be covered by medicare part D for dually eligible ~~consumers~~ recipients are not covered by medicaid. Medicaid does not pay medicare cost sharing for medicare part D services.

(I) Provider types described in rule 5160-9-01 of the Administrative Code are required to submit a complete response to the cost of dispensing survey conducted according to section 5164.752 of the Revised Code.

(1) A complete response to the cost of dispensing survey includes supplying complete information about the terminal distributor for, at the least, all of the following categories:

(a) Demographics;

(b) Number of prescriptions dispensed annually, broken out by medicaid fee-for-service and other payers, and including a total volume for the location;

(c) Sales and cost of goods sold;

(d) Direct expenses;

(e) Overhead expenses; and

(f) Certification that the person submitting the survey believes the information to be true, correct, and complete.

(2) Providers that do not submit a complete response to the cost of dispensing survey may be paid a lower professional dispensing fee (PDF) in accordance with rule 5160-9-05 of the Administrative Code.

(3) Newly-enrolled providers are assigned to the dispensing fee described in rule 5160-9-05 of the Administrative Code.

(a) If the provider received the new provider number due to a change in ownership, the department uses the number of prescriptions reported by the previous ownership to determine the PDF.

(b) In a situation other than a change of ownership, a provider is newly enrolled if the date of approval for an application to enroll as a provider, or the date of approval of a specialty pharmacy designation, is

less than ninety days prior to the distribution of the most recently conducted cost of dispensing survey then the date of approval is not the effective date of the provider agreement or specialty designation when the effective date is made retroactive by ODM.

(4) If a provider experiences a change in prescription volume during the first nine months following the implementation of a PDF category significant enough that it would result in the provider falling into a different PDF category, the provider may submit a written request with supporting documentation to ODM, no later than the thirtieth day of April of the first year, requesting assignment to a different category. If the supporting documentation justifies an adjustment, ODM will assign a new PDF category effective the first day of July for the second year.

5160-9-07 **Pharmacy services: drug coverage review process.**

(A) For a drug to be considered for coverage without prior authorization in accordance with rule 5160-9-03 of the Administrative Code, the following information may be requested from the manufacturer or labeler:

(1) Trade name of the drug.

(2) Generic name of the drug.

(3) National drug code number (NDC).

(4) Package sizes available.

(5) Strengths.

(6) Therapeutic use(s).

(7) List of therapeutic ingredients.

(8) Direct, average wholesale price, wholesale acquisition cost and average manufacturer price.

(9) Bioavailability and bioequivalency data.

(10) Letter(s) of approval of new drug application (NDA), or abbreviated new drug application (ANDA).

(11) Product labeling as approved by the food and drug administration.

(12) A statement of justification for coverage without prior authorization including cost effectiveness and relative merits.

(B) Final determination by the Ohio department of medicaid (ODM) of a drug's inclusion on or removal from the list described in paragraph (C) of rule 5160-9-03 of the Administrative Code will be based on a review and analysis of the information required in paragraph (A) of this rule in addition to an analysis of such factors as:

(1) Specific attributes and/or benefits of the drug.

(2) Availability and cost effectiveness of the drug in relation to alternative products.

(3) Availability of bioequivalent generic products.

(4) Provision of a supplemental rebate payment for a drug that reduces the acquisition cost.

(C) Newly-marketed drugs

(1) New products with the same active ingredient, dosage form, and brand or generic designation as a product that is already covered by ODM will be added to coverage under the same conditions as the existing covered product.

(2) New products within a therapeutic category listed on the "ODM Preferred Drug List" (PDL) will be added to coverage with prior authorization using the same criteria outlined in the PDL document until the new product is reviewed by the ODM pharmacy and therapeutics committee.

(3) New products not within a therapeutic category listed on the ODM PDL will be added to coverage with prior authorization criteria consistent with the product labeling approved by the federal food and drug administration.