

HUMAN SERVICES DEPARTMENT[441]

Adopted and Filed

**Rule making related to pharmacy protocols for naloxone,
nicotine replacement therapy, and vaccines**

The Human Services Department hereby amends Chapter 77, “Conditions of Participation for Providers of Medical and Remedial Care,” Chapter 78, “Amount, Duration and Scope of Medical and Remedial Services,” and Chapter 79, “Other Policies Relating to Providers of Medical and Remedial Care,” Iowa Administrative Code.

Legal Authority for Rule Making

This rule making is adopted under the authority provided in Iowa Code section 249A.4.

State or Federal Law Implemented

This rule making implements, in whole or in part, Iowa Code section 249A.4.

Purpose and Summary

The Iowa Board of Pharmacy, in collaboration with the Iowa Department of Public Health, developed statewide protocols for pharmacists ordering and dispensing naloxone and nicotine replacement therapy (NRT) tobacco cessation products, as well as for pharmacists ordering and administering vaccines. In order to allow these expanded pharmacist practice protocols under Medicaid, the following changes are made:

- Adding “pharmacist” as a provider type eligible to enroll in the Medicaid program.
- Clarifying qualified prescriber and prescription requirements based on the pharmacist expanded practice standards.
- Amending the section related to pharmacies administering an influenza vaccine to children to apply to pharmacists providing all Medicaid-covered vaccines to children and adults, pursuant to 657—Chapter 39 and the statewide protocols. The rule making also adds Medicaid verification and reporting requirements. These changes will enable pharmacists to take advantage of the expanded practice standards while clarifying the Medicaid verification and reporting requirements for vaccines.
- Amending the section related to basis of reimbursement for vaccines related to pharmacists. All billing and reimbursement of vaccines, regardless of provider type, will be through the Healthcare Common Procedure Coding System (HCPCS) to ensure consistency among providers as well as a coordinated Medicaid immunization record for the member.

Public Comment and Changes to Rule Making

Notice of Intended Action for this rule making was published in the Iowa Administrative Bulletin on March 11, 2020, as **ARC 4964C**. The Department received four comments from 46 respondents on the proposed amendments. The comments and corresponding responses from the Department are divided into four topic areas as follows:

A. Enrollment of pharmacists.

Twenty-four respondents expressed support for allowing pharmacists to enroll as providers, which included updating the list of qualified prescribers.

Department response: The Department agrees with the comment; this was the reason the Department initiated the addition of a pharmacist as a new provider type, as well as updates to the qualified prescriber subrule.

B. Vaccine administration fee.

Forty-five respondents requested reconsideration of a higher amount for the vaccine administration fee or the ability of pharmacists to bill additional codes (consistent with what other providers are authorized to do) to compensate for the services. Additionally, comments indicated pharmacists should be reimbursed for vaccine administration consistent with other health care providers and not reimbursed at a reduced rate. Comments also indicated the fee would be insufficient to allow many pharmacies to continue providing this service.

Department response: As noted in the proposed amendments, the vaccine administration reimbursement for a pharmacist is set equal to the physician fee schedule. Pharmacists will be reimbursed consistent with other providers, since the physician fees are the basis for reimbursement of vaccine administration for other provider types. Any increase to the fee schedule would require additional funding, which has not been appropriated. While the proposed amendments referenced two vaccine administration procedure codes, there are six procedure codes reimbursed by Iowa Medicaid for vaccination administration. These codes take into consideration the age of the patient, the order and route of vaccines administered, and whether face-to-face counseling was provided.

The administration codes 90460–90461 or 90471–90474 are reported in addition to the vaccine product code.

- Codes 90460 and 90461 do not differentiate by routes of administration; they identify order of “first” versus “each additional” administration.

- The age designation for codes 90460 and 90461 (i.e., through the age of 18) is consistent with the age requirements under the federal Vaccines for Children (VFC) program.

- When the physician or qualified health care professional (e.g., nonphysicians if allowed under state scope of practice) provides face-to-face counseling for the patient and family during the administration of a vaccine to a patient 18 years or younger, code 90460 or a combination of codes 90460 and 90461 is reported. The medical record documentation must support that the physician or other qualified health care professional provided the vaccine counseling.

- When the physician or qualified health care professional does not provide the vaccine counseling to the patient or family or when vaccines are administered to patients older than 18 years, with or without counseling, codes 90471–90474 are reported instead of codes 90460–90461.

- Code 90471 or 90473 is reported for the “first” vaccine administered to a patient on a calendar date, and codes 90472 and 90474 are reported for “each additional vaccine” given on the same date based on its route of administration. If an immunization is the only service rendered, no enrolled Medicaid provider is authorized to bill additional codes; only the appropriate vaccine administration code and drug product code are to be billed for reimbursement.

The process to review the reimbursed rates for the codes is to use the current Medicare rate, if one exists, and determine the fiscal impact of changing the rate. The administration rates have only changed with legislative direction. They were updated to the Medicare rate for two years due to the Affordable Care Act and then dropped back to the original Medicaid rates. The last update was a 1 percent increase effective July 1, 2013. The administration codes, descriptions and reimbursed amounts are listed below.

Procedure Code	Procedure Description	Fee
Use the following codes for vaccine administration to patients 18 and under, with face-to-face counseling of the patient/family during the vaccine administration:		
90460	Immunization administration through 18 years of age by any route of administration, with counseling by physician or other qualified health care professional; first or only component of each vaccine or toxoid administered	\$19.68 VFC \$20.90 non-VFC
90461	Immunization administration through 18 years of age by any route of administration, with counseling by physician or other qualified health care professional; each additional vaccine or toxoid component administered (list separately in addition to code for primary procedure)	\$10.51 VFC and non-VFC
Use the following codes for vaccine administration to patients of any age when the administration is not accompanied by any face-to-face counseling of patients under 18, or for administration to patients over 18 with or without counseling:		
90471	Immunization administration (includes percutaneous, intradermal, subcutaneous, or intramuscular injections); one vaccine (single or combination vaccine or toxoid) with no counseling to patients under 18 years of age, or when vaccines are administered to patients older than 18 years	\$5.09
90472	Immunization administration (includes percutaneous, intradermal, subcutaneous, or intramuscular injections); each additional vaccine (single or combination vaccine or	\$5.09

	toxoid) with no counseling to patients under 18 years of age, or when vaccines are administered to patients older than 18 years (list separately in addition to code for primary procedure)	
90473	Immunization administration by intranasal or oral route; one vaccine (single or combination vaccine or toxoid) with no counseling to patients under 18 years of age, or when vaccines are administered to patients older than 18 years	\$12.88
90474	Immunization administration by intranasal or oral route; each additional vaccine (single or combination vaccine or toxoid) with no counseling to patients under 18 years of age, or when vaccines are administered to patients older than 18 years (list separately in addition to code for primary procedure)	\$6.86

Refer to the fee schedule in the Provider Services section of the Iowa Medicaid Enterprise (IME) website for the most up-to-date rate information. No changes were made to the amendments based on these comments.

C. State immunization registry.

One respondent commented that by only requiring one type of vaccinator (pharmacist) to report to the state immunization registry, it creates uneven and unnecessary administrative burdens. The respondent also provided in-text edits of proposed subrule 78.42(3), regarding verification and reporting.

Department response: This section of the amendments replicates what is required under 657—Chapter 39 and the statewide protocols related to vaccine administration by pharmacists. The exception is that the rule defines the reporting period specifically as 30 calendar days following the administration of any vaccine, rather than “as soon as reasonably possible.” No changes have been made to this section.

D. Department of Public Health Vaccines for Children (VFC) Program.

One respondent recommended consideration by the Department’s VFC program to make updates to the program to overcome operational and administrative barriers, including inventory management and ordering processes. The respondent also provided in-text edits of proposed subrule 78.42(1) by striking “Payment will be made for the vaccine cost only if the VFC program stock has been depleted” and adding “Pharmacists will be allowed to use their own vaccine stock instead of the VFC program stock and be reimbursed for the cost of vaccine.”

Department response: The rule does not address the operational or administrative requirements under the Iowa Department of Public Health VFC program. Rather, the rule continues the requirement that providers enroll and obtain vaccines from the VFC program if the vaccines are being administered to a Medicaid-enrolled child. Payment by Medicaid is made for the vaccine cost only if the VFC program stock has been depleted. Section 13631 of the Omnibus Budget Reconciliation Act (OBRA) of 1993 created the VFC program as Section 1928 of the Social Security Act on August 10, 1993. Consistent with the program requirements, Medicaid-eligible children must receive vaccines through that program when available. No changes have been made to this section.

No changes from the Notice have been made.

Adoption of Rule Making

This rule making was adopted by the Department on August 11, 2020.

Fiscal Impact

To the extent that naloxone and NRT are currently being provided to Medicaid members based on a currently authorized prescriber prescription, these amendments create a different access point to the products. If a Medicaid member is not currently accessing these products through a currently authorized Medicaid provider, these amendments could increase the number of prescriptions for these categories of drugs, resulting in an increase in expenditures. The extent of this potential fiscal impact cannot be determined. To the extent pharmacists are currently administering vaccines dispensed through pharmacy point of sale, there could be two potential fiscal impacts depending on the route of vaccine administration.

1. There could potentially be savings related to the difference in the current dispensing fee (\$10.07) paid under pharmacy policy and the transition to the reimbursement of the 90471 (percutaneous, intradermal, subcutaneous or intramuscular injections) administration fee (\$5.09) under medical policy.

2. There could be an increased cost related to the difference in the current dispensing fee (\$10.07) paid under pharmacy policy and the transition to the reimbursement of the 90473 (intranasal or oral route) administration fee (\$12.88) under medical policy.

However, this only compares two procedure codes and there are six procedure codes reimbursed by Iowa Medicaid for vaccination administration. The codes take into consideration the age of the patient, the order and route of vaccines administered, and whether face-to-face counseling is provided.

Additionally, there is a potential for an increase in the number of vaccines billed by the pharmacy with these amendments, which could lead to an increase in total vaccine expenditures (product plus administration cost). The extent of this potential fiscal impact cannot be determined.

Jobs Impact

After analysis and review of this rule making, no impact on jobs has been found.

Waivers

Any person who believes that the application of the discretionary provisions of this rule making would result in hardship or injustice to that person may petition the Department for a waiver of the discretionary provisions, if any, pursuant to rule 441—1.8(17A,217A).

Review by Administrative Rules Review Committee

The Administrative Rules Review Committee, a bipartisan legislative committee which oversees rule making by executive branch agencies, may, on its own motion or on written request by any individual or group, review this rule making at its [regular monthly meeting](#) or at a special meeting. The Committee's meetings are open to the public, and interested persons may be heard as provided in Iowa Code section 17A.8(6).

Effective Date

This rule making will become effective on July 30, 2020.

The following rule-making actions are adopted:

ITEM 1. Adopt the following **new** rule 441—77.57(249A):

441—77.57(249A) Pharmacists. An authorized pharmacist licensed to practice in the state of Iowa is eligible to participate in the program.

This rule is intended to implement Iowa Code section 249A.4.

ITEM 2. Amend subrule 78.2(1) as follows:

78.2(1) *Qualified prescriber.* All drugs are covered only if prescribed or ordered by a ~~legally qualified practitioner~~ an Iowa Medicaid-enrolled practitioner licensed or registered to prescribe as specified in Iowa Code section 155A.3(38). ~~Pursuant to Public Law 111-148, Section 6401, any practitioner prescribing drugs must be enrolled with the Iowa Medicaid enterprise in order for such prescribed drugs to be eligible for payment.~~

ITEM 3. Amend subrule 78.2(2) as follows:

78.2(2) *Prescription required.* As a condition of payment for all drugs, including “nonprescription” or “over-the-counter” drugs that may otherwise be dispensed without a prescription or drug order, a prescription or drug order shall be transmitted as specified in Iowa Code sections 124.308, 155A.3 and 155A.27 by the practitioner to the pharmacy, subject to the provisions of Iowa Code section 155A.29 regarding refills. All prescriptions or drug orders shall be available for audit by the department.

ITEM 4. Rescind rule 441—78.42(249A) and adopt the following **new** rule in lieu thereof:

441—78.42(249A) Pharmacists providing covered vaccines. When the authorized pharmacist providing the vaccine meets all Iowa board of pharmacy expanded practice standards and Medicaid requirements, payment will be made for the following:

78.42(1) *Vaccines administered to children.* Payment will be made to an enrolled provider for an administration fee for vaccines available through the Vaccines for Children (VFC) program administered by the department of public health if the provider is enrolled in the VFC program. Payment will be made for the vaccine cost only if the VFC program stock has been depleted.

78.42(2) *Vaccines administered to adults.* Payment will be made to an enrolled provider for an administration fee and vaccine cost.

78.42(3) *Verification and reporting.* Prior to the ordering and administration of an immunization pursuant to statewide protocol, the authorized pharmacist shall consult and review the Iowa Immunization Registry Information System (IRIS) or Iowa Health Information Network (IHIN). Within 30 calendar days following administration of any vaccine, the pharmacist shall report such administration to the patient’s primary health care provider, primary physician, and IRIS or IHIN. If a patient does not have a primary health care provider, the pharmacist shall provide the patient with a written record of the vaccine administered to the patient and shall advise the patient to consult a physician.

This rule is intended to implement Iowa Code section 249A.4.

ITEM 5. Amend subrule **79.1(2)**, provider category of “Pharmacy administration of influenza vaccine to children,” as follows:

Pharmacy Pharmacist vaccine administration of influenza vaccine to children	Physician fee schedule for immunization administration	Fee schedule in effect 6/30/13 plus 1%.
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ITEM 6. Amend paragraph **79.1(8)“a,”** introductory paragraph, as follows:

a. Except as provided below in paragraphs 79.1(8)“d” through ~~“i,”~~ “h,” all providers are reimbursed for covered drugs as follows:

ITEM 7. Rescind paragraph **79.1(8)“i.”**

ITEM 8. Reletter paragraphs **79.1(8)“j”** to **“l”** as **79.1(8)“i”** to **“k.”**

[Filed 8/18/20, effective 6/1/21]

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EDITOR’S NOTE: For replacement pages for IAC, see IAC Supplement 9/9/20.