

HUMAN SERVICES DEPARTMENT[441]

Notice of Intended Action

Twenty-five interested persons, a governmental subdivision, an agency or association of 25 or more persons may demand an oral presentation hereon as provided in Iowa Code section 17A.4(1)“b.”

Notice is also given to the public that the Administrative Rules Review Committee may, on its own motion or on written request by any individual or group, review this proposed action under section 17A.8(6) at a regular or special meeting where the public or interested persons may be heard.

Pursuant to the authority of Iowa Code section 249A.4, the Department of Human Services hereby gives Notice of Intended Action to amend 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.

The federal Indian Health Service (IHS) approves encounter rates for inpatient and outpatient medical care provided by IHS and tribal facilities to American Indians or Alaskan natives who are beneficiaries of Medicare, Medicaid, or other federal programs. The Indian Health Facilities in Iowa requested that Iowa Medicaid adopt the encounter rate for prescribed drugs, in lieu of payment for the particular drugs provided.

The Centers for Medicare and Medicaid Services (CMS) released a final rule that implements provisions of the Patient Protection and Affordable Care Act of 2010 as amended by the Health Care and Education Reconciliation Act of 2010 (collectively referred to as the Affordable Care Act) pertaining to Medicaid reimbursement for covered outpatient drugs. Key aspects of the final rule require Medicaid agencies to comply by documenting the reimbursement methodology for specific entities in their state plan no later than April 1, 2017. Specific entities that must be addressed include: (1) a covered entity described in Section 1927(a)(5)(B) of the Social Security Act (“340B” entities), (2) a contract pharmacy under contract with a covered 340B entity, and (3) a facility authorized to purchase drugs through the federal supply schedule (FSS). Corresponding clarifications, which do not represent a change from current policy, are being made in the rules. Additionally, CMS has required that ingredient cost reimbursement for drugs acquired by providers at nominal prices and excluded from the calculation of the drug’s “best price” not exceed the provider’s actual acquisition cost. A terminology clarification is also being made by changing the term “maximum allowable cost” (MAC) to “federal upper limit” (FUL) to conform to the Code of Federal Regulations (CFR). Lastly, the final rule indicates states may, at their option, provide coverage of and receive federal financial participation for investigational drugs, under specific conditions. The proposed rule clarifies that Iowa Medicaid does not cover investigational drugs that are the subject of an investigational new drug (IND) application that has been allowed to proceed by the Food and Drug Administration (FDA) but that do not meet the definition of a covered outpatient drug as set forth in 42 U.S.C. 1396r-8(k)(2)-(4).

These amendments change the outpatient prescribed drug reimbursement methodology for drugs provided to Medicaid recipients who are American Indians or Alaskan natives by health facilities that are operated by IHS or under the Indian Self-Determination and Education Assistance Act (P.L. 93-638) by an “Indian tribe,” “tribal organization,” or “urban Indian organization” as those terms are defined in 25 U.S.C. 1603 (referred to as Indian Health Facilities). Such drugs will be reimbursed through an outpatient encounter rate per day rather than through reimbursement for each individual prescription provided. The amendments also clarify the facilities that will receive this encounter rate for drugs. Because Medicaid reimbursement for services provided to Medicaid recipients who are American Indians or Alaskan natives by these facilities are 100 percent federally funded, there is no state expenditure involved in this change of reimbursement methodology.

These amendments also change the outpatient prescribed drug reimbursement methodology for drugs acquired by providers at nominal prices and excluded from the calculation of the drug’s “best price”

pursuant to 42 CFR 447.508. For such drugs, the ingredient cost may not exceed the provider's actual acquisition cost (not to exceed the nominal price paid).

Additionally, these amendments clarify the following:

- The current reimbursement methodology utilized for covered outpatient drugs for 340B covered entities, 340B contract pharmacies, and facilities (such as Department of Veterans Affairs facilities) purchasing through the FSS under the General Services Administration.
- The terminology of maximum allowable cost (MAC) by updating to the conventional label of federal upper limit (FUL) and maintaining the definition for the FUL in accordance with 42 CFR 447.514(a)-(c).
- Payment is not made for outpatient investigational drugs that are the subject of an IND application that has been allowed by the FDA to proceed, which is optional with the state.
- Insertion of the word "state" in the phrase "average actual acquisition cost (AAC)" so that the phrase reads "average state actual acquisition cost (AAC)" to distinguish that limit from the provider-specific actual acquisition costs that also limit reimbursement of 340B covered entities and FSS facilities.
- Separation in the drug reimbursement methodology of the "submitted charge" and the "providers' usual and customary charge" to reflect that, if the amounts are different, the lower of the two is utilized for reimbursement.

Any interested person may make written comments on the proposed amendments on or before December 13, 2016. Comments should be directed to Harry Rossander, Bureau of Policy Coordination, Department of Human Services, Hoover State Office Building, Fifth Floor, 1305 East Walnut Street, Des Moines, Iowa 50319-0114. Comments may be sent by fax to (515) 281-4980 or by e-mail to policyanalysis@dhs.state.ia.us.

These amendments do not provide for waivers in specified situations because requests for the waiver of any rule may be submitted under the Department's general rule on exceptions at 441—1.8(17A,217).

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

These amendments are intended to implement Iowa Code section 249A.4.

The following amendments are proposed.

ITEM 1. Amend rule 441—77.45(249A) as follows:

441—77.45(249A) Indian health service 638 facilities. A health care facility ~~owned and operated by American Indian or Alaskan native tribes or tribal organizations with funding authorized by Title I or Title III of the U.S. Indian Health Service or under the Indian Self-Determination and Education Assistance Act (P.L. 93-638) by an "Indian tribe," "tribal organization," or "Urban Indian organization," as those terms are defined in 25 U.S.C. 1603,~~ is eligible to participate in the medical assistance program if the following conditions are met:

77.45(1) and 77.45(2) No change.

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

ITEM 2. Adopt the following **new** subparagraph **78.2(4)“b”(12)**:

(12) Investigational drugs, including drugs that are the subject of an investigational new drug (IND) application allowed to proceed by the U.S. Food and Drug Administration (FDA) but that do not meet the definition of a covered outpatient drug in 42 U.S.C. 1396r-8(k)(2)-(3).

ITEM 3. Amend paragraph **79.1(1)“h”** as follows:

h. Indian health ~~service 638~~ facilities.

(1) Indian health ~~service 638~~ facilities as defined at enrolled pursuant to rule 441—77.45(249A) are paid a special daily base encounter rate for all Medicaid-covered services rendered to American Indian or Alaskan native persons who are Medicaid-eligible at the current daily visit rates approved by the U.S. Indian Health Service (IHS) for services provided by IHS facilities to Medicaid beneficiaries, as published in the Federal Register. This rate is updated periodically and published in the Federal Register after being approved by the Office of Management and Budget. For services provided to American Indians or Alaskan natives, Indian health ~~service 638~~ facilities may bill ~~only one charge~~ for one visit per

patient per calendar day for medical services ~~provided to American Indians or Alaskan natives (at the “outpatient per visit rate (excluding Medicare)”)~~, which shall ~~include~~ constitute payment in full for all medical services provided on that day, except as follows:

1. For services provided to American Indians and Alaskan natives, Indian health facilities may bill for multiple visits per patient per calendar day for medical services (at the “outpatient per visit rate (excluding Medicare)”) only if medical services are provided for different diagnoses or if distinctly different medical services from different categories of services are provided for the same diagnoses in different units of the facility. For this purpose, the categories of medical services are vision services; dental services; mental health and addiction services; early and periodic screening, diagnosis, and treatment services for children; other outpatient services; and other inpatient services. A visit is a face-to-face contact between a patient and a health professional at or through the facility.

2. For services provided to American Indians or Alaskan natives, Indian health facilities may also bill for one visit per patient per calendar day for outpatient prescribed drugs provided by the facility (at the “outpatient per visit rate (excluding Medicare)”), which shall constitute payment in full for all outpatient prescribed drugs provided on that day.

(2) Services provided to Medicaid recipients who are not American Indians or Alaskan natives will be paid at the ~~fee schedule~~ reimbursement rate otherwise allowed by Iowa Medicaid for the services provided and will be billed separately by CPT code on the CMS-1500 Health Insurance Claim Form or through pharmacy point of sale. Claims for nonpharmacy services provided to Medicaid recipients who are not American Indians or Alaskan natives must be submitted by the individual practitioner enrolled in the Iowa Medicaid program, but may be paid to the facility if the provider agreement so stipulates.

ITEM 4. Amend subrule **79.1(2)**, provider category of “Indian health service 638 facilities,” as follows:

<u>Provider category</u>	<u>Basis of reimbursement</u>	<u>Upper limit</u>
Indian health service 638 facilities	<p>1. Base rate as determined by the United States Office of Management and Budget for outpatient visits for American Indian and Alaskan native members. Daily visit rate approved by the U.S. Indian Health Service (IHS) for services provided to American Indian and Alaskan native members. See 79.1(1)“h.”</p> <p>2. Fee schedule for service provided for all other Medicaid members.</p>	<p>1. Office of Management and Budget rate IHS-approved rate published in the Federal Register for as outpatient per visit rate (excluding Medicare).</p> <p>2. Fee schedule.</p>

ITEM 5. Rescind subrule 79.1(8) and adopt the following **new** subrule in lieu thereof:

79.1(8) Drugs.

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

(1) Reimbursement for covered generic prescription drugs and for covered nonprescription drugs shall be the lowest of the following, as of the date of dispensing:

1. The average state actual acquisition cost (AAC), determined pursuant to paragraph 79.1(8)“b,” plus the professional dispensing fee determined pursuant to paragraph 79.1(8)“c.”

2. The federal upper limit (FUL), defined as the upper limit for a multiple source drug established in accordance with the methodology of the Centers for Medicare and Medicaid Services as described in 42 CFR 447.514(a)-(c), plus the professional dispensing fee determined pursuant to paragraph 79.1(8)“c.”

3. The total submitted charge.

4. Providers’ usual and customary charge to the general public.

(2) Reimbursement for covered brand-name prescription drugs shall be the lowest of the following, as of the date of dispensing:

1. The average state AAC, determined pursuant to paragraph 79.1(8)“b,” plus the professional dispensing fee determined pursuant to paragraph 79.1(8)“c.”

2. The total submitted charge.

3. Providers’ usual and customary charge to the general public.

b. For purposes of this subrule, average state AAC is defined as retail pharmacies’ average prices paid to acquire drug products. Average state AAC shall be determined by the department based on a survey of invoice prices paid by Iowa Medicaid retail pharmacies. Surveys shall be conducted at least once every six months, or more often at the department’s discretion. The average state AAC shall be calculated as a statistical mean based on one reported cost per drug per pharmacy. The average state AAC determined by the department shall be published on the Iowa Medicaid enterprise Web site. If no current average state AAC has been determined for a drug, the wholesale acquisition cost (WAC) published by Medi-Span shall be used as the average state AAC.

c. For purposes of this subrule, the professional dispensing fee shall be a fee schedule amount determined by the department based on a survey of Iowa Medicaid participating pharmacy providers’ costs of dispensing drugs to Medicaid beneficiaries. The survey shall be conducted every two years beginning in state fiscal year 2014-2015.

d. For an oral solid dispensed to a patient in a nursing home in unit dose packaging prepared by the pharmacist, an additional one cent per dose shall be added to reimbursement based on acquisition cost or FUL.

e. 340B-purchased drugs.

(1) Notwithstanding paragraph 79.1(8)“a” above, reimbursement to a covered entity as defined in 42 U.S.C. 256b(a)(4) for covered outpatient drugs acquired by the entity through the 340B drug pricing program will be the lowest of:

1. The submitted 340B covered entity actual acquisition cost (not to exceed the 340B ceiling price) plus the professional dispensing fee pursuant to paragraph 79.1(8)“c”;

2. The average state AAC determined pursuant to paragraph 79.1(8)“b” plus the professional dispensing fee pursuant to paragraph 79.1(8)“c”;

3. For generic prescription drugs and nonprescription drugs only, the FUL pursuant to 79.1(8)“a”(1)“2” plus the professional dispensing fee pursuant to paragraph 79.1(8)“c”;

4. The total submitted charge; or

5. Providers’ usual and customary charge to the general public.

(2) Reimbursement for covered outpatient drugs to a 340B contract pharmacy, under contract with a covered entity described in 42 U.S.C. 256b(a)(4), will be according to paragraph 79.1(8)“a” because covered outpatient drugs purchased through the 340B drug pricing program cannot be billed to Medicaid by a 340B contract pharmacy.

f. Federal supply schedule (FSS) drugs. Notwithstanding paragraph 79.1(8)“a” above, reimbursement for drugs acquired by a provider through the FFS program managed by the federal General Services Administration will be the lowest of:

(1) The provider’s actual acquisition cost, not to exceed the FSS price, plus the professional dispensing fee pursuant to paragraph 79.1(8)“c”;

(2) The average state AAC determined pursuant to paragraph 79.1(8)“b” plus the professional dispensing fee pursuant to paragraph 79.1(8)“c”;

(3) For generic prescription drugs and nonprescription drugs only, the FUL pursuant to 79.1(8)“a”(1)“2” plus the professional dispensing fee pursuant to paragraph 79.1(8)“c”;

(4) The total submitted charge; or

(5) Providers’ usual and customary charge to the general public.

g. Nominal-price drugs. Notwithstanding paragraph 79.1(8)“a” above, reimbursement for drugs acquired by providers at nominal prices and excluded from the calculation of the drug’s “best price” pursuant to 42 CFR 447.508 will be the lowest of:

(1) The provider's actual acquisition cost (not to exceed the nominal price paid) plus the professional dispensing fee pursuant to paragraph 79.1(8) "c";

(2) The average state AAC determined pursuant to paragraph 79.1(8) "b" plus the professional dispensing fee pursuant to paragraph 79.1(8) "c";

(3) For generic prescription drugs and nonprescription drugs only, the FUL pursuant to 79.1(8) "a"(1)"2" plus the professional dispensing fee pursuant to paragraph 79.1(8) "c";

(4) The total submitted charge; or

(5) Providers' usual and customary charge to the general public.

h. Indian health facilities enrolled pursuant to rule 441—77.45(249A). For all drugs provided to American Indians or Alaskan natives by Indian health facilities enrolled pursuant to rule 441—77.45(249A), reimbursement is one pharmacy encounter payment per date of service, notwithstanding paragraphs 79.1(8) "a" through "f." The pharmacy encounter rate is the current "outpatient per visit rate (excluding Medicare)" approved by the U.S. Indian Health Service (IHS) for services provided by IHS facilities to Medicaid beneficiaries, as published in the Federal Register, and includes reimbursement for the dispensing fees, ingredient cost, and any necessary counseling by the pharmacist.

i. Vaccines for Children Program. All providers administering vaccines available through the Vaccines for Children Program to Medicaid members shall enroll in the Vaccines for Children Program. In lieu of payment, vaccines available through the Vaccines for Children Program shall be accessed from the department of public health for Medicaid members. Providers may receive Medicaid reimbursement for the administration of vaccines to Medicaid members through the otherwise applicable reimbursement for inpatient or outpatient services.

j. Physician-administered drugs. Notwithstanding paragraphs 79.1(8) "a" through "f," payment to physicians for physician-administered drugs billed with healthcare common procedure coding system (HCPCS) Level II "J" codes, as a physician service, shall be pursuant to the physician payment policy under subrule 79.1(2).

k. Under this subrule, no payment shall be made for sales tax.

l. For purposes of this subrule, the Medicaid program relies on information published by Medi-Span to classify drugs as brand-name or generic.