DEPARTMENT OF HEALTH AND SOCIAL SERVICES

PROPOSED CHANGES TO REGULATIONS

7 AAC 105, 120, 145, 160. Pharmacy Reimbursement.

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PUBLIC REVIEW DRAFT

September 12, 2012

COMMENT PERIOD ENDS: November 30, 2012

Please see public notice for details about how to comment on these proposed changes.

Notes to reader:

1. Except as discussed in note 2, proposed new text that amends an existing regulation is **bolded and underlined**.

2. If the lead-in line states that a new section, subsection, paragraph, subparagraph, or clause is being added, or that an existing section, subsection, etc. is being repealed and readopted (replaced), the new (or replaced) text is not bolded or underlined.

3. [ALL-CAPS TEXT WITHIN BRACKETS] indicates text that is proposed to be deleted.

4. When the word "including" is used, Alaska Statutes provide that it means "including, but not limited to."

Title 7. Health and Social Services.

7 AAC 105.610(a)(4) is repealed and readopted to read:

(4) $0.50 for each prescription for prescribed drugs that is filled or refilled with a payment for service of $50.00 or less and $3.50 for each prescription for prescribed drugs that is filled or refilled with a payment for service of greater than $50.00. Covered prescriptions for recipients eligible for Chronic and Acute Medical Assistance under 7 AAC 48.560 have no copay [$2 FOR EACH PRESCRIPTION FOR PRESCRIBED DRUGS THAT IS FILLED OR REFILLED].

(Eff. 2/1/2010, Register 193; am _____/_____/2013, Register _____)

Authority: AS 47.05.010 AS 47.07.020 AS 47.07.042

7 AAC 120.110 is amended to read;

7 AAC 120.110. Covered drugs and home infusion therapy. (a) Except as provided in (e) of this section, the department will pay for

(1) a **covered outpatient** drug that requires a prescription;

(2) a compounded prescription, if

(A) at least one ingredient **is a covered outpatient drug that** requires a prescription for dispensing and the recipient's drug therapy needs cannot be met by commercially available dosage strengths or forms of the therapy;

(B) claims for compound drugs are submitted using the national drug code (NDC) number and quantity for each compensable ingredient in the compound;

(C) no more than 25 ingredients are reimbursed in any compound; and

(D) reimbursement for each drug component is determined in accordance with 7 AAC 145.400;

(3) insulin;

(4) except for a recipient who is in a long-term care facility or an intermediate care facility for the mentally retarded, a drug that has been prescribed even if that drug may be sold without a prescription, as follows:

(A) [LAXATIVES AND BISMUTH PREPARATIONS;

(B) CLOTRIMAZOLE AND MICONAZOLE VAGINAL CREAMS AND SUPPOSITORIES];

(C) prenatal vitamins for pregnant and nursing women;

(D) nonoxynol-9 contraceptive creams, gels, foams, and sponges;

(E) respiratory saline products;

(F) [BACITRACIN OINTMENT];

(G) [FERROUS SULFATE AND FERROUS GLUCONATE IN NONSUSTAINED RELEASE FORMS];

(H) tobacco cessation products for nicotine replacement therapy;

(I) loratadine;

(J) omeprazole;

(K) [CALCIUM]**;**

(L) fexogenadine;

(M) cetirizine;

(N) lansoprazole.

(b) The department will pay for tobacco cessation medication therapy management

(1) if initially ordered by a physician, an advanced nurse practitioner, or a physician assistant **in addition to a tobacco cessation medication**;

(2) if provided by a pharmacist who

(A) has successfully completed a continuing education course in tobacco cessation; and

(B) provides practical counseling in person to a recipient for at least three minutes and no more than 10 minutes; practical counseling must be in accordance with *Quick Reference Guide for Clinicians: Treating Tobacco Use and Dependence*, adopted by reference under 7 AAC 160.900; and

(C) maintains a record of the delivered practical counseling; and

(3) no more than once per 30-day period for a recipient.

(c) The department will pay for vaccine administration if provided to a recipient under 21 years of age by a pharmacist whom the Board of Pharmacy has approved to exercise collaborative practice authority under 12 AAC 52.240. However, the department will pay for recipients 21 years of age or older under 7 AAC 110.405(b)(2) and (3).

(d) **Repealed _____/_____**/2013 [THE DEPARTMENT WILL PAY A PROVIDER FOR PACKAGING PRESCRIPTION MEDICATIONS INTO A

(1) MEDISET FOR A RECIPIENT LIVING IN A CONGREGATE LIVING HOME, A RECIPIENT OF HOME AND COMMUNITY-BASED WAIVER SERVICES, A RECIPIENT ELIGIBLE FOR MEDICAID UNDER A CATEGORY SET OUT IN 7 AAC 100.002(b) OR (d) WHO IS BLIND OR DISABLED, A RECIPIENT WHO IS AN ADULT

EXPERIENCING A SERIOUS MENTAL ILLNESS, OR A RECIPIENT WHO IS A CHILD EXPERIENCING A SEVERE EMOTIONAL DISTURBANCE IF, FOR EACH SPECIFIC MEDICATION IN THE MEDISET,

(A) THE PRESCRIBING PROVIDER ALSO PRESCRIBES THAT THE MEDICATION BE PACKAGED IN A MEDISET; AND

(B) THE PHARMACY INDICATES ON THE CLAIM THAT THE FEE IS FOR DISPENSING A PHARMACY UNIT DOSE; OR

(2) UNIT DOSE TO BE USED IN A LONG-TERM CARE FACILITY, IF THE PHARMACY INDICATES ON THE CLAIM THAT THE FEE IS FOR DISPENSING A PHARMACY UNIT DOSE].

(e) **Notwithstanding (a) – (d) of this section, the** [THE] department will not pay for the following:

(1) a drug used to treat infertility, obesity, or baldness;

(2) a hair or wrinkle remover;

(3) drugs that are prohibited from receiving federal Medicaid matching funds [UNDER 42 C.F.R. 441.25];

(4) drugs, except for birth control drugs and drugs listed in (a)(4) of this section [IF DISPENSED IN AN UNOPENED CONTAINER,] for which more than a **34-day** [30-day] supply is ordered per prescription;

(5) drugs used for the symptomatic relief of coughs and colds;

(6) **non-prescription medications,** [ORAL] vitamins, **and dietary or herbal supplements,** except **as listed in (a)(4) of this section**

[(A) PRENATAL;

(B) FLUORIDE PREPARATIONS;

(C) FOLIC ACID;

(D) VITAMIN A;

(E) VITAMIN K;

(F) VITAMIN D;

(G) ANALOGS; AND

(H) B-COMPLEX VITAMINS AS MEDICALLY NECESSARY];

(7) a brand-name drug if a therapeutically equivalent generic drug is on the market, unless

(A) the brand name drug is included **as a preferred medication** on the *Alaska Medicaid Preferred Drug List*, adopted by reference in 7 AAC 160.900; or

(B) the prescriber writes on the prescription **"brand-name medically necessary"** ["BRAND-NAME MEDICALLY NECESSARY DRUG" OR "ALLERGIC TO THE INERT INGREDIENTS OF THE GENERIC DRUG"]; the information may be submitted electronically or telephonically; if the information is submitted telephonically, the prescriber must document it in the recipient's record**; the department may require prior authorization under 7 AAC 120.130 for a brand name drug with a therapeutically equivalent generic drug on the market**;

(8) an outpatient drug for which, as described in 7 AAC 105.110(18), payment

under CMS' drug rebate program is unavailable[, EXCEPT THAT THE DEPARTMENT WILL PAY FOR

(A) ACTIVE PHARMACEUTICAL INGREDIENTS FOR WHICH A DRUG REBATE IS UNAVAILABLE, IF THE INGREDIENT IS USED IN A COMPOUNDED PRESCRIPTION IN ACCORDANCE WITH (a)(2) OF THIS SECTION;

(B) DRUGS LISTED IN (a)(4)(A), (G), AND (K) OF THIS SECTION; AND

(C) HEPARIN, IF USED TO OPEN INTRAVENOUS LINES].

(f) Outpatient drugs payable under Medicaid that are not prescribed by electronic transmission in accordance with 12 AAC 52.490 or by verbal communication must be tamper-resistant by being executed on tamper-resistant paper or being printed on plain paper with tamper-resistant features generated through an electronic medical record practice system in order to be paid by the department as the primary or secondary payor. Each prescription form must contain the prescriber's National Provider Identifier (NPI) number under 45 C.F.R. 162.402 - 162.414.

(g) The requirements in (f) of this section do not apply to a

(1) prescription for which retroactive Medicaid eligibility has been determined under 7 AAC 100.072, except for refills that are filled after the retroactive eligibility determination date; or

(2) prescription prepared in an institutional pharmacy, if the prescriber writes the prescription into the medical record, the medical staff gives the order directly to the institutional pharmacy, and the patient does not handle or have the opportunity to handle the prescription; in this paragraph, "institutional pharmacy" has the meaning given in 12 AAC 52.995(a).

(h) The tamper-resistant paper or tamper-resistant printing required under (f) of this section must include at least one industry-recognized feature designed to prevent unauthorized copying of a completed prescription, at least one industry-recognized feature designed to prevent the erasure or modification of information written on the prescription by the prescriber, and at least one industry-recognized feature designed to prevent the use of counterfeit prescription forms**.** **Any one feature may not be used more than once for proof of tamper resistance**. For purposes of this subsection, industry-recognized features designed to prevent

(1) unauthorized copying of a completed or blank prescription form include

(A) high-security watermarks on the reverse side of blank prescriptions;

(B) thermochromic ink that changes color or disappears when warmed;

(C) security patterns;

(D) "void", "copy", or "illegal" pantographs, with or without a reverse prescription;

(E) microprinting with a font size of 0.5 point or less;

(F) prismatic printing;

(G) lenticular patterns; and

(H) repealed 7/7/2010;

(2) erasure or modification of information written on the prescription by the prescriber include tamper-resistant background ink that shows erasures or attempts to change written information in accordance with any of the following techniques:

(A) toner anchorage used to complicate the removal of toner;

(B) chemical stains used to reveal chemical eradication attempts against ink or toner;

(C) laid lines used to reveal cut-paste attempts on an item;

(D) chemical reactive inks used to reveal washing attacks;

(E) overcoatings, laminates, and varnishes used to secure written content on the item;

(F) erasable ink backgrounds used to reveal attempts at ink and toner removal;

(G) borders and fill characters used to complicate attempts to add-on extra information;

(H) on-item encodation techniques, bar codes, and patterns used to validate item content; and

(I) quantity check-off boxes; and

(3) the use of counterfeit prescription forms include

(A) serially numbered blanks;

(B) duplicate or triplicate blanks;

(C) thermochromic ink that changes color or disappears when warmed;

(D) color-shifting ink that changes color when viewed from different angles; and

(E) security features and descriptions listed on the prescription; [ANY ONE FEATURE MAY NOT BE USED MORE THAN ONCE FOR PROOF OF TAMPER RESISTANCE].

(i) The department will pay a provider for filling a prescription that does not comply with (f) - (h) of this section if the pharmacy verifies the authenticity of the prescription by

(1) contacting the prescriber; and

(2) documenting on the prescription form

(A) the name of the prescriber or prescriber's representative who verified the prescription; and

(B) the date the prescription was verified.

(j) If a written prescription does not comply with (f) - (i) of this section, the monetary value of that prescription claim may be recouped by the department during pre- or postpayment review.

(k) Repealed 1/1/2011.

(*l*) For purposes of billing for prescribed drugs, the date of service is the date a prescription is filled. If the recipient or the recipient's representative does not receive the drug during the 10-day period that begins on the date the prescription is filled, the pharmacy shall reverse the claim and refund the payment to the department.

(m) A pharmacy shall maintain documentation of receipt of prescribed drugs by recipients. The documentation may be kept as a signature log showing which prescription numbers are received or as mailing labels if prescribed drugs are mailed to the recipient.

(n) In this section,

(1) **"covered outpatient drug" means of those drugs which are treated as a prescribed drug for the purposes of section 1905(a)(12) of the Act, a drug which may be dispensed only upon a prescription; a drug can only be considered a covered outpatient drug if it is**

(A) is approved for safety and effectiveness as a prescription drug by the FDA under section 505 or 507 of the Federal Food Drug and Cosmetic Act (FFDCA) where the manufacturer has obtained a new drug application (NDA) and also under section 505(j) of the FFDCA where the manufacturer has obtained an abbreviated new drug application (ANDA);

(B) is a biologic product other than a vaccine that may only be dispensed upon a prescription and is licensed under section 351 of the Public Health Service Act (PHSA) and is produced at an establishment licensed under section 351 of the PHSA to produce such product; or

(C) is insulin certified under section 506 of the FFDCA

[(1) "CONGREGATE LIVING HOME" INCLUDES A LONG-TERM CARE FACILITY, AN ASSISTED LIVING HOME LICENSED UNDER AS 47.32, A RESIDENTIAL PSYCHIATRIC TREATMENT CENTER, OR OTHER GROUP HOME;

(2) "MEDISET" MEANS A QUANTITY OR UNIT DOSE OF A PRESCRIPTION MEDICATION THAT THE PROVIDER REPACKAGES INTO SINGLE-DOSE PACKING TO HELP A RECIPIENT ADHERE TO DIFFICULT DOSING REGIMENS;

(3) "UNIT DOSE" MEANS A QUANTITY OF A DRUG THAT THE PROVIDER RE-PACKAGES INTO SINGLE DOSAGE PACKING].

(o) A covered outpatient drug does not include:

(1) any drug product, prescription or over the counter product, for which a national drug code (NDC) number is not required by the FDA;

(2) a drug product that is not listed electronically with the FDA;

(3) a drug product for which a manufacturer has not submitted to CMS evidence to demonstrate that the drug product satisfies the criteria in (n)(1)(A) of this section; or

(4) a drug product or biological used for a medical indication which is not a medically accepted indication.

(p) The department may designate one or more enrolled pharmacy provider for the purchase of specialty drugs through a contract for services under AS 36.30.

(q) The department will develop, maintain, and publish a list of specialty drugs on the Alaska Medicaid website.

(r) The department may include a drug on the specialty drug list if the department determines that the drug meets all of the following criteria:

(1) the drug is used to treat and is prescribed for a person with a complex, chronic, or rare medical condition that can be debilitating or fatal if left untreated or under treated, or for a condition for which there is no known cure; medical conditions including cancer, chronic renal failure, Crohn's disease, cystic fibrosis, endocrine disorders, growth hormone deficiency, hemophilia and blood clotting diseases, hepatitis, immune deficiency,

inflammatory conditions, iron toxicity, multiple sclerosis, pulmonary hypertension, respiratory syncytial virus prevention, rheumatoid arthritis, and organ transplantation may be included on the specialty drug list;

(2) the drug is not routinely stocked at a majority of community retail pharmacies. (Eff. 2/1/2010, Register 193; am 6/13/2010, Register 194; am 7/7/2010, Register 195; am 1/1/2011, Register 196; am 9/7/2011, Register 199; am 1/4/2012, Register 201; am _____/_____/2013, Register _____)

Authority: AS 47.05.010 AS 47.07.030 AS 47.07.040

7 AAC 145.400 is amended to read:

7 AAC 145.400. Covered drug payment rates and home infusion therapy drug rates. (a) In addition to complying with the requirements of 7 AAC 105.220, and before submitting a claim for payment from the department, a pharmacy provider shall bill any third-party prescription drug plan in which the recipient is enrolled and that is in effect on the date of service. After the pharmacy provider receives notification from the third-party prescription drug plan of the amount, if any, that the third-party prescription drug plan will pay, the pharmacy provider may submit a claim for payment from the department for the remaining cost of service. The department will pay the pharmacy provider **the lesser of** the difference between the payment by the third-party prescription drug plan and the department-calculated allowable payment, minus any recipient cost-sharing amounts imposed under AS 47.07.042 by the department **or the remaining patient liability amount, minus any recipient cost-sharing amounts imposed under AS 47.07.042 by the department**. The department will consider the payment to be payment in full. [THE DEPARTMENT WILL PROVIDE AN EXEMPTION TO A LIMIT ESTABLISHED UNDER 7 AAC 120.130 FOR A THERAPEUTIC DRUG CLASS, IF THE THIRD-PARTY PRESCRIPTION DRUG PLAN HAS A DIFFERENT LIMIT FOR THE THERAPEUTIC DRUG CLASS.]

(b) The department will pay the provider for reasonable and necessary postage**, up to $16 per prescription or package,** [OR FREIGHT COSTS] incurred in the delivery of the prescription from the dispensing pharmacy to the recipient. **The postage costs must be divided by the number of prescriptions shipped and the partial postage amount is to be billed on each prescription claim.**

(c) The department may establish a state maximum allowable cost for a drug [IF TWO OR MORE MULTIPLE-SOURCE, NON-INNOVATOR DRUGS WITH A SIGNIFICANT COST DIFFERENCE EXIST FOR THE GIVEN DRUG AND THE UNITED STATES FOOD AND DRUG ADMINISTRATION HAS FOUND THEM, UNDER 21 C.F.R. PART 314, TO BE THERAPEUTICALLY EQUIVALENT]. The state maximum allowable cost will be established by reviewing [THE] pricing sources, **including the** wholesale acquisition cost, **purchase invoices, or** [AND] direct price for the drug as identified in the First Data Bank *National Drug Data File (NDDF) Plus*, taking into consideration the cost of the most frequently dispensed drugs.

(d) The department will maintain on its website a current listing of drugs and their corresponding state maximum allowable costs.

(e) **Notwithstanding (f) - (p) of this section and 7 AAC 145.020, the department will pay the lesser of the calculated allowed amount less any cost sharing amount under 7 AAC 105.610 or the provider's usual and customary charge less any cost sharing amount under 7 AAC 105.610 for all pharmacy claims. The usual and customary charge is the lowest amount a provider charges to the general public and reflects all advertised savings, discounts, special promotions, or other programs** [RECONSIDERATION OF A STATE MAXIMUM ALLOWABLE COST PRICE FOR A DRUG IS SUBJECT TO THE FOLLOWING PROCEDURES:

(1) THE PROVIDER MUST SUBMIT, BY ELECTRONIC MAIL OR FACSIMILE TRANSMISSION, A COMPLETED *ALASKA MEDICAID MAC PRICE RESEARCH REQUEST FORM*, ADOPTED BY REFERENCE IN 7 AAC 160.900; THE PROVIDER MUST INCLUDE WITH THE FORM A COPY OF THE INVOICE LISTING THE CURRENT ACQUISITION COST;

(2) THE PROVIDER MUST CONTACT THE DEPARTMENT IN WRITING AND MUST INCLUDE ALL INFORMATION SUPPORTING THE REQUEST FOR RECONSIDERATION, INCLUDING THE NATIONAL DRUG CODE (NDC) FOR THE DRUG IN QUESTION;

(3) A REQUEST FOR RECONSIDERATION OF A STATE MAXIMUM ALLOWABLE COST PRICE FOR A DRUG WILL BE INVESTIGATED AND RESOLVED NO MORE THAN THREE DAYS AFTER THE DEPARTMENT RECEIVES THE WRITTEN CONTACT DESCRIBED IN (2) OF THIS SUBSECTION;

(4) THE PROVIDER WILL BE SUPPLIED WITH THE NAMES, IF AVAILABLE, OF ONE OR MORE MANUFACTURERS THAT HAVE A PRICE COMPARABLE TO THE STATE MAXIMUM ALLOWABLE COST PRICE;

(5) THE STATE MAXIMUM ALLOWABLE COST PRICE AND EFFECTIVE DATE OF THAT PRICE WILL BE ADJUSTED ACCORDINGLY, RETROACTIVE TO THE DATE OF SERVICE FOR THE STATE MAXIMUM ALLOWABLE COST PRICE PRESCRIPTION IN QUESTION, IF

(A) THE DEPARTMENT DETERMINES THAT ALL MANUFACTURERS' COSTS EXCEED THE STATE MAXIMUM ALLOWABLE COST; OR

(B) THE PROVIDER IS ABLE TO DOCUMENT THAT DESPITE REASONABLE EFFORTS TO OBTAIN ACCESS, THE PROVIDER DOES NOT HAVE ACCESS TO THE ONE OR MORE MANUFACTURERS WHOSE NAMES THE DEPARTMENT SUPPLIED TO THE PROVIDER;

(6) WHEN THE CHANGE IN STATE MAXIMUM ALLOWABLE COST PRICE FOR A PRICE THAT IS ADJUSTED BECOMES EFFECTIVE, THE PROVIDER WILL BE INFORMED THAT THE CLAIM MAY BE RESUBMITTED FOR THE PRICE ADJUSTMENT].

(f) The payment for [MULTIPLE-SOURCE] drugs [FOR WHICH CMS HAS ESTABLISHED A SPECIFIC UPPER LIMIT AMOUNT IN ACCORDANCE WITH 42 C.F.R. 447.514, ADOPTED BY REFERENCE IN 7 AAC 160.900,] is the lowest of the following:

(1) the submitted drug cost plus the dispensing fee set under 7 AAC 145.410;

(2) **any federal**[that] upper limit **established by CMS in accordance with 42 C.F.R. 447.514** plus the dispensing fee;

(3) the [IN-STATE] estimated acquisition cost of the drug plus the dispensing fee;

(4) the state maximum allowable cost plus the dispensing fee.

(g) The department will pay for vaccines at the lowest of the following:

(1) the submitted vaccine cost plus the submitted vaccine administration fee **under 7 AAC 145.410**;

(2) the state maximum allowable cost plus the vaccine administration fee [SET UNDER 7 AAC 145.410];

(3) any federal upper limit established under 42 C.F.R. 447.514 plus the submitted vaccine administration fee;

(4) the [IN-STATE] estimated acquisition cost plus the vaccine administration fee [SET UNDER 7 AAC 145.410].

(h) The payment [FOR DRUGS OTHER THAN THOSE DESCRIBED IN (c) AND (f) OF THIS SECTION, AND] for brand names of multiple-source drugs specified by the prescriber in accordance with 42 C.F.R. 447.512[, ADOPTED BY REFERENCE,] is the lowest of the following:

(1) the submitted drug cost plus the dispensing fee set under 7 AAC 145.410;

(2) the [IN-STATE] estimated acquisition cost of the drug plus the dispensing fee**:**

(3) the state maximum allowable cost plus the dispensing fee.

(i) A provider may not submit a charge to the department in excess of the amount applicable to a specific drug under 7 AAC 145.020.

(j) The department will pay for [IN-STATE] compound prescriptions the sum of the [COMPOUND] dispensing fee set under 7 AAC 145.410 and the cost of each ingredient, with the cost of each ingredient set at the lowest of the following:

(1) the submitted cost for that ingredient;

(2) any federal upper limit established under 42 C.F.R. 447.514 for that ingredient;

(3) the state maximum allowable cost for that ingredient;

(4) the [IN-STATE]estimated acquisition cost for that ingredient.

(k) A provider that dispenses drugs in unit doses to a recipient in a long-term care facility shall return unused medications to the pharmacy, and the claim will be adjusted.

(*l*) The department will pay a provider for [COMPOUND] home infusion therapy drugs for patients in a long-term care facility the sum of the [COMPOUND] dispensing fee set under 7 AAC 145.410 and the cost of each ingredient, with the cost of each ingredient set at the lowest of the following:

(1) the submitted cost for that ingredient;

(2) the state maximum allowable cost for that ingredient;

(3) the federal upper limit established under 42 C.F.R. 447.514 for that ingredient;

(4) the [IN-STATE] estimated acquisition cost for that ingredient.

(m) **Repealed** ___/___/2013 [THE DEPARTMENT WILL PAY FOR HOME INFUSION THERAPY DRUGS THAT ARE SUPPLIED FOR PATIENTS IN A LONG-TERM CARE FACILITY WITHOUT COMPOUNDING AT THE LOWEST OF THE FOLLOWING:

(1) THE SUBMITTED DRUG COST PLUS THE DISPENSING FEE SET UNDER 7 AAC 145.410;

(2) THE STATE MAXIMUM ALLOWABLE COST PLUS THE DISPENSING FEE;

(3) THE FEDERAL UPPER LIMIT ESTABLISHED UNDER 42 C.F.R. 447.514 PLUS THE DISPENSING FEE;

(4) THE IN-STATE ESTIMATED ACQUISITION COST OF THE DRUG PLUS THE DISPENSING FEE].

(n) The department will pay, for [COMPOUND] home infusion therapy drugs for patients outside a long-term care facility, the sum of the ingredient costs **without a dispensing fee**, with the cost of each ingredient set at the lowest of the following:

(1) the submitted cost for that ingredient;

(2) the state maximum allowable cost for that ingredient;

(3) the federal upper limit established under 42 C.F.R. 447.514 for that ingredient;

(4) the [IN-STATE] estimated acquisition cost for that ingredient.

(o) If a facility is a covered entity [AND RECEIVES DRUGS] as described in 42 U.S.C. 256b **and indicates to the United States Department of Health and Human Services that it will use medications purchased through the 340B drug pricing program to bill Medicaid**, the facility **must notify the department and** may not **submit a** charge **to** Medicaid **for** more than the actual acquisition cost of the medication[, A FREIGHT CHARGE OF FIVE PERCENT OF THE INGREDIENT COST,] and a dispensing fee calculated under 7 AAC 145.410. **If the facility indicates that it will use medications purchased through the 340B drug pricing program to bill Medicaid, then all medications billed to Medicaid by that facility must be purchased through the 340B drug pricing program.** If a covered entity as defined in 42 U.S.C. 256b notifies the United States Department of Health and Human Services, Health Resources and Services Administration, Office of Pharmacy Affairs **of any changes in their enrollment or participating in the program, including** that the entity's pharmacy is not included under 42 U.S.C. 256b**, the pharmacy** [OR] is [USING AN ALTERNATIVE MECHANISM OR CARVING OUT] **going to begin using medications purchased through the 340B program to bill Medicaid, or the pharmacy is no longer going to use medications purchased through the 340B program to bill Medicaid**, the entity shall also notify the department. **Payment for medications from a facility indicating to the United**

States Department of Health and Human Services that it will use medications purchased through the 340B drug pricing program to bill Medicaid will be the lesser of the following:

(1) the submitted actual acquisition drug cost plus the dispensing fee set under 7 AAC 145.410;

(2) any federal upper limit established by CMS in accordance with 42 C.F.R. 447.514 plus the dispensing fee;

(3) the wholesale acquisition cost of the drug minus 25 percent plus the dispensing fee;

(4) the state maximum allowable cost plus the dispensing fee.

(p) **If a facility purchases medications through the Federal Supply Schedule or drug pricing program under Section 601, 602, or 603 of the Veterans Health Care Act of 1992 other than through the 340B drug pricing program, the facility must notify the department and may not submit a charge to Medicaid for more than the actual acquisition cost of the medication and a dispensing fee calculated under 7 AAC 145.410. The facility must notify the Department of any changes in participation in purchasing medications through the Federal Supply Schedule or drug pricing program under Section 601, 602, or 603 of the Veterans Health Care Act of 1992. Payment for medications from a facility purchasing medications through the Federal Supply Schedule or drug pricing program under Section 601, 602, or 603 of the Veterans Health Care Act of 1992 other than through the 340B drug pricing program will be the lesser of the following:**

(1) the submitted actual acquisition drug cost plus the dispensing fee set under 7 AAC 145.410;

(2) any federal upper limit established by CMS in accordance with 42 C.F.R. 447.514 plus the dispensing fee;

(3) the wholesale acquisition cost of the drug minus 20 percent plus the dispensing fee;

(1) **the state maximum allowable cost plus the dispensing fee** [PAYMENT TO A PROVIDER OF DRUGS OR COMPOUNDED PRESCRIPTIONS THAT IS LOCATED IN ANOTHER STATE OR COUNTRY IS SUBJECT TO THIS SECTION, EXCEPT AS FOLLOWS:

(1) FOR PURPOSES OF (f) - (h), (j), AND (*l*) - (o) OF THIS SECTION, THE DISPENSING FEE IS THE OUT-OF-STATE DISPENSING FEE SET UNDER 7 AAC 145.410;

(2) FOR PURPOSES OF (f)(3), (g)(4), (h)(2), (j)(4), (*l*)(4), (m)(4), AND (n)(1)(D) OF THIS SECTION, THE ESTIMATED ACQUISITION COST IS THE OUT-OF-STATE ESTIMATED ACQUISITION COST].

(q) For purposes of this section,

(1) "home infusion therapy" means drugs that require the use of a laminar flow hood or clean room for the protection of either the product or preparing personnel, and include cancer chemotherapy drugs, intravenous antibiotics, and hyperalimentation drugs;

(2) "[IN-STATE] estimated acquisition cost" means the wholesale acquisition cost plus **one** [EIGHT] percent;

(3) **repealed** ___/___/2013 ["OUT-OF-STATE ESTIMATED ACQUISITION COST" MEANS THE WHOLESALE ACQUISITION COST PLUS ONE PERCENT];

(4) "wholesale acquisition cost" means the manufacturer's list price for the drug to wholesalers or direct purchasers in the United States, not including prompt-pay or other discounts, rebates, or reductions in price, for the most recent month for which the information is available, as reported in wholesale price guides or other publications of drug pricing data.

(Eff. 2/1/2010, Register 193; am 1/1/2011, Register 196; am _____/_____/2013, Register _____)

Authority: AS 47.05.010 AS 47.07.030 AS 47.07.040

Editor's note: The *American Druggist Blue Book* is a service subscribed to by the department that provides weekly updated comprehensive electronic data on available drugs, drug classifications, national drug code (NDC) numbers, and wholesale pricing. To see how this information is used, an individual must make arrangements for an in-person visit by contacting the office of the Department of Health and Social Services, Division of Health Care Services, 4501 Business Park Boulevard, Suite 24, Anchorage, Alaska 99503-7167.

7 AAC 145.410 is amended to read:

7 AAC 145.410. Dispensing fee. (a) The department will pay a dispensing fee to **a** [AN IN-STATE] pharmacy **or dispensing provider** in accordance with the following schedule:

(1) for a [LOW-VOLUME] pharmacy **located on the road system**, the dispensing fee is **$13.36** [$26.74], to be paid no more than once every **20** [28] days per individual medication strength;

(2) for a [MEDIUM-VOLUME] pharmacy **not located on the road system**, the dispensing fee is **$21.28** [$16.98], to be paid no more than once every **20** [28] days per individual medication strength; and

(3) [FOR A HIGH-VOLUME PHARMACY,] the dispensing fee **for an out-of-state pharmacy** is **$13.36** [$12.12], to be paid no more than once every **20** [28] days per individual medication strength**;**

(4) the dispensing fee for an enrolled pharmacy, dispensing provider, or facility purchasing medications through the Federal Supply Schedule, 340B drug pricing program, or drug pricing program under Section 601, 602, or 603 of the Veterans Health Care Act of 1992 is the assigned dispensing fee under (a)(1) - (a)(3), or (g) of this section, plus 2 dollars, to be paid no more than once every 20 days per individual medication strength;

(5) the dispensing fee for compounded medications is the applicable fee listed in (a)(1) - (a)(4) and (g) of this section;

(6) claims submitted by a provider for a recipient for the same medication

strength for which a dispensing fee was paid within the last 20 days, will be paid without the dispensing fee listed in (a)(1) - (a)(5) and (g) of this section if the claim satisfies all coverage criteria under 7 AAC 120.110 – 7 AAC 120.140.

(b) **Repealed** ___/___/2013 [THE DISPENSING FEE FOR AN OUT-OF-STATE PHARMACY IS $3.50, TO BE PAID NO MORE THAN ONCE EVERY 28 DAYS PER INDIVIDUAL MEDICATION STRENGTH].

(c) The department will pay, under (a) or **(g)** [(b)] of this section, the lesser of the [PHARMACY'S] assigned dispensing fee or the submitted dispensing fee. [A NEWLY ESTABLISHED IN-STATE PHARMACY THAT DOES NOT HAVE THE INFORMATION AVAILABLE TO ESTABLISH A FEE WILL BE ASSIGNED THE LOWEST DISPENSING FEE OF $12.12 UNTIL THAT PHARMACY CAN PROVIDE 12 MONTHS OF PRESCRIPTION DATA TO THE DEPARTMENT, AFTER WHICH THE NEW DISPENSING FEE WILL BE APPLIED TO PHARMACY PAYMENTS WITHIN TWO WEEKS FOR FUTURE PRESCRIPTION CLAIMS.]

(d) **Repealed** ___/___/2013 [A MEDISET FEE OF $5 PER CLAIM TO BE BILLED NO MORE THAN ONCE EVERY SEVEN DAYS WILL BE PAID TO A MEDISET PHARMACY FOR A RECIPIENT LIVING IN A CONGREGATE LIVING HOME, A RECIPIENT OF HOME AND COMMUNITY-BASED WAIVER SERVICES, A RECIPIENT ELIGIBLE FOR MEDICAID UNDER A CATEGORY SET OUT IN 7 AAC 100.002(b) OR (d) WHO IS BLIND OR DISABLED, A RECIPIENT WHO IS AN ADULT EXPERIENCING A SERIOUS MENTAL ILLNESS, OR A RECIPIENT WHO IS A CHILD EXPERIENCING A SEVERE EMOTIONAL DISTURBANCE].

(e) **Repealed** ___/___/2013 [THE COMPOUND DISPENSING FEE FOR AN IN-STATE PHARMACY IS THE LOWEST OF

(1) THE SUBMITTED COMPOUND DISPENSING FEE; OR

(2) TWO TIMES THE ASSIGNED DISPENSING FEE IN (a) OF THIS SECTION].

(f) Upon request by the department, a pharmacy shall produce business records and invoice information relevant to the cost of drugs and the cost of dispensing. If a pharmacy does not provide cost of drugs or dispensing fee data as requested by the department, the department may **assign** [EITHER PAY] that pharmacy the dispensing fee of $3.45 **and** [OR] sanction the pharmacy as provided under 7 AAC 105.400 - 7 AAC 105.490.

(g) **The dispensing fee for an outpatient prescription medication dispensed by a dispensing provider to a recipient for outpatient use is $8.42 to be paid no more than once every 20 days per individual medication strength. Covered medications administered to an outpatient recipient by a physician, nurse practitioner, physician assistant or nurse midwife billed using a covered CPT or HCPCS code will be reimbursed at the estimated acquisition cost defined at 7 AAC 145.400(q)(2) with no dispensing fee. Covered medications administered to an outpatient recipient using a covered CPT or HCPCS code by a provider or entity that were obtained through a drug pricing program under Section 601, 602, or 603 of the Veterans Health Care Act of 1992, including the 340B program, must be billed for and will be reimbursed at the actual acquisition cost of the medication**

with no dispensing fee [NOTWITHSTANDING THE PROVISIONS OF (a) OF THIS SECTION, PAYMENT WILL BE MADE TO A DISPENSING PROVIDER FOR THE ESTIMATED ACQUISITION COST OF A DRUG. A DISPENSING FEE WILL NOT BE INCLUDED, EXCEPT THAT A DISPENSING PROVIDER LOCATED OVER 45 MILES FROM A RETAIL PHARMACY THAT IS NOT A COVERED ENTITY UNDER 42 U.S.C. 256b MAY RECEIVE A DISPENSING FEE OF $5.73].

(h) In addition to a dispensing fee under (a) - (c) of this section for tobacco cessation medication, the department will pay for tobacco cessation medication therapy management that meets the requirements of 7 AAC 120.110(b) at the rate **$16, no more than once every 30 days** [PAID TO AN ADVANCED NURSE PRACTITIONER FOR SERVICES ASSIGNED CODE 99406 IN THE *CURRENT PROCEDURAL TERMINOLOGY, PROFESSIONAL EDITION*, ADOPTED BY REFERENCE IN 7 AAC 160.900].

(i) The department will pay for vaccine administration if provided by a pharmacist to a recipient and reimbursed under 7 AAC 145.400(g). The vaccine administration fee is $17.46.

(j) **Repealed** ___/___/2013 [IN ADDITION TO A DISPENSING FEE UNDER (a) - (c) OF THIS SECTION, THE DEPARTMENT WILL PAY A CLOZAPINE MEDICATION THERAPY MANAGEMENT FEE OF $15 NO MORE THAN ONCE EVERY 30 DAYS].

(k) A pharmacy may not refuse to fill an interim prescription occurring before the end of **20** [28] days **because an additional dispensing fee will not be paid** [AS THE MONTHLY DISPENSING FEE COVERS THE MONTHLY PERIOD].

(*l*) In this section,

(1) repealed ["HIGH-VOLUME PHARMACY" MEANS A PHARMACY FILLING MORE THAN 85,000 PRESCRIPTIONS A YEAR];

(2) repealed ["LOW-VOLUME PHARMACY" MEANS A PHARMACY FILLING FEWER THAN 29,500 PRESCRIPTIONS A YEAR];

(3) repealed ["MEDISET" HAS THE MEANING GIVEN IN 7 AAC 120.110(n)];

(4) repealed ["MEDIUM-VOLUME PHARMACY" MEANS A PHARMACY FILLING AT LEAST 29,500 AND FEWER THAN 85,000 PRESCRIPTIONS A YEAR];

(2) repealed ["UNIT DOSE" HAS THE MEANING GIVEN IN 7 AAC 120.110(n)];

(3) repealed ["MEDISET PHARMACY" MEANS A PHARMACY DISPENSING 75 PERCENT OR MORE OF THE TOTAL ANNUAL MEDICAID PRESCRIPTIONS IN PRESCRIBER-ORDERED MEDISETS OR UNIT DOSES]**;**

(7) "out-of-state pharmacy" means an enrolled pharmacy physically located in any state other than Alaska;

(8) "pharmacy located on the road system" means a pharmacy that is physically located in a city, town, or village that is directly or indirectly connected to Anchorage by road;

(9) "pharmacy not located on the road system" means a pharmacy that is physically located in a city, town, or village that is not connected to Anchorage by road.

(Eff. 2/1/2010, Register 193; am 1/1/2011, Register 196; am 9/7/2011, Register 199; am 1/4/2012, Register 201; am _____/_____/2013, Register _____)
Authority: AS 47.05.010 AS 47.07.030 AS 47.07.040

7 AAC 160.900(a)(22) is repealed:

(a) The following documents referenced in 7 AAC 105 - 7 AAC 160 are adopted by reference:

. . . .

(22) [THE MAGELLAN MEDICAID ADMINISTRATION, *ALASKA MEDICAID MAC PRICE RESEARCH REQUEST FORM*, REVISED AS OF SEPTEMBER 13, 2010];

7 AAC 160.900(b)(9) is repealed:

(b) The following provisions of federal statutes and regulations are adopted by reference:

. . . .

(9) repealed [42 C.F.R. 447.512 (DRUGS: AGGREGATE UPPER LIMITS OF PAYMENT), REVISED AS OF OCTOBER 1, 2008];

7 AAC 160.900(b)(10) is repealed:

(b) The following provisions of federal statutes and regulations are adopted by reference:

. . . .

(10) repealed [42 C.F.R. 447.514 (UPPER LIMITS FOR MULTIPLE SOURCE DRUGS), REVISED AS OF OCTOBER 1, 2008];

(Eff. 2/1/2010, Register 193; am 8/25/2010, Register 195; am 12/1/2010, Register 196; am 1/1/2011, Register 196; am 1/15/2011, Register 197; am 2/9/2011, Register 197; am 3/1/2011, Register 197; am 10/1/2011, Register 199; am 12/1/2011, Register 200; am 1/26/2012, Register 201; am 3/8/2012, Register 201; am 4/1/2012, Register 201; add'l am 4/1/2012, Register 201; am 5/11/2012, Register 202; am _____/_____/2013, Register _____; am _____/_____/2013, Register _____)
Authority: AS 47.05.010 AS 47.07.030 AS 47.07.040
AS 47.05.012

Publisher: *In the editor's note that follows 7 AAC 160.900, please delete the 33rd paragraph, as follows*:

[THE MAGELLAN MEDICAID ADMINISTRATION *ALASKA MEDICAID MAC PRICE RESEARCH REQUEST FORM* MAY BE OBTAINED FROM FIRST HEALTH SERVICES, MAGELLAN MEDICAID ADMINISTRATION AT: HTTP://WWW.MEDICAIDALASKA.COM]