



THE STATE
of **ALASKA**
GOVERNOR BILL WALKER

Department of
Health and Social Services

DIVISION OF HEALTH CARE SERVICES
PHARMACY & ANCILLARY SERVICES UNIT

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March 31, 2017

Re: Federal Covered Outpatient Drug Rule; CMS-2345-FC

Dear Pharmacists, Prescribers, and Members:

Effective April 1, 2017, the federal Covered Outpatient Drug Rule [CMS-2345-FC; 42 CFR 447.500-522] will go into effect.

The purpose of this notice is to identify alignment of current state regulation with the new federal regulation and provide for areas of clarification for compliance with the new rule. This notice does not represent a change in reimbursement methodology codified under current state regulations found in 7 AAC 120.110 – 7 AAC 120.112 and 7 AAC 145.400 – 7 AAC 145.410.

- (1) A covered outpatient drug will continue to be defined as one
 - a. that may be dispensed only upon a prescription;
 - b. for which the United States Food and Drug Administration (FDA) requires a national drug code (NDC) number;
 - c. that is listed electronically with the FDA;
 - d. for which the manufacturer has obtained a new drug application, an abbreviated new drug application, or an approved biologics license application from the FDA; and
 - e. for which federal Medicaid matching funds are available. [7 AAC 120.110 – 7 AAC 120.112]
- (2) Reimbursement for covered outpatient drugs, including hemophilia factor, will be based on the acquisition cost plus a professional dispensing fee. Alaska Medicaid will use 'lesser of' reimbursement logic as defined in 7 AAC 145.400 and 7 AAC 145.410. The Department will consider the federal upper limit established by CMS in reimbursement logic when available as well as the providers' usual and customary charges to the general public. The Department's state maximum allowable cost, effective July 1, 2014, will remain the National Average Drug Acquisition Cost (NADAC) when available. The Department may establish a state maximum allowable cost, with sufficient 30-day notice, for items without a NADAC price by reviewing alternate pricing sources. When a specific state maximum allowable cost, such as NADAC, is not available, the Department will consider the wholesale acquisition cost (WAC) plus 1% as part of its reimbursement logic until such time a new dispense fee survey is completed.
 - a. For Indian Health Service, Tribal, and Urban Indian Organizations and other entities purchasing drugs through the Federal Supply Schedule of the United States General Services Administration or drug pricing program under 38 USC 8126, 42 USC 256b, or 42 USC 1396r-8, other than the 340B drug pricing program, the Department will consider the wholesale acquisition cost minus 15% in the reimbursement logic [7 AAC 145.400(o)].

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- b. For 340B covered entities described in 42 USC 256b who choose to carve-in Medicaid, the entity may not submit a charge to the Department for more than the actual acquisition cost plus the calculated dispensing fee noted in 7 AAC 145.410. Contract pharmacies of covered entities enrolled with Alaska Medicaid are not considered covered entities and should not be utilizing 340B drugs for Medicaid members.
- (3) Drugs, biologics, or insulin provided incident to services noted in 42 CFR 447.502 that are administered to an outpatient recipient by a physician, advanced nurse practitioner, or physician assistant; available from manufacturers participating in the Medicaid Drug Rebate Program; approved by the FDA as safe and effective; and billed using a covered code under the Current Procedural Terminology (CPT) or Healthcare Common Procedure Coding System (HCPCS) will be reimbursed at the wholesale acquisition cost plus 1% with no dispensing fee [7 AAC 145.410].

A State Plan Amendment (SPA) will be submitted to CMS prior to June 30, 2017 with an April 1, 2017 effective date to reflect the minor changes and clarifications. An opportunity for public comment on the SPA will be provided.

Please contact me at erin.narus@alaska.gov with any questions about this notice.

Sincerely,

A handwritten signature in blue ink that reads "Erin Narus, PharmD, RPh". The signature is written in a cursive, flowing style.

Erin Narus, PharmD, RPh
Lead Pharmacist, Pharmacy & Ancillary Services Unit