HUMAN SERVICES DEPARTMENT[441]

Adopted and Filed Emergency

Pursuant to the authority of Iowa Code section 249A.4, the Department of Human Services amends Chapter 78, "Amount, Duration and Scope of Medical and Remedial Services," Iowa Administrative Code.

These amendments move the Medicaid coverage provisions for pharmaceutical compounding supplies from coverage as a pharmacy item to coverage as a medical supply item. The Centers for Medicare and Medicaid Services has issued notice that effective January 1, 2011, active pharmaceutical ingredients and excipients used in drug compounding will be classified as nondrug products. (An excipient is an inert substance added to a prescription to give the desired consistency or form.) These supplies will no longer be eligible for the drug rebate program but may continue to be covered as medical supply items.

If there is a commercially available prescription product that duplicates an extemporaneous (pharmacy-mixed) compound that a Medicaid member has been receiving, the member will be required to transition to that product rather than continuing to receive the extemporaneous compound. Medicaid will continue to cover certain active pharmaceutical ingredients and excipients as listed on the Preferred Drug List when a commercial product is not applicable. Pharmacies will continue to provide the active pharmaceutical ingredients and excipients and bill Medicaid in the same manner, but the expenditures will be recorded as medical supplies and not as drugs. Consistent with their current coverage as drugs, dispensing of compounding supplies will be limited to a 31-day supply.

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

The Council on Human Services adopted these amendments November 10, 2010.

In compliance with Iowa Code section 17A.4(3), the Department finds that notice and public participation are unnecessary because these amendments do not expand the coverage of these products, which have previously been covered as a drug benefit.

The Department also finds, pursuant to Iowa Code section 17A.5(2)"b"(2), that the normal effective date of these amendments should be waived so that the new coverage is in place effective with the date of the federal restrictions on drug coverage.

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

These amendments shall become effective on January 1, 2011.

The following amendments are adopted.

ITEM 1. Amend subrule 78.10(4), introductory paragraph, as follows:

78.10(4) *Medical supplies*. Medical supplies are nondurable items consumed in the process of giving medical care, for example, nebulizers, gauze, bandages, sterile pads, adhesive tape, and sterile absorbent cotton. Medical supplies are payable for a specific medicinal purpose. This does not include food or drugs. However, active pharmaceutical ingredients and excipients that are identified as preferred on the preferred drug list published by the department pursuant to Iowa Code section 249A.20A are covered. Medical supplies are shall not to be dispensed at any one time for in quantities exceeding a 31-day supply for active pharmaceutical ingredients and excipients or a three-month supply for all other items. After the initial dispensing of medical supplies, the provider must document a refill request from the Medicaid member or the member's caregiver for each refill.

ITEM 2. Amend paragraph **78.10(4)"a"** by adding the following \underline{new} item to the list of covered supplies:

Active pharmaceutical ingredients and excipients identified as preferred on the preferred drug list published pursuant to Iowa Code section 249A.20A.

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EDITOR'S NOTE: For replacement pages for IAC, see IAC Supplement 12/1/10.