

Form 6

Department of Social Services Notice of Public Hearing to Adopt Rules

A public hearing will be held telephonically on Tuesday, April 6, 2021, at 2:00 p.m., to consider the adoption and amendment of proposed rules numbered §§ 67:16:01:08, 67:16:14:05. Interested parties may attend by calling 1-844-833-2681 and using conference code 0094258#.

The effect of the rule change will be to update rules to clarify that emergency use authorization is a unique status and that services, procedures, and drugs approved under this status are not excluded from coverage on the basis of Medicaid's non-coverage of experimental services, procedures, and drugs. This change is consistent with current practice.

The reason for adopting the proposed rules is to clarify emergency use authorization is a different status than "experimental" or "investigational," which indicates an item has not received any approval from the FDA. Emergency use authorization is a status used by the FDA in emergency situations to make a product available to the public based on the best available evidence, without waiting for all the evidence that would be needed for full FDA approval or clearance.

Persons interested in presenting data, opinions, and arguments for or against the proposed rules may do so by appearing telephonically at the hearing or mail them to Teresa Schulte, Administrative Rules, Department of Social Services, 811 East 10th Street, Sioux Falls, SD 57103. Material sent by mail must reach the Department of Social Services by April 16, 2021, to be considered.

After the public hearing, the Department of Social Services will consider all written and oral comments it receives on the proposed rules. The Department of Social Services may modify or amend a proposed rule at that time to include or exclude matters that are described in this notice.

For Persons with Disabilities: This hearing will be located at a physically accessible place. Please contact Department of Social Services at least 48 hours before the public hearing if you have special needs for which special arrangements can be made by calling (605)-367-5444 ext. 1000309.

Copies of the proposed rules may be obtained without charge from: Teresa Schulte, Department of Social Services, 811 East 10th Street, Sioux Falls, SD 57103. Copies of the proposed rules are also available at: <http://rules.sd.gov>.

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