



STATE OF HAWAII
DEPARTMENT OF HUMAN SERVICES

Med-QUEST Division
Clinical Standards Office
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December 11, 2020

MEMO NO.
QI-2038

MEMORANDUM

TO: Physicians, Clinic Providers, Hospitals and Free Standing Ambulatory Surgical Centers

FROM: Judy Mohr Peterson, PhD *JP*
Med-QUEST Division Administrator

SUBJECT: ORALLY ADMINISTERED DRUGS TO TERMINATE A PREGNANCY DURING THE PUBLIC HEALTH EMERGENCY (PHE)¹

The Med-QUEST Division (MQD) covers an oral "medical abortion/intentional termination of Pregnancy (ITOP)" using orally administered drugs to terminate a pregnancy under the following conditions:

- The pregnancy must be in the early first trimester within nine (9) weeks gestation; and
- The drugs used are mifepristone (S0190) one 200 mg tablet in combination with misoprostol (S0191) up to four (4) 200 mcg tabs and taken within the first nine (9) weeks.

On July 13, 2020, a federal judge imposed a nationwide injunction lifting the federal Food and Drug Administration (FDA) requirement that medications for early ITOPs must be dispensed in person. The Court found that the in-person requirement imposes a substantial obstacle to patients seeking non-invasive medication abortion care. The ruling recognized that this requirement imposed unnecessary COVID-19 risks and other burdens on patients who were required to physically go to the office/clinic to pick up the medication and sign a form in the midst of the PHE.

¹Public Health Emergency as determined by the United States Secretary of Health and Human Services. Public Health Emergency Declarations can be found at <https://www.phe.gov/emergency/news/healthactions/phe/Pages/default.aspx>.

The injunction therefore allows ITOP medications discussed in this memorandum to be mailed to the patient's residence during the PHE and an additional thirty (30) days after the end of the PHE and will be covered by the Hawaii Medicaid program.

The allowance for these medications to be mailed is based on the current federal injunction ordered by Theodore D. Chuang, United States District Judge, on July 13, 2020. If the injunction is lifted prior to the end of the PHE, this memorandum and its allowances will be considered rescinded and the requirement that the medications must be picked up in person will be reinstated in accordance with FDA requirements.

The PHE is currently scheduled to end January 20, 2021. Should the PHE be extended and the injunction is still in effect, this memorandum should be followed until up to 30 days after the PHE ends.

Telehealth (audio-visual modality) may be used for evaluation and management services performed prior to the date of the medical ITOP. Codes in the range of 99201-99215 with modifiers 95, GQ, or GT are allowed.

Only allowed during the COVID-19 PHE, evaluation and management services can also be completed telephonically prior to or on the date of the oral medication ITOP. The code range for telephonic services is 99441-99443.

Providers shall still meet the FDA Risk Evaluation and Mitigation Strategy (REMS) requirements for medication ITOPs when dispensing mifepristone (Mifeprex) from their offices/clinics or hospitals as follows:

- Mifeprex must be ordered, prescribed, and dispensed by or under the supervision of a healthcare provider who prescribes and who meets certain qualifications;
- Healthcare providers who wish to prescribe Mifeprex must complete a Prescriber Agreement Form prior to ordering and dispensing Mifeprex;
- Mifeprex may only be dispensed under the supervision of a certified healthcare provider; and
- The healthcare provider must obtain a valid signed Patient Agreement Form before dispensing Mifeprex to be kept in the patient's medical records.

The guidance in this memorandum that addresses the federal injunction will allow increased access to medical care for women and their families impacted by the PHE and will reduce the need for individuals to travel, sometimes requiring inter-island travel, to obtain the necessary medications.