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May 7, 2021

MEMO NO.
FFS 21-05

MEMORANDUM

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

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

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

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 ten (10) 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 ten (10) weeks.

In an April 13, 2021, letter to the American College of Obstetricians and Gynecologists (ACOG)[1], Dr. Janet Woodcock, Acting Commissioner of the United States Federal Food and Drug Administration (FDA), provided findings from a recent evaluation of issues regarding in-person requirements for medical termination of early pregnancy raised by ACOG. The evaluation concluded that "findings from available studies do not appear to show increases in serious safety concerns (such as hemorrhage, ectopic pregnancy, or surgical interventions) occurring with medical abortion as a result of modifying the in-person dispensing requirement during the COVID-19 pandemic"(1).

[1] "FDA_acting_commissioner_letter_to_acog." *PDF.js Viewer*, ACLU, 12 Apr. 2021, www.aclu.org/sites/all/libraries/pdf.js/web/viewer.html?file=https%3A%2F%2Fwww.aclu.org%2Fsites%2Fdefault%2Ffiles%2Ffield_document%2Ffda_acting_commissioner_letter_to_acog_april_12_2021.pdf.

Dr. Woodcock indicated that the FDA Center for Drug Evaluation and Research (CDER) "intends to exercise enforcement discretion during the COVID-19 PHE with respect to the in-person dispensing requirement of the Mifepristone (Mifeprex) Risk Evaluation and Mitigation Strategy (REMS) Program, including any in-person requirements that may be related to the Patient Agreement Form"(1).

This enforcement discretion therefore allows ITOP medications discussed in this memorandum to be mailed to the patient's residence during the PHE and will be covered by the Hawaii Medicaid program.

The allowance for these medications to be mailed is based on the current enforcement discretion indicated by the FDA. If the FDA lifts this enforcement discretion 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 REMS Program requirements[2].

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 REMS requirements for medication ITOPs when dispensing Mifepristone from their offices/clinics or hospitals as follows:

- Mifepristone must be ordered, prescribed, and dispensed by or under the supervision of a healthcare provider who prescribes and who meets FDA REMS qualifications;
- Healthcare providers who wish to prescribe Mifepristone must complete a Prescriber Agreement Form prior to ordering and dispensing Mifepristone;
- Mifepristone 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 Mifepristone to be kept in the patient's medical records.

The guidance in this memorandum that addresses the FDA enforcement discretion 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.

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[2] FDA. (2019, April 11). *Approved Risk Evaluation and Mitigation Strategies (REMS)*. https://www.accessdata.fda.gov/scripts/cder/rems/index.cfm?event=RemsDetails.page&REMS=390