

**Report to the Utah State Legislature
Health and Human Services Interim Committee**

**Hemp Extract Registration Act
2016 Implementation Update**

**Prepared by the Utah Department of Health
Office of Vital Records and Statistics**

October 31, 2016



INTRODUCTION

The Utah Department of Health (UDOH), Office of Vital Records and Statistics (OVRs) is pleased to report on its implementation of the Hemp Extract Registration Act (Utah Code 26-55). This report includes a legislative background of the Act, an update regarding a study of hemp extract requested by the Utah Legislature, and information about issuance of hemp extract registration cards. Information provided in this report is current as of October 24, 2016.

LEGISLATIVE BACKGROUND

Lawmakers approved H.B. 105: Plant Extract Amendments during the 2014 General Legislative Session. H.B. 105 created the Hemp Extract Registration Act (Utah Code 26-55) and granted authority to UDOH to adopt Utah Admin. Rule R436-55. Pursuant to H.B. 105, UDOH issues hemp extract registration cards to qualified applicants who are being treated by a licensed neurologist for intractable epilepsy.

In 2016, lawmakers approved H.B. 58 which made certain amendments to the Hemp Extract Registration Act. H.B. 58 required that UDOH request proposals to conduct a study of hemp extract.

HEMP EXTRACT STUDY UPDATE

Pursuant to H.B. 58, UDOH issued a Request for Proposals (RFP) for the purpose of entering into a contract with researchers at a higher education institution to conduct a study of hemp extract. In July 2016, the RFP was awarded to researchers at the University of Utah School of Medicine, Division of Pediatric Neurology. The overall purpose of the study is to analyze experiences of patients who obtained hemp extract registration cards in Utah. The RFP awarded \$40,000 to the University to help fund the study. As part of this study, University researchers will complete the deliverables outlined in the paragraphs below.

- **Study proposal.** The University will submit a hemp extract study proposal to UDOH describing its plan to collect and analyze the experience of patients with intractable epilepsy who obtained a hemp extract registration card in Utah. The proposal will also outline the University's plan to achieve specific study objectives.
- **Collect patient information.** Authorization to collect information regarding patients who received hemp extract registration cards will be obtained from the University of Utah Institutional Review Board (IRB) and the Utah Department of Health IRB. The study proposal will specify the types of information, the parties the University will contact and the processes involved to obtain the information. Information collected will include both electronic medical records and paper records.

- **Analyze patterns of use among Utah families with hemp extract registration cards.** Information regarding the following parameters will be collected: product(s) used, source of these vernacular products, cost per month, ease of access to products, source(s) of information for dosing, unanticipated problems encountered and knowledge about dosing. Descriptive statistics will be used to describe the range of patterns of use applicable to patients.
- **Analyze patterns of clinical response.** Self-reported seizure frequency before and after hemp extract treatment will be assessed. When possible, attempts will be made to correlate these responses with hemp extract doses assessed as amount of cannabidiol (CBD) administered per day (in mg/kg/day). In addition, parents/patients will be asked about their overall assessment of benefit using a “global impression of change” scale. Descriptive statistics will be used to delineate the patterns of clinical response identified accordingly.
- **Analyze rate and nature of adverse effects.** Follow-up patient notes will be reviewed for any adverse effects. With IRB approval, a questionnaire circulated to all registrants will ask them to account for all potential adverse events. Descriptive statistics will be used to delineate the patterns of adverse events reported by families.
- **Executive summary of study results.** Information collected and analyzed will be presented in a written executive summary to be submitted to UDOH. The summary format will be that of a typical peer-reviewed scientific/medical manuscript designed for publication in a peer-reviewed international medical or public health journal.
- **Presentation of study results.** Results of the study will be reported in person to UDOH and Utah legislative committees as requested.

University researchers are preparing a formal study proposal to be approved by OVRS and submitted to Institutional Review Boards (IRB) at the University of Utah and UDOH. Once IRB approval is obtained, University researchers will begin collecting data from UDOH, patients, and providers.

NUMBER OF CARDS ISSUED

The first hemp extract registration card was issued in July 2014. As of October 24, 2016, cards have been issued to 166 patients.

CARD RENEWAL

Hemp extract registration cards expire one year from the issuance date. 50 of the 110 patients who were issued cards before October 24, 2015 have renewed their cards for a renewal rate of 47%. As of October 24, 2016, 97 patients hold active cards.

CARD HOLDER DEMOGRAPHICS

Basic demographic information is collected from each applicant. This information includes the patient's name, mailing address, telephone number, email address, date of birth and sex. If one or both parents of the patient are listed on the record, the parent name, mailing address, telephone number, date of birth, and email address are collected.

- 101 cards were issued to patients under the age of 18. 65 cards were issued to patients 18 and over.
- 85 patients with the card are female and 81 are male.

NEUROLOGIST INFORMATION

The 166 patients who have been issued cards had neurologist evaluations from 17 physicians. Of the 17, 12 are affiliated with the University of Utah. Of the 166 patients, 135 have a physician affiliated with the University of Utah. Information in the neurologist certification and patient evaluation forms are the only information about patients that physicians provide OVRs.

REGISTRATION DATABASE

OVRs uses a database called the Utah Plant Extract Registry (UPER) to electronically store information about each card issued. The Utah Department of Public Safety has access to UPER so it can electronically verify the card of an individual found in possession of hemp extract.

For more information about the hemp extract registration program, please visit the registry website at hemp.utah.gov/hempregistry or contact Richard J. Oborn, OVRs Director, at (801) 538-6262 or roborn@utah.gov.
