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February 3, 2020

TO: The Honorable Senator Russell E. Ruderman, Chair
Senate Committee on Human Services

The Honorable Senator Rosalyn H. Baker, Chair
Senate Committee on Commerce, Consumer Protection, and Health

FROM: Pankaj Bhanot, Director

SUBJECT: **SB 2324 – RELATING TO MEDICAID**

Hearing: February 5, 2020, 2:45 p.m.
Conference Room 016, State Capitol

DEPARTMENT'S POSITION: The Department of Human Services (DHS) offers comments with concerns on the bill.

PURPOSE: The purpose of this bill is to expand Medicaid coverage to the routine costs of care for Medicaid beneficiaries participating in an approved clinical trial.

DHS supports the underlying intent of the bill to offer this coverage, but suggests that the bill may not be necessary and potentially in conflict with current policy.

DHS agrees that coverage for routine costs of care for beneficiaries participating in a clinical trial should be provided. As such, in December 2019, DHS clarified that standard costs of care for individuals participating in approved clinical trials is covered.

DHS developed this policy after months of working with the University of Hawai'i Cancer Center (UH Cancer Center) and other stakeholders. One aspect of the collaboration between DHS and UH Cancer Center was a focus on using expert national standards that could be applied to Med-QUEST. The current policy guidance reflects the best practices toward

coverage of routine costs of care for Medicaid beneficiaries participating in an approved clinical trial.

The bill's language does not mirror current DHS policy, and DHS has concerns that the differences in the bill may affect our coverage of routine costs to the detriment of our beneficiaries. The preference of DHS is to continue to offer coverage for routine costs of care through policy guidance because it will allow us to remain in alignment with expert standards as they evolve and change over time. Codifying definitions and coverage provisions for clinical trials may prevent DHS from doing what the Legislature intends.

Thank you for the opportunity to testify on this bill.

January 28, 2020

SENATOR RUSSELL RUDERMAN, CHAIR
SENATOR KARL RHOADS, VICE-CHAIR
MEMBERS OF THE SENATE HUMAN SERVICES COMMITTEE

Re: **Senate Bill (SB) 2324 - COMMENTS**
RELATING TO MEDICAID.
Beginning January 1, 2021, requires contracted health plans under the State's medicaid managed care and fee-for-service programs to cover routine costs of care of enrollees participating in an approved clinical trial.

Dear Chair, Vice-Chair and Members of the Committee:

The Hawaii Society of Clinical Oncology (HSCO) is a local community of oncologists, nurse practitioners, physician assistants, and other allied health professionals who provide a voice for multidisciplinary cancer care teams and the patients they serve. Founded in 1996, HSCO is the largest oncology professional organization in the state.

While we appreciate the intent of this measure which seeks to provide some Medicaid coverage for clinical trials, we do not recommend that this bill move forward because: (1) it does not appear to take into account the recent December 18, 2019 policy from Med-QUEST; (2) undermines some of the strides made under that policy; and (3) goes against several provisions in the Medicare NCD 310.1 policy. As such, we recommend that the bill be deferred.

Attached, please find a copy of the December 18, 2019 "Med-QUEST Guidance Regarding the Coverage of Routine Costs Associated with Qualifying Clinical Trials." We appreciate Med-QUEST's good faith efforts and discussions over the last several months with leading oncology professionals to reach the culmination of this memo which we believe makes significant strides forward for our oncology patients and their access to care. Therefore, we support this administrative approach, rather than the one taken in this bill.

We also believe that there are some issues of coverage that are better and broader in the memo than in the bill, and we also believe that there may be some federal issues with the bill's language:

1. Page 1, lines 13-15: a health plan is not liable for adverse effects of the trial.
   - If the intent of this section is to deny coverage for the monitoring, preventing, diagnosing, and treating complications while on the trial, then this goes against Medicare NCD 310.1, ACA, and the new Medicaid policy.

2. Page 3, lines 6-8: no coverage for drugs/devices that are not FDA approved.
    - This specific language is not in the Medicare, ACA, or new Medicaid policy and would deny coverage of routine care costs for patients enrolled in expanded access programs approved by the FDA.

3. Page 3, lines 9-11: no coverage for items/services required solely for provision of drug, device, service.
    - This is opposite of Medicare, ACA, and new Medicaid policy; e.g. supplies required for the administration/infusion of drug would not be covered

4. Page 3, lines 12-14: no coverage for items/services provided solely for monitoring of drug, device, service.
    - This is opposite of Medicare, ACA, and new Medicaid policy; e.g. standard monitoring of thyroid function blood test for patients on immunotherapy would not be covered if the investigational agent is an immunotherapy drug.

We sincerely appreciate the legislature's and the introducer's desire to help and assist our most needy patients during this very difficult time in their healthcare. We look forward to more and additional discussions on finding these important approaches and solutions for all of the patients and issues associated with our field. However, we do not believe that this bill is a prudent way to proceed on these issues.

Thank you for your consideration of our testimony.

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STATE OF HAWAII
DEPARTMENT OF HUMAN SERVICES
Med-QUEST Division
Clinical Standards Office
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December 18, 2019

MEMORANDUM

MEMO NO.
QI-1934

TO: QUEST Integration Health Plans

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

SUBJECT: MED-QUEST GUIDANCE REGARDING THE COVERAGE OF ROUTINE COSTS ASSOCIATED WITH QUALIFYING CLINICAL TRIALS

The purpose of the memorandum is for the Med-QUEST Division (MQD) to provide guidance to the QUEST Integration (QI) health plans and Medicaid FFS program regarding the coverage of routine costs associated with qualifying clinical trials (QCT). The QI health plans shall provide coverage for all routine patient care costs related to participation in qualifying clinical trials for the prevention, diagnosis, treatment, or supportive care of cancer, as well as medically necessary items and services used to prevent, diagnose and treat complications arising from participation in clinical trials.

Clinical Trial

There are two main types of clinical studies: Clinical trials (also called interventional studies) and observational studies. A clinical trial, as defined by the National Institutes of Health (NIH), is a research study in which human subjects are prospectively assigned to interventions to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes. In a clinical trial, participants receive specific interventions according to the research plan or protocol designed by the investigators. Clinical trials may compare a new medical

approach to a standard one that is already available, to a placebo that contains no active ingredients, or to no intervention. Some clinical trials compare interventions that are already available to each other.

Qualifying Clinical Trial

A qualifying clinical trial (QCT) is a trial that meets the requirement set forth in Clinical Trial Policy (Refer to Attachment NCD 310.1) by the Center for Medicare and Medicaid Services (CMS). This policy delineates the requirements that a trial must meet to be designated as a QCT.

A QCT means a phase I, phase II, phase III, or phase IV clinical trial that is conducted in relation to the prevention, diagnosis, treatment, palliative care or supportive care of cancer and is described in any of the following clauses:

1. Trials reviewed and approved by one or more of the following:
    a. The National Institutes of Health (NIH), including National Cancer Institute (NCI)-designated Cancer Centers with an approved Scientific Review Committee
    b. The Centers for Disease Control and Prevention (CDC)
    c. The Agency for Healthcare Research and Quality (AHRQ)
    d. The Centers for Medicare and Medicaid Services (CMS)
    e. The Department of Defense (DOD)
    f. The Department of Veterans Affairs (VA)
2. Trials supported by centers or cooperative groups that are funded by the NIH, CDC, AHRQ, CMS, DOD, and VA; and
3. Trials conducted under an investigational new drug application (IND) reviewed by the Food and Drug Administration (FDA).

Routine Costs

Medicaid covers the routine costs of QCT's, as such costs are defined below, as well as medically necessary items and services used to diagnose and treat complications arising from participation in all clinical trials. All other Medicaid rules apply. The QCT must use in-network providers and be located in the state of Hawaii. Out-of-state clinical trials may be considered on a case by case basis.

"Routine patient care costs" include all items and services that are a benefit under a health plan that would be covered if the covered person were not involved in a clinical trial. Trials of therapeutic interventions must enroll patients with diagnosed disease rather than healthy volunteers. Trials of diagnostic interventions may enroll healthy patients in order to have a proper control group.

"Routine patient care costs" include:

a. Items or services that are typically provided absent a clinical trial;
b. Items or services required solely for the provision of the investigational item or service, the clinically appropriate monitoring of the effects of the item or service, or the prevention of complications;
c. Items or services needed for medically necessary care arising from the provision of an investigational item or service, in particular, for the diagnosis or treatment of complications.

"Routine patient care costs" does not include:

a. The investigational item or service, itself unless otherwise covered outside of the clinical trial;
b. Items and services provided solely to satisfy data collection and analysis needs and that are not used in direct clinical management of the patient;
c. Items and services customarily provided by the research sponsors free-of-charge for any enrollee in the trial;
d. Health care services that, except for the fact that they are being provided in a clinical trial, are otherwise specifically excluded from coverage under the enrollee's health plan;
e. Items or services that are excluded from Medicaid coverage; and
f. Items or services for a clinical trial that does not have therapeutic intent. These are trials that are designed exclusively to test toxicity or pathophysiology without therapeutic intent.

For most QCT's, it is best practice to have a formal coverage analysis that provides guidance regarding the designation of items or services as routine care vs. non-routine care. This coverage analysis may have been generated at the national level by the sponsor (i.e. National Cancer Institute or Industry sponsor) or at the local level. If desired, a copy of the coverage analysis may be requested from the local billing or trial coordinating entity.

Clinical trials allow for the advancement of medicine while improving the quality of care for patients. Our intent is to assure that our Medicaid beneficiaries have the same access to clinical trials and treatment options as would the non-Medicaid beneficiaries.

For any questions, please contact our Med-QUEST Medical Director, Dr. Curtis Toma at ctoma@dhs.hawaii.gov or (808) 692-8105.

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Senate Committee on Human Services
Senator Russell Ruderman, Chair
Senator Karl Rhoads, Vice Chair

Senate Committee on Commerce, Consumer Protection, and Health
Senator Rosalyn H. Baker, Chair
Senator Stanley Chang, Vice Chair

SB 2324 – RELATING TO MEDICAID

Cory Chun, Government Relations Director – Hawaii Pacific
American Cancer Society Cancer Action Network

Thank you for the opportunity to provide comments on SB 2324, which requires Medicaid managed care plans and fee-for-service programs to cover routine care costs of clinical trials.

Clinical trials are the key step in advancing potential new cancer treatments from the research setting to the clinic, and patient participation in trials is crucial to this success. Most patients express a willingness to participate in clinical research, yet only a small fraction ultimately enrolls in cancer clinical trials because of barriers that make participation difficult or even impossible. Among those barriers is health insurance that excludes coverage of routine care costs for patients in clinical trials. As you are aware, Medicaid is not required to cover the routine costs of care in clinical trials, and thus several states, like Hawaii, have chosen to provide this coverage through their Medicaid program. The American Cancer Society Cancer Action Network (ACS CAN) applauds Hawaii's efforts to see that Medicaid beneficiaries have the same access to clinical trials and treatment options as non-Medicaid beneficiaries.

The Department of Human Services, in collaboration with the University of Hawaii Cancer Center, issued guidance for the coverage of routine costs of care in cancer clinical trials at the end of 2019. This guidance covers nearly all types of cancer clinical trials, with some notable exceptions. While we recognize the need for coverage in all clinical trials, we also recognize the work that DHS and the UHCC have done in good faith for the Medicaid cancer patients. To be specific, the DHS memorandum:

- covers certain phase 1 through 4 trials;
- covers certain trials on the prevention, detection, and treatment of cancer as well as supportive and palliative care;

- covers complications;
- provides a comprehensive definition of routine costs of care;
- gives a definition of excluded routine costs of care that is similar to the definition the Centers for Medicare & Medicaid Services (CMS) used in its 2000 National Coverage Determination on Medicare coverage of clinical trials;
- allows out-of-state trials to be considered; and
- provides a reasonable suggested formal coverage analysis.

All of these provisions are very helpful to cancer patients. Still I must note here that because the DHS memorandum uses the definition of a qualified clinical trial that CMS used in 2000, not all clinical trials covered by the Affordable Care Act or recommended by ACS CAN would be covered by Hawaii Medicaid. We are glad to see that SB 2324 moves in that direction and expands on the definition of a qualified clinical trial in the memorandum by adding trials "that are exempt by federal law from the requirement to submit an investigational new drug application to the United States Food and Drug Administration." If the state were to re-visit the issue of qualified clinical trials (in either the DHS memorandum or SB 2324), we would recommend that it cover these additional trials:

- Trials reviewed and approved by the Patient-Centered Outcomes Research Institute (PCORI) (established in 2010 under the Affordable Care Act),
- Trials approved or funded (including in-kind contributions) by the Department of Energy if the clinical trial has been reviewed and approved through a system of peer review that the state's Secretary of Health or equivalent determines
    - to be comparable to the system of peer review of studies and investigations used by the National Institutes of Health; and
    - assures unbiased review of the highest scientific standards by qualified individuals with no interest in the outcome of the review.

Additionally, ACS CAN strongly encourages the Senate to amend SB 2324 so that the legislation, like the DHS memorandum, specifies coverage of complications (in line with Medicare policy and the Affordable Care Act). We also encourage the Senate to specify that the legislation covers trial phases 1, 2, 3, and 4, as the memorandum does. Also, the bill excludes from routine costs of care "Items or services required solely for the provision of the drug, device, or service being tested in the approved Clinical trial" while the administrative order covers these costs.

While we applaud the efforts of the Legislature and both the Department of Human Services and UH Cancer Center, ACS CAN believes that more can and should be done to strengthen these efforts through amending the current legislation in order to ensure that the language in this bill addresses the issue of routine care costs that Medicaid patients face when enrolling in a clinical trial and more importantly, addressing the implementation of these requirements for Hawaii's Medicaid population.

Thank you for the opportunity to provide testimony on this important matter, and we are happy to work with you on appropriate modifications to the bill.