Assembly Bill No. 214–Assemblywoman Neal

CHAPTER.....

AN ACT relating to clinical trials; requiring the Division of Public and Behavioral Health of the Department of Health and Human Services to establish a program to encourage participation in clinical trials of drugs and medical devices by certain groups; requiring certain state and local governmental entities to adopt a policy concerning the identification and recruitment of members of those groups to participate in such trials; and providing other matters properly relating thereto.

Legislative Counsel's Digest:

Existing law requires the Division of Public and Behavioral Health of the Department of Health and Human Services to establish various programs relating to the provision of health care and the improvement of public health in this State. (NRS 439.495, 439.501, 439.517, 439.5295) This bill requires the Division to establish a program to encourage participation in clinical trials of drugs and medical devices by persons who are members of demographic groups that are underrepresented in such trials. This bill also requires each state or local governmental entity that conducts such trials to adopt a policy concerning the identification and recruitment of such persons to participate in those trials.

EXPLANATION – Matter in ***bolded italics*** is new; matter between brackets ~~[omitted material]~~ is material to be omitted.

THE PEOPLE OF THE STATE OF NEVADA, REPRESENTED IN SENATE AND ASSEMBLY, DO ENACT AS FOLLOWS:

Section 1. Chapter 439 of NRS is hereby amended by adding thereto a new section to read as follows:

1. It is the policy of this State to:

(a) Improve the completeness and quality of data concerning diverse demographic groups that is collected, reported and analyzed for the purposes of clinical trials of drugs and medical devices;

(b) Identify barriers to participation in clinical trials by persons who are members of demographic groups that are underrepresented in such trials and employ strategies recognized by the United States Food and Drug Administration to encourage greater participation in clinical trials by such persons; and

(c) Make data concerning demographic groups that is collected, reported and analyzed for the purposes of clinical trials more available and transparent.

2. To assist in carrying out this policy:

(a) The Division shall review the most recent version of "Collection of Race and Ethnicity Data in Clinical Trials—Guidance for Industry and Food and Drug Administration Staff," published by the United States Food and Drug Administration, and establish, using existing infrastructure and tools, a program to encourage participation in clinical trials of drugs and medical devices by persons who are members of demographic groups that are underrepresented in such clinical trials. The program must include, without limitation:

(1) Collaboration with medical facilities, health authorities and other local governmental entities, nonprofit organizations and scientific investigators and institutions that are performing research relating to drugs or medical devices to assist such investigators and institutions in identifying and recruiting persons who are members of underrepresented demographic groups to participate in clinical trials; and

(2) The establishment and maintenance of an Internet website that:

(I) Provides information concerning methods recognized by the United States Food and Drug Administration for identifying and recruiting persons who are members of underrepresented demographic groups to participate in clinical trials; and

(II) Contains links to Internet websites maintained by medical facilities, health authorities and other local governmental entities, nonprofit organizations and scientific investigators and institutions that are performing research relating to drugs or medical devices in this State.

(b) With the assistance of the Office of Grant Procurement, Coordination and Management of the Department of Administration, the Division shall apply for grants from any source, including, without limitation, the Federal Government, to fund the program established pursuant to paragraph (a).

(c) Not later than May 1 of each even-numbered year, the Division shall submit to the Director of the Legislative Counsel Bureau for transmittal to the Legislature a report concerning the status and results of the program established pursuant to paragraph (a).

(d) Each state or local governmental entity that conducts clinical trials of drugs or medical devices, including, without limitation, the Board of Regents of the University of Nevada, shall adopt a policy concerning the identification and recruitment of persons who are members of underrepresented demographic

groups to participate in those clinical trials. Such a policy must include, without limitation, requirements that investigators who are conducting clinical trials collaborate with community-based organizations and use methods recognized by the United States Food and Drug Administration to identify and recruit such persons to participate in those clinical trials.

3. For the purposes of this section, demographic groups that are underrepresented in clinical trials may include, without limitation, persons who are underrepresented by race, sex, sexual orientation, socioeconomic status and age.

4. The Division may accept gifts, grants and donations from any source for the purpose of carrying out the provisions of this section.

5. As used in this section, "medical facility" has the meaning ascribed to it in NRS 449.0151.

Sec. 1.5. The provisions of subsection 1 of NRS 218D.380 do not apply to any provision of this act which adds or revises a requirement to submit a report to the Legislature.

Sec. 2. This act becomes effective on July 1, 2017.