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LEGISLATURE OF NEBRASKA

ONE HUNDRED SIXTH LEGISLATURE

SECOND SESSION

LEGISLATIVE BILL 1182

Introduced by Wayne, 13.

Read first time January 23, 2020

Committee: Health and Human Services

A BILL FOR AN ACT relating to drugs; to amend section 71-7611, Revised Statutes Supplement, 2019; to provide for notice of new drug or biologics license applications and for a study of drug costs; to provide a penalty; and to repeal the original section.

Be it enacted by the people of the State of Nebraska,

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Section 1. Section 71-7611, Revised Statutes Supplement, 2019, is amended to read:

71-7611 (1) The Nebraska Health Care Cash Fund is created. The State Treasurer shall transfer (a) sixty million three hundred thousand dollars on or before July 15, 2014, (b) sixty million three hundred fifty thousand dollars on or before July 15, 2015, (c) sixty million three hundred fifty thousand dollars on or before July 15, 2016, (d) sixty million seven hundred thousand dollars on or before July 15, 2017, (e) five hundred thousand dollars on or before May 15, 2018, (f) sixty-one million six hundred thousand dollars on or before July 15, 2018, (g) sixty-two million dollars on or before July 15, 2019, (h) sixty-one million four hundred fifty thousand dollars on or before July 15, 2020, and (i) sixty-one million one hundred thousand dollars on or before every July 15 thereafter from the Nebraska Medicaid Intergovernmental Trust Fund and the Nebraska Tobacco Settlement Trust Fund to the Nebraska Health Care Cash Fund, except that such amount shall be reduced by the amount of the unobligated balance in the Nebraska Health Care Cash Fund at the time the transfer is made. The state investment officer shall advise the State Treasurer on the amounts to be transferred first from the Nebraska Medicaid Intergovernmental Trust Fund until the fund balance is depleted and from the Nebraska Tobacco Settlement Trust Fund thereafter in order to sustain such transfers in perpetuity. The state investment officer shall report electronically to the Legislature on or before October 1 of every even-numbered year on the sustainability of such transfers. The Nebraska Health Care Cash Fund shall also include money received pursuant to section 77-2602 and section 2 of this act. Except as otherwise provided by law, no more than the amounts specified in this subsection may be appropriated or transferred from the Nebraska Health Care Cash Fund in any fiscal year.

The State Treasurer shall transfer ten million dollars from the Nebraska Medicaid Intergovernmental Trust Fund to the General Fund on

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June 28, 2018, and June 28, 2019.

Except as otherwise provided in subsection (6) of this section, it is the intent of the Legislature that no additional programs are funded through the Nebraska Health Care Cash Fund until funding for all programs with an appropriation from the fund during FY2012-13 are restored to their FY2012-13 levels.

(2) Any money in the Nebraska Health Care Cash Fund available for investment shall be invested by the state investment officer pursuant to the Nebraska Capital Expansion Act and the Nebraska State Funds Investment Act.

(3) The University of Nebraska and postsecondary educational institutions having colleges of medicine in Nebraska and their affiliated research hospitals in Nebraska, as a condition of receiving any funds appropriated or transferred from the Nebraska Health Care Cash Fund, shall not discriminate against any person on the basis of sexual orientation.

(4) The State Treasurer shall transfer fifty thousand dollars on or before July 15, 2016, from the Nebraska Health Care Cash Fund to the Board of Regents of the University of Nebraska for the University of Nebraska Medical Center. It is the intent of the Legislature that these funds be used by the College of Public Health for workforce training.

(5) It is the intent of the Legislature that the cost of the staff and operating costs necessary to carry out the changes made by Laws 2018, LB439, and not covered by fees or federal funds shall be funded from the Nebraska Health Care Cash Fund for fiscal years 2018-19 and 2019-20.

(6) It is the intent of the Legislature to fund the grants to be awarded pursuant to section 75-1101 with the Nebraska Health Care Cash Fund for FY2019-20 and FY2020-21.

Sec. 2. (1) For purposes of this section:

(a) Biologics license application means an application filed pursuant to 21 C.F.R. 601.2, as such regulation existed on January 1,

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(b) Breakthrough therapy has the same meaning as provided in 21 U.S.C. 356, as such section existed on January 1, 2020;

(c) Drug means (i) articles recognized in the official United States Pharmacopoeia, official Homeopathic Pharmacopoeia of the United States, official National Formulary, or any supplement to any of them, (ii) substances intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in human beings or animals, and (iii) substances intended for use as a component of any article specified in subdivision (i) or (ii) of this subdivision;

(d) Manufacturer has the same meaning as in 21 C.F.R. 316.3, as such regulation existed on January 1, 2020;

(e) Orphan drug has the same meaning as provided in 21 C.F.R. 316.3, as such regulation existed on January 1, 2020;

(f) Pipeline drug means a drug containing a new molecular entity for which a sponsor has filed a new drug application or biologics license application with, and received an action date from, the federal Food and Drug Administration; and

(g) Sponsor has the same meaning as in 21 C.F.R. 316.3, as such regulation existed on January 1, 2020.

(2) Beginning on January 1, 2021, each sponsor shall submit to the Department of Health and Human Services in a form and manner specified by the department, written notice informing the department that such sponsor has filed with the federal Food and Drug Administration:

(a) A new drug application or biologics license application for a pipeline drug, not later than sixty days after such sponsor receives an action date from the federal Food and Drug Administration regarding such application; or

(b) A biologics license application for a biosimilar drug, not later than sixty days after such sponsor's receipt of an action date from the federal Food and Drug Administration regarding such application.

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(3)(a) Beginning on January 1, 2021, the Department of Health and Human Services may conduct a study, not more frequently than once annually, of each manufacturer of a pipeline drug that, in the opinion of the Director of Medicaid and Long-Term Care of the Division of Medicaid and Long-Term Care of the department may have a significant impact on state expenditures under the Medical Assistance Act for outpatient prescription drugs. The department may utilize existing state resources and contracts, or contract with a third party, including, but not limited to, an accounting firm, to conduct such study.

(b) Each manufacturer that is the subject of a study conducted pursuant to this subsection shall submit to the department, or any contractor engaged by the department, to perform such study, the following information for the pipeline drug that is the subject of such study:

(i) The primary disease, condition, or therapeutic area studied in connection with such drug and whether such drug is therapeutically indicated for such disease, condition, or therapeutic area;

(ii) Each route of administration studied for such drug;

(iii) Clinical trial comparators, if applicable, for such drug;

(iv) The estimated year of market entry for such drug;

(v) Whether the federal Food and Drug Administration has designated such drug as an orphan drug, a fast-track product, or a breakthrough therapy; and

(vi) Whether the federal Food and Drug Administration has designated such drug for accelerated approval and, if such drug contains a new molecular entity, for priority review.

(4)(a) On or before March 1, 2021, and annually thereafter, the Director of Medicaid and Long-Term Care and the Director of Public Health of the Division of Public Health of the Department of Health and Human Services, shall prepare a list of not more than ten outpatient prescription drugs that the Director of Medicaid and Long-Term Care, in

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the director's discretion, determines are (i) provided at substantial cost to the state, considering the net cost of such drugs, or (ii) critical to public health. The list shall include outpatient prescription drugs from different therapeutic classes of outpatient prescription drugs and at least one generic outpatient prescription drug.

(b) The list shall not include any outpatient prescription drug under this section unless the wholesale acquisition cost of the drug, less all rebates paid to the state for such drug during the immediately preceding calendar year, (i) increased by at least (A) twenty percent during the immediately preceding calendar year or (B) fifty percent during the immediately preceding three calendar years and (ii) was sixty dollars or more for (A) a thirty-day supply of such drug or (B) a course of treatment of such drug lasting less than thirty days.

(c) The manufacturer of an outpatient prescription drug included on the list prepared pursuant to this section shall provide to the department, in a form and manner specified by the department, (i) a written, narrative description, suitable for public release, of all factors that caused the increase in the wholesale acquisition cost of the listed outpatient prescription drug and (ii) aggregate, company-level research and development costs and such other capital expenditures that the Director of Medicaid and Long-Term Care, in the director's discretion, deems relevant for the most recent year for which final audited data are available.

(5) The quality and types of information and data that a manufacturer submits to the department under this section shall be consistent with the quality and types of information and data that the manufacturer includes in (a) such manufacturer's annual consolidated report on Securities and Exchange Commission Form 10-K, or (b) any other public disclosure.

(6) The department shall establish a standardized form for reporting information and data pursuant to this section after consulting with

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manufacturers. The form shall be designed to minimize the administrative burden and cost of reporting on the department and manufacturers.

(7)(a) The department may, after notice and a hearing, impose a penalty of not more than seven thousand five hundred dollars on a manufacturer or sponsor for each violation of this section by the manufacturer or sponsor.

(b) The department shall remit any amounts paid to the State Treasurer for credit to the Nebraska Health Care Cash Fund.

(8) The department may adopt and promulgate rules and regulations to carry out the purposes of this section.

Sec. 3. Original section 71-7611, Revised Statutes Supplement, 2019, is repealed.