HB3268

LRB10109724KTG54824b

101ST GENERAL ASSEMBLY

State of Illinois

2019 and 2020

HB3268

by Rep. Sara Feigenholtz

SYNOPSIS AS INTRODUCED:

305 ILCS 5/5-30.11 new

Amends the Illinois Public Aid Code. Provides that the Department of Healthcare and Family Services shall not make recommendations or determinations that are more restrictive than federal labeling requirements by the U.S. Food and Drug Administration when making coverage recommendations or determinations affecting medical assistance recipients' access to (1) drugs and biological products for rare diseases and (2) drugs and biological products that are genetically targeted therapies. Requires the Department to implement an open and transparent process that includes clear guidelines for open public comment for the review and study of those drugs and biological products for rare diseases and those that are genetically targeted therapies. Requires the Illinois Drug and Therapeutics Advisory Board (Board) to develop and maintain a list of external experts who (i) possess scientific or medical training with respect to one or more rare diseases and (ii) are qualified to provide advice on rare disease issues and specified topics, including the impact of particular coverage, utilization management, and other relevant drug access policies. Requires the Department to adopt rules to ensure that any provisions of the Illinois Title XIX State Plan that affect medical assistance recipients' access to drugs and biological products for rare diseases are available to the public in a user-friendly and searchable format. Prohibits the Department from disclosing any confidential commercial or trade secret information of a drug manufacturer. Provides that the Board shall not be subject to the 6-month review moratorium for new drugs and shall review new drugs and biological products for rare diseases at the next regularly scheduled meeting. Effective immediately.

LRB101 09724 KTG 54824 b

FISCAL NOTE ACT
MAY APPLY

A BILL FOR

AN ACT concerning public aid.

Be it enacted by the People of the State of Illinois, represented in the General Assembly:

Section 5. The Illinois Public Aid Code is amended by adding Section 5-30.11 as follows:

(305 ILCS 5/5-30.11 new)

Sec. 5-30.11. Consultation with external experts on rare diseases and genetically targeted treatments.

(a) When making coverage recommendations or determinations affecting recipients access to (i) drugs and biological products for rare diseases, as defined in the federal Orphan Drug Act of 1983 (Public Law 97-414) and (ii) drugs and biological products that are genetically targeted therapies, the Department of Healthcare and Family Services shall not make recommendations or determinations that are more restrictive than federal labeling requirements by the United States Food and Drug Administration. In accordance with this Section, the Department shall also implement an open and transparent process that includes clear guidelines for open public comment for the review and study of access to drugs and biological products for rare diseases and drugs and biological products that are genetically targeted therapies.

(b)(1) The Illinois Drug and Therapeutics Advisory Board

shall develop and maintain a list of external experts who:

(A) possess scientific or medical training that the Illinois Drug and Therapeutics Advisory Board lacks with respect to one or more rare diseases; and

(B) because of their special expertise, are qualified to provide advice on rare disease issues, including topics described in subsection (c).

(2) The Illinois Drug and Therapeutics Advisory Board shall ensure that opportunities exist, at a time the Board determines appropriate, for consultations with external experts on the topics described in subsection (c).

(3) When appropriate to address a specific question related to drugs and biological products for rare diseases or drugs and biological products that are genetically targeted therapies, the Illinois Drug and Therapeutics Advisory Board may consult external experts on issues related to coverage, payment, drug utilization review, medication therapy management, prior authorization, appeals for coverage, or other topics the Board chooses regarding functions performed by the Board.

(c) Topics for consultation may include, but are not limited to:

(1) Rare diseases.

(2) The severity of rare diseases.

(3) The unmet medical need associated with rare diseases.

(4) The impact of particular coverage, utilization

management, prior authorization, medication therapy management, or other policies on access to rare disease therapies under the Medical Assistance Program.

(5) An assessment of the benefits and risks of therapies to treat rare diseases.

(6) The impact of particular coverage, utilization management, prior authorization, medication therapy management, or other policies on patients' adherence to the treatment regimen prescribed or otherwise recommended by their physicians.

(7) Whether beneficiaries who need treatment from or a consultation with a rare disease specialist have adequate access and, if not, what factors are causing the limited access.

(8) The demographics and the clinical description of patient populations.

(d) All recommendations made by external experts to the Illinois Drug and Therapeutics Advisory Board, including recommendations for other drug review processes performed under the Medical Assistance Program on an applicable treatment of a rare disease shall be:

(1) provided in writing to members of the Illinois Drug and Therapeutics Advisory Board;

(2) summarized and explained during public hearings; and

(3) posted on the Department of Healthcare and Family

Services' website.

(e) The Department of Healthcare and Family Services, in consultation with the Illinois Drug and Therapeutics Advisory Board and external experts and stakeholders including the Illinois Rare Disease Commission, shall adopt rules and procedures to ensure that any provisions under the Illinois Title XIX State Plan that affect beneficiaries' access to drugs and biological products that are for rare diseases or that are genetically targeted therapies are available to the public in a user-friendly and searchable format. The rules and procedures adopted in accordance with this subsection shall include:

(1) prior authorization or other utilization management policies;

(2) preferred drug list policies; and

(3) policies for stakeholder input and public comment at meetings of the Illinois Drug and Therapeutics Advisory Board, which policies shall:

(A) include at least 60 days' notice of any proposed policy, and the meeting date, time, and location;

(B) comply with the Open Meetings Act; and

(C) ensure that the written or verbal public comments received regarding the proposed policies are carefully and systematically considered by the Department of Healthcare and Family Services before the Department develops final policies.

(f)(1) Except as provided in paragraph (2), nothing in this Section shall be construed to alter any laws, regulations, or policies concerning the disclosure of any confidential commercial or trade secret information obtained by the Department of Healthcare and Family Services or the Illinois Drug and Therapeutics Advisory Board during a consultation with an external expert as provided under this Section.

(2) The Department of Healthcare and Family Services shall not disclose any confidential commercial or trade secret information obtained from an expert consulted under this Section unless the Department has received prior written consent from the drug manufacturer whose commercial or trade secret information was initially disclosed by the expert.

Any expert consulted under this Section is subject to the same restrictions on disclosure of confidential commercial or trade secret information as the Department of Healthcare and Family Services and may not disclose information discussed with the Department of Healthcare and Family Services unless the disclosure is authorized by law.

(g) Nothing in this Section shall be construed to:

(1) limit the ability of the Department of Healthcare and Family Services to consult with individuals and organizations for purposes other than the purposes described in this Section; and

(2) create a legal right for a consultation on any matter, or require the Illinois Drug and Therapeutics

Advisory Board or the Department of Healthcare and Family Services to meet with any particular expert or stakeholder.

(h) The requirements of this Section apply only where the consultation with an external expert is undertaken solely under the authority of this Section. The requirements of this Section do not apply to any consultation with an external expert initiated under any other authority.

(i) For the purposes of any review of new drugs and biological products for rare diseases and drugs and biological products that are genetically targeted therapies, the Illinois Drug and Therapeutics Advisory Board shall not be subject to the 6-month review moratorium for new drugs and shall review such drugs at the next regularly scheduled board meeting or no later than 90 days after the drug is approved by the United States Food and Drug Administration. Prior to a review of any new drug, access shall be granted on a case-by-case basis according to the federal labeling requirement by the United States Food and Drug Administration.

Section 99. Effective date. This Act takes effect upon becoming law.