ASSEMBLY, No. 5147

STATE OF NEW JERSEY

221st LEGISLATURE

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Sponsored by:
Assemblyman JOHN V. AZZARITI JR., M.D.
District 39 (Bergen)

SYNOPSIS

Requires certain NJ FamilyCare providers to provide information to, and obtain consent form from, parent or guardian of child that provider is prescribing antipsychotic drug.

CURRENT VERSION OF TEXT

As introduced.

AN ACT concerning NJ FamilyCare providers and supplementing Title 30 of the Revised Statutes.

BE IT ENACTED *by the Senate and General Assembly of the State of New Jersey:*

1. a. As a condition of enrollment in NJ FamilyCare, a health care provider who practices under a State license with the authority to prescribe psychotropic drugs shall:

(1) provide the following to the parent or guardian of a child for whom the provider is prescribing a psychotropic drug, prior to issuing the initial prescription and each time a prescription is refilled for the child:

(a) the drug's Medication Guide, as defined and regulated under 21 C.F.R. 208 et seq., provided that such a Medication Guide is required by the United States Food and Drug Administration for the drug;

(b) information regarding any evidence-based alternatives to the use of the psychotropic drug to treat the child's diagnosis; and

(c) information on how to use and access the United States Food and Drug Administration's Adverse Event Reporting System Public Dashboard, MedWatch Online Voluntary Reporting Form, and any subsequent tools implemented by the United States Food and Drug Administration to replace or supplement these two tools;

(2) obtain a signed consent form from the parent or guardian of a child for whom the provider is prescribing a psychotropic drug, immediately following the fulfillment of the provisions outlined in paragraph (1) of subsection a. of this section, stating that the parent or guardian:

(a) understands any potential risks or side effects of the drug,

(b) is aware of any evidenced-based alternatives to the use of the drug; and

(c) has been informed of the existing tools available from the United States Food and Drug Administration to report adverse effects of the drug on the child and to research reports of adverse effects of the drug on other patients; and

(3) retain the signed consent form, completed pursuant to paragraph (2) of subsection a. of this section, in the child's patient file.

b. As used in this section:

"Child" means an individual 18 years of age and younger who is enrolled in NJ FamilyCare.

"NJ FamilyCare" means the program established pursuant to P.L.2005, c.156 (C.30:4J-8 et al.), which includes the Medicaid program and the Children's Health Insurance Program.

"Psychotropic drug" means a medication prescribed to a patient, such as a stimulant, anti-anxiety, anti-depressant, anti-psychotic,

and mood stabilizer drug, to affect the central nervous system and to treat a behavioral health disorder or illness.

2. The Commissioner of Human Services shall apply for such State plan amendments or waivers as may be necessary to implement the provisions of this act and to secure federal financial participation for State expenditures under the federal Medicaid program and Children's Health Insurance Program.

3. The Commissioner of Human Services, pursuant to the "Administrative Procedure Act," P.L.1968, c.410 (C.52:14B-1 et seq.), shall adopt rules and regulations necessary to implement the provisions of this act.

4. This act shall take effect on the first day of the third month following enactment, except that the Commissioner of Human Services may take such anticipatory administrative action in advance thereof as shall be necessary for the implementation of this act.

STATEMENT

This bill, as a condition of enrollment in NJ FamilyCare, requires a health care provider who practices under a State license with the authority to prescribe psychotropic drugs to provide information to, and obtain a consent form from, the parent or guardian of a child for whom the provider is prescribing an antipsychotic drug. NJ FamilyCare is the State health insurance program for low-income residents, and includes Medicaid and the Children's Health Insurance Program. Under the bill, the definition of a child includes all NJ FamilyCare enrollees, 18 years of age and younger. "Psychotropic drug" means a medication prescribed to a patient, such as a stimulant, anti-anxiety, anti-depressant, anti-psychotic, or mood stabilizer drug, to affect the central nervous system and to treat a behavioral health disorder or illness.

Specifically, the bill mandates the provider to share the following with the parent or guardian: the drug's Medication Guide approved by the United States Food and Drug Administration (FDA), if applicable; information regarding any evidence-based alternatives to the use of the psychotropic drug to treat the child's diagnosis; and information on how to use and access the FDA's Adverse Event Reporting System (FAERS) Public Dashboard, MedWatch Online Voluntary Reporting Form, and any subsequent tools implemented by the FDA to replace or supplement these two tools. The FAERS dashboard offers the public a means to search for data on adverse events reported to the FDA for many drug and biologic products, while MedWatch is a voluntary reporting tool

open to the public to submit observed or suspected adverse events regarding human medical products to the FDA.

Under the bill, providers are also required to obtain a signed consent form from the parent or guardian of a child stating that the parent or guardian: understands any potential risks or side effects of the drug, is aware of any evidenced-based alternatives to the use of the drug; and has been informed of the existing tools available from the FDA to report adverse effects of the drug on the child and to research reports of adverse effects of the drug on other patients. The provider is to retain this signed consent form in the child's patient file.