SB 4050 Protecting Patients from Deceptive Drug Ads Online Act

(Bill as Introduced September 12, 2024)

SECTION 1. SHORT TITLE

This Act may be cited as the **"Protecting Patients from Deceptive Drug Ads Online Act"**.

SEC. 2. REGULATION OF CERTAIN COMMUNICATIONS REGARDING PRESCRIPTION DRUGS

(a) Regulation of Communications

1. **In general**
   Section 303 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 333) is amended by adding the following:

(h) False or Misleading Communications
(1) A social media influencer or healthcare provider who makes false or misleading communications regarding an FDA-approved drug (section 505) or a drug licensed under the Public Health Service Act (section 351), and subject to section 503(b), shall be liable to the U.S. for civil penalties as described in paragraph (g)(1). This will be processed similarly to paragraph (g)(2).

(2) **Definitions**:
(A) **False or Misleading Communications**
(i) Includes advertisements or promotional communications on social media platforms from which there is financial benefit to the person promoting the drug if:

- (I) They knowingly or recklessly make a false or inaccurate statement or omit material facts about the drug.
- (II) They fail to include a summary of side effects, contraindications, and effectiveness, as required in prescription drug ads (section 502(n)).

(ii) Exclusions:
Does not include:

- (I) Statements made in bona fide patient care or medical research by professionals.
- (II) Statements that express personal experience, opinion, or value judgment.

(B) **Social Media Influencer**:
A private individual with perceived credibility or popularity who promotes products or information on social media to an audience with the intent of influencing behavior.

2. **Guidance**
    - Within 180 days of enactment, the Secretary of Health and Human Services (HHS) will issue guidance on administering paragraph (h) of section 303, including:
        - (A) What constitutes false or misleading statements, such as safety, efficacy, or approved use.
        - (B) Whether including required information alone is sufficient to avoid false claims.
        - (C) Compliance actions taken by influencers or healthcare providers.
        - (D) Platform-specific characteristics like speed of dissemination.
3. **Telehealth Providers**
   (A) **Definition Update**
    - Section 502(n) is amended to include people who facilitate connections between patients and prescribers or dispensers through electronic means.

(B) **Regulations**

- Within one year of enactment, the Secretary shall update regulations for section 502(n).

4. **Rule of Construction**
    - Drug manufacturers are allowed to take corrective action to mitigate patient harm from false or misleading communications.
5. **Effective Date**
    - The amendments will take effect 180 days after regulations described in paragraph (3)(B) are finalized.

(b) Reporting Requirement

1. **In general**
   Payments made for drug promotion or communication regarding a covered drug must be reported and made publicly available, similar to requirements in section 1128G of the Social Security Act.
2. **Payments Described**
    - Includes payments by drug manufacturers to healthcare providers or influencers, or by healthcare providers to influencers.

3. **Definitions**
    - **Applicable Manufacturer**: As defined in section 1128G(e) of the Social Security Act.
    - **Covered Drug**: Any drug for which payment is available under Medicare or Medicaid.

(c) Market Surveillance of Prescription Drug Advertising or Promotion

1. **In general**
   The Secretary of HHS may conduct market surveillance of drug promotion on social media. Activities may include:
    - (A) Analyzing public communications, potentially with AI, to track relationships between drug manufacturers and influencers.
    - (B) Developing tools to review promotional content.
    - (C) Engaging social media platforms to address false or misleading drug promotions.
    - (D) Creating educational materials for drug manufacturers, social media platforms, and the public.
2. **FDA Notice to Manufacturers**
    - The FDA may notify drug manufacturers of instances where communications by healthcare providers or influencers fail to meet the required standards for disclosure of side effects, contraindications, and effectiveness.
3. **Reporting**
    - The Secretary will submit reports to Congress on the activities under this section two and four years after enactment, respectively. Enforcement actions will be posted on the FDA's website.
4. **Authorization of Appropriations**
    - $15 million is authorized for fiscal years 2025-2029 to carry out these activities.

(d) Social Media Influencer Definition

- Defined as stated in paragraph (h) of section 303 (as amended).

(e) Severability

- If any provision or amendment of this Act is held invalid, the remaining provisions or amendments will still apply