AB 315

Assembly Bill 315 (Wood – Healdsburg) amends certain provisions in the California Business and Professions Code as well as the Health and safety Code. Specifically, the bill would do the following:

"Gag Clauses"
AB 315 prohibits "gag clauses," which are used by Pharmacy Benefit Managers (PBMs) to prevent pharmacies from informing their patients of a less costly alternate method of payment for their medication. Beginning January 1, 2019, a pharmacy shall inform a customer whether the retail price is lower than the applicable cost-sharing amount for the prescription drug, unless the pharmacy automatically charges the customer the lower price. If the customer pays the retail price, the pharmacy shall submit the claim to the health care service plan or health insurer in the same manner as if the customer had purchased the prescription drug by paying the cost-sharing amount and the payment shall constitute the applicable cost sharing and shall apply to the deductible, if any, and also to the maximum out-of-pocket limit in the same manner as if the patient had purchased the prescription drug by paying the cost-sharing amount.

Covered Entities
AB 315 defines the types of entities that are covered by the statute. Covered entities include purchasers, which are health benefit plan sponsors or other third-party payers with whom a pharmacy benefit manager contracts to provide the administration and management of prescription drug benefits. It does not cover a health care service plan licensed as a Knox-Keene Health Care Service Plan.

Additionally, AB 315 requires that PBMs shall exercise good faith and fair dealing, and that PBMs must notify purchasers in writing of any activity, policy, or practice that directly or indirectly presents a conflict of interest that interferes with the discharge of the pharmacy benefit manager's duty to the purchaser to exercise good faith and fair dealing.

Disclosures and Contracting
The pharmacy benefit manager shall, on a quarterly basis, disclose, upon the request of the purchaser, the following information:

(1) The aggregate wholesale acquisition costs (WAC) from a pharmaceutical manufacturer for each therapeutic category of drugs containing three or more drugs, as outlined in the state's essential health benefits benchmark plan.

(2) The aggregate amount of rebates received by the pharmacy benefit manager by therapeutic category of drugs containing three or more drugs, as outlined in the state's essential health benefits benchmark plan. The aggregate amount of rebates shall include any utilization discounts the pharmacy benefit manager receives from a pharmaceutical manufacturer or labeler.

(3) Any administrative fees received from the pharmaceutical manufacturer or labeler.

(4) Whether the pharmacy benefit manager has a contract, agreement, or other arrangement with a pharmaceutical manufacturer to exclusively dispense or provide a drug to a purchaser's employees, insureds, or enrollees, and the application of all consideration or economic benefits collected or received pursuant to that arrangement.

(5) Aggregate prescription drug utilization information for the purchaser's enrollees or insureds.

(6) The aggregate of payments made by the pharmacy benefit manager to pharmacies *owned or controlled* by the pharmacy benefit manager.

(7) The aggregate of payments made by the pharmacy benefit manager to pharmacies *not owned or controlled* by the pharmacy benefit manager.

(8) The aggregate amount of the fees imposed on, or collected from, network pharmacies or other assessments against network pharmacies, and the application of those amounts collected pursuant to the contract with the purchaser.

The information disclosed under this section applies to all retail, mail order, specialty, and compounded prescription products.

Additionally, in this section, a pharmacy benefit manager shall disclose to a pharmacy provider or its contracting agent at least 30 days before the date of the change to the provision, any material change to its contract that affects:

- The terms of reimbursement
- The process for verifying benefits and eligibility
- Dispute resolution
- Procedures for verifying drugs included on the formulary, and
- Contract termination

A pharmacy benefit manager shall not notify an individual patient or enrollee that a pharmacy has been terminated from the pharmacy benefit manager's network until the notification of termination has been provided to that pharmacy pursuant to above. Additionally, a pharmacy benefit manager shall not include in a contract with a pharmacy network provider or its contracting agent a provision that prohibits the provider from informing a patient of a less costly alternative to a prescribed medication.

Restricted Network Prohibitions
Effective January 1, 2020 a pilot project will be established in Sonoma and Riverside Counties. In that pilot program, a health care service plan or PBM shall not prohibit a pharmacy provider from dispensing a particular amount of a prescribed medication if the plan or pharmacy benefit manager allows that amount to be dispensed through a pharmacy owned or controlled by the plan or pharmacy benefit manager (unless the distribution is restricted by the federal Food and Drug Administration or requires special handling, provider coordination, or patient education that cannot be provided by a retail pharmacy).

This section shall not be construed to prohibit a health care service plan or PBM from requiring the same reimbursement and terms and conditions for a pharmacy network provider as for a pharmacy owned or controlled by the health care service plan or PBM, and, this section shall not be construed to prohibit differential cost sharing designed to encourage or discourage the use of mail-order pharmacy services or preferred pharmacies.

A report shall be submitted annually to the Department of Managed Healthcare and this section shall automatically terminate after January 1, 2023.

Department of Managed Care Authority (DMHC)
AB 315 requires PBMs to register with the Department. Additionally, it clarifies that as a health plan's contracted vendor, PBMs are subject to the relevant laws set forth in this bill and are to be regulated by DMHC. It further clarifies existing law that, by way of this contractual relationship, a health plan cannot delegate its legal liability to a contracted PBM. Additionally, this bill will also provide patients and providers a path for conflict resolution and complaints as requiring an 800 telephone number be established through DMHC.

Regulation of PBMs
A health plan that contracts with a PBM shall require the pharmacy benefit manager to do all of the following:

(1) Comply with the provisions of Section 1385.003, which states that a health care service plan disclose to a contracted pharmacy provider or its contracting agent the prescription drug information contained in subdivision (a) of Section 1363.03, including, but not limited to, the telephone number pharmacy providers may call for assistance and information necessary to process a pharmacy claim. Additionally, a health care service plan shall not include in a contract with a pharmacy provider or its contracting agent a provision that prohibits the provider from informing a patient of a less costly alternative to a prescribed medication.

(2) Register with DMHC pursuant to the requirements of this article.

(3) Exercise good faith and fair dealing in the performance of its contractual duties to a health care service plan.

(4) Comply with the requirements with Section 4430 of the Business and Professions Code, which outlines the provisions and restraints under which a PBM can audit a pharmacy's claims.

(5) Inform all pharmacists under contract with or subject to contracts with the PBM of the pharmacist's rights to submit complaints to DMHC under Section 1371.39, which states providers may report to the department's Office of Plan and Provider Relations, either through the toll-free provider line (877-525-1295) or e-mail address (plans-providers@dmhc.ca.gov), instances in which the provider believes a plan is engaging in an unfair payment pattern; and of the pharmacist's rights as a provider under Section 1375.7 – the Health Care Providers' Bill of Rights.

Finally, a pharmacy benefit manager shall notify a health care service plan in writing of any activity, policy, or practice of the pharmacy benefit manager that directly or indirectly presents a conflict of interest that interferes with the discharge of the pharmacy benefit manager's duty to the health care service plan to exercise good faith and fair dealing in the performance of its contractual duties pursuant to the above.

Enforcement
The failure by a health care service plan to comply with the contractual requirements shall constitute grounds for disciplinary action. The director of DMHC shall, as appropriate, investigate and take enforcement action against a health care service plan that fails to comply with these requirements and shall periodically evaluate contracts between health care service plans and pharmacy benefit managers to determine if any audit, evaluation, or enforcement actions should be undertaken by the department.

Cost Reporting
By July 1, 2019, DMHC, in collaboration with other agencies, departments, advocates, experts, health care service plan representatives, and other entities and stakeholders that it deems appropriate, shall convene a Task Force on Pharmacy Benefit Management Reporting to determine what information related to pharmaceutical costs, if any, the department should require to be reported by health care service plans or their contracted PBMs, in addition to reporting required by Section 1367.243. The task force shall consider inclusion of information including, but not limited to, the following:

(1) Wholesale acquisition costs of pharmaceuticals.
(2) Rebates obtained by the health care service plan or the pharmacy benefit manager from pharmaceutical manufacturers.
(3) Payments to network pharmacies.
(4) Exclusivity arrangements between health care service plans or contracted pharmacy benefit managers with pharmaceutical manufacturers.

The task force shall consider the results of information reporting pursuant to Section 1367.243 and Chapter 9 (commencing with Section 127675) of Part 2 of Division 107 in determining what information should be reported as outlined above. The department shall submit a report of the Task Force on Pharmacy Benefit Management Reporting to the President pro Tempore of the Senate, the Speaker of the Assembly, and the Senate and Assembly Committees on Health, with the recommendations of the task force no later than February 1, 2020, on which date the task force shall cease to exist.