HOUSE BILL 978

By: Delegate Kelly
Introduced and read first time: February 5, 2020
Assigned to: Health and Government Operations

A BILL ENTITLED

AN ACT concerning

Maryland Insurance Administration – Pharmacy Services Administrative Organizations – Regulation

FOR the purpose of requiring, on or after a certain date, pharmacy services administrative organizations to register with the Maryland Insurance Commissioner before providing certain services in the State; requiring certain applicants to file an application on a certain form and pay a certain fee; providing for the expiration and renewal of a certain registration; prohibiting certain pharmacy services administrative organizations from entering into certain contracts; authorizing the Commissioner to deny, refuse to renew, suspend, or revoke a registration under certain circumstances; requiring a pharmacy services administrative organization to maintain certain books and records in a certain manner and for a certain time period; authorizing the Commissioner to examine the affairs, transactions, accounts, and records of a registered pharmacy services administrative organization; requiring that the examination be conducted, the expense of the examination be paid, and the reports be issued in accordance with certain laws; authorizing and requiring the Commissioner to adopt certain regulations; prohibiting certain contracts and amendments to certain contracts from becoming effective except under certain circumstances; requiring a pharmacy services administrative contract to include a certain provision requiring a pharmacy services administrative organization to provide certain documents and information to a certain pharmacy within a certain period of time; requiring a pharmacy services administrative organization to disclose certain information concerning certain ownership or control to the Commissioner and notify the Commissioner of certain changes in ownership or control within a certain period of time; requiring a pharmacy services administrative organization to provide certain disclosures before entering into certain contracts with certain entities; requiring a pharmacy services administrative organization to provide notice of certain changes in ownership or control to certain entities within a certain period of time; requiring a certain contract that authorizes a pharmacy benefits manager to conduct a certain audit of a pharmacy services administrative organization to contain certain language that authorizes the pharmacy benefits manager to obtain

EXPLANATION: CAPITALS INDICATE MATTER ADDED TO EXISTING LAW.
[Brackets] indicate matter deleted from existing law.
certain information regarding certain pharmacies for certain purposes; requiring a pharmacy services administrative contract to require certain remittances to be passed from a pharmacy services administrative organization to a certain pharmacy within a certain period of time; requiring a pharmacy services administrative organization to submit a certain annual report to the Commissioner under certain circumstances; requiring the Commissioner to make certain reports available to the public; prohibiting a pharmacy services administrative organization from requiring a certain pharmacy to purchase certain drugs, biologics, or medical devices from a certain entity as a condition for entering into a pharmacy services administrative contract; requiring a pharmacy services administrative organization that owns or is owned by a certain entity to disclose to the Commissioner certain agreements; requiring certain disclosures to comply with certain privacy standards; requiring certain pharmacy services administrative organizations to establish certain policies and procedures; establishing certain prohibited acts; authorizing the Commissioner to issue certain cease and desist orders, take certain action, and impose certain penalties under certain circumstances; providing for the service of a certain order; providing that a request for a certain hearing does not stay a certain portion of a certain order; authorizing the Commissioner to file a certain petition in a certain court and to recover certain fees and costs under certain circumstances; providing that certain provisions of this Act do not limit certain regulatory authority; providing for the construction of this Act; defining certain terms; and generally relating to pharmacy services administrative organizations.


SECTION 1. BE IT ENACTED BY THE GENERAL ASSEMBLY OF MARYLAND, That the Laws of Maryland read as follows:

Article – Insurance

SUBTITLE 20. PHARMACY SERVICES ADMINISTRATIVE ORGANIZATIONS.


(A) IN THIS SUBTITLE THE FOLLOWING WORDS HAVE THE MEANINGS INDICATED.

(B) “INDEPENDENT PHARMACY” MEANS A PHARMACY OPERATING WITHIN THE STATE THAT IS UNDER COMMON OWNERSHIP WITH NOT MORE THAN TWO OTHER PHARMACIES.
(C) “Pharmacy benefits manager” has the meaning stated in § 15–1601 of this title.

(D) “Pharmacy services administrative contract” means a contractual agreement between a pharmacy services administrative organization and an independent pharmacy under which a pharmacy services administrative organization agrees to negotiate with third-party payers or pharmacy benefits managers on behalf of one or more independent pharmacies.

(E) (1) “Pharmacy services administrative organization” means an entity operating within the state that:

   (I) contracts with independent pharmacies to conduct business on their behalf with third-party payers;

   (II) provides administrative services to independent pharmacies; or

   (III) negotiates and enters into contracts with third-party payers or pharmacy benefits managers on behalf of independent pharmacies.

(2) “Pharmacy services administrative organization” includes a person that performs one or more of the following administrative services for an independent pharmacy:

   (I) claims assistance;

   (II) audit assistance;

   (III) centralized payment;

   (IV) special care programs certification;

   (V) compliance support;

   (VI) flat fee setting for generic drugs;

   (VII) store layout assistance;

   (VIII) inventory management;
(IX) MARKETING SUPPORT;

(X) PAYMENT AND DRUG DISPENSING DATA MANAGEMENT AND ANALYSIS; OR

(XI) PROVISION OF RESOURCES FOR RETAIL CASH CARDS.

(F) (1) “THIRD–PARTY PAYER” MEANS AN ENTITY OPERATING WITHIN THE STATE THAT PAYS OR INSURES HEALTH, MEDICAL, OR PRESCRIPTION DRUG EXPENSES ON BEHALF OF BENEFICIARIES.

(2) “THIRD–PARTY PAYER” INCLUDES A PLAN SPONSOR, A NONPROFIT HEALTH SERVICE PLAN, A HEALTH MAINTENANCE ORGANIZATION, AND AN INSURER.


15–2002.

(A) ON OR AFTER JULY 1, 2021, A PHARMACY SERVICES ADMINISTRATIVE ORGANIZATION SHALL REGISTER WITH THE COMMISSIONER AS A PHARMACY SERVICES ADMINISTRATIVE ORGANIZATION BEFORE PROVIDING SERVICES AS A PHARMACY SERVICES ADMINISTRATIVE ORGANIZATION IN THE STATE TO INDEPENDENT PHARMACIES.

(B) AN APPLICANT FOR REGISTRATION SHALL:

(1) FILE WITH THE COMMISSIONER AN APPLICATION ON THE FORM THAT THE COMMISSIONER PROVIDES; AND

(2) PAY TO THE COMMISSIONER A REGISTRATION FEE SET BY THE COMMISSIONER.


(A) A PHARMACY SERVICES ADMINISTRATIVE ORGANIZATION REGISTRATION EXPIRES ON THE SECOND SEPTEMBER 30 AFTER ITS EFFECTIVE DATE UNLESS IT IS RENEWED AS PROVIDED UNDER THIS SECTION.

(B) A PHARMACY SERVICES ADMINISTRATIVE ORGANIZATION MAY RENEW ITS REGISTRATION FOR AN ADDITIONAL 2–YEAR TERM IF THE PHARMACY SERVICES
ADMINISTRATIVE ORGANIZATION:

(1) OTHERWISE IS ENTITLED TO BE REGISTERED;

(2) FILES WITH THE COMMISSIONER A RENEWAL APPLICATION ON THE FORM THAT THE COMMISSIONER REQUIRES; AND

(3) PAYS TO THE COMMISSIONER A RENEWAL FEE SET BY THE COMMISSIONER.


A PHARMACY SERVICES ADMINISTRATIVE ORGANIZATION THAT HAS NOT REGISTERED WITH THE COMMISSIONER MAY NOT ENTER INTO AN AGREEMENT OR A CONTRACT WITH AN INDEPENDENT PHARMACY OR A PHARMACY BENEFITS MANAGER.


SUBJECT TO THE APPLICABLE HEARING PROVISIONS OF TITLE 2 OF THIS ARTICLE, THE COMMISSIONER MAY DENY A REGISTRATION TO A PHARMACY SERVICES ADMINISTRATIVE ORGANIZATION OR REFUSE TO RENEW, SUSPEND, OR REVOKE THE REGISTRATION OF A PHARMACY SERVICES ADMINISTRATIVE ORGANIZATION IF THE PHARMACY SERVICES ADMINISTRATIVE ORGANIZATION, OR AN OFFICER, A DIRECTOR, OR AN EMPLOYEE OF THE PHARMACY SERVICES ADMINISTRATIVE ORGANIZATION:

(1) MAKES A MATERIAL MISSTATEMENT OR MISREPRESENTATION IN AN APPLICATION FOR REGISTRATION;

(2) FRAUDULENTLY OR DECEPTIVELY OBTAINS OR ATTEMPTS TO OBTAIN A REGISTRATION;

(3) IN CONNECTION WITH THE ADMINISTRATION OF PHARMACY SERVICES ADMINISTRATIVE ORGANIZATION SERVICES, COMMITS FRAUD OR ENGAGES IN ILLEGAL OR DISHONEST ACTIVITIES; OR

(4) VIOLATES THIS SUBTITLE OR A REGULATION ADOPTED UNDER THIS SUBTITLE.


A PHARMACY SERVICES ADMINISTRATIVE ORGANIZATION SHALL MAINTAIN
ADEQUATE BOOKS AND RECORDS REGARDING EACH INDEPENDENT PHARMACY FOR WHICH THE PHARMACY SERVICES ADMINISTRATIVE ORGANIZATION PROVIDES SERVICES AS A PHARMACY SERVICES ADMINISTRATIVE ORGANIZATION:

(1) IN ACCORDANCE WITH PRUDENT STANDARDS OF RECORD KEEPING;

(2) FOR THE DURATION OF THE AGREEMENT BETWEEN THE PHARMACY SERVICES ADMINISTRATIVE ORGANIZATION AND THE INDEPENDENT PHARMACY; AND

(3) FOR 3 YEARS AFTER THE PHARMACY SERVICES ADMINISTRATIVE ORGANIZATION CEASES TO PROVIDE SERVICES AS A PHARMACY SERVICES ADMINISTRATIVE ORGANIZATION FOR THE INDEPENDENT PHARMACY.


(A) WHENEVER THE COMMISSIONER CONSIDERS IT ADVISABLE, THE COMMISSIONER MAY EXAMINE THE AFFAIRS, TRANSACTIONS, ACCOUNTS, AND RECORDS OF A REGISTERED PHARMACY SERVICES ADMINISTRATIVE ORGANIZATION.

(B) THE EXAMINATION SHALL BE CONDUCTED IN ACCORDANCE WITH § 2–207 OF THIS ARTICLE.

(C) THE EXPENSE OF THE EXAMINATION SHALL BE PAID IN ACCORDANCE WITH § 2–208 OF THIS ARTICLE.

(D) THE REPORTS OF THE EXAMINATION AND INVESTIGATION SHALL BE ISSUED IN ACCORDANCE WITH § 2–209 OF THIS ARTICLE.


THE COMMISSIONER MAY ADOPT REGULATIONS TO IMPLEMENT THIS SUBTITLE.

15–2009.

THIS SUBTITLE MAY NOT BE CONSTRUED TO DIMINISH THE AUTHORITY OF THE OFFICE OF THE ATTORNEY GENERAL OR THE COMMISSIONER TO OBTAIN INFORMATION RELATING TO A PHARMACY SERVICES ADMINISTRATIVE ORGANIZATION AND USE THE INFORMATION IN ANY PROCEEDING.
(A) A PHARMACY SERVICES ADMINISTRATIVE CONTRACT OR AN AMENDMENT TO A PHARMACY SERVICES ADMINISTRATIVE CONTRACT OR A CONTRACT OR AN AMENDMENT TO A CONTRACT BETWEEN A PHARMACY SERVICES ADMINISTRATIVE ORGANIZATION, ON BEHALF OF AN INDEPENDENT PHARMACY, AND A PHARMACY BENEFITS MANAGER OR GROUP PURCHASING ORGANIZATION MAY NOT BECOME EFFECTIVE UNLESS:

1. At least 30 days before the contract or amendment is to become effective, the pharmacy services administrative organization files the contract or amendment with the Commissioner in the form required by the Commissioner; and

2. The Commissioner does not disapprove the filing within 30 days after the contract or amendment is filed.

(B) The Commissioner shall adopt regulations to establish the circumstances under which the Commissioner may disapprove a contract.

15–2011.

A PHARMACY SERVICES ADMINISTRATIVE CONTRACT SHALL INCLUDE A PROVISION THAT REQUIRES THE PHARMACY SERVICES ADMINISTRATIVE ORGANIZATION TO PROVIDE TO THE INDEPENDENT PHARMACY A COPY OF ANY CONTRACTS, AMENDMENTS, PAYMENT SCHEDULES, OR REIMBURSEMENT RATES WITHIN 3 CALENDAR DAYS AFTER THE EXECUTION OF A CONTRACT, OR AN AMENDMENT TO A CONTRACT, SIGNED ON BEHALF OF THE INDEPENDENT PHARMACY BY THE PHARMACY SERVICES ADMINISTRATIVE ORGANIZATION.

15–2012.

(A) Each pharmacy services administrative organization shall disclose to the Commissioner the extent of any ownership or control of the pharmacy services administrative organization by any parent company, subsidiary, or other organization that:

1. Provides pharmacy services;

2. Provides prescription drug or device services; or

3. Manufactures, sells, or distributes prescription drugs,
BIOLOGICS, OR MEDICAL DEVICES.

(B) EACH PHARMACY SERVICES ADMINISTRATIVE ORGANIZATION SHALL NOTIFY THE COMMISSIONER IN WRITING WITHIN 5 CALENDAR DAYS AFTER ANY MATERIAL CHANGE IN ITS OWNERSHIP OR CONTROL RELATING TO ANY COMPANY, SUBSIDIARY, OR OTHER ORGANIZATION DESCRIBED UNDER SUBSECTION (A) OF THIS SECTION.

15–2013.

(A) BEFORE ENTERING INTO A PHARMACY SERVICES ADMINISTRATIVE CONTRACT, A PHARMACY SERVICES ADMINISTRATIVE ORGANIZATION SHALL PROVIDE TO AN INDEPENDENT PHARMACY A WRITTEN DISCLOSURE OF OWNERSHIP OR CONTROL.

(B) THE DISCLOSURE REQUIRED UNDER SUBSECTION (A) OF THIS SECTION SHALL INCLUDE THE EXTENT OF ANY OWNERSHIP OR CONTROL BY ANY PARENT COMPANY, SUBSIDIARY, OR OTHER ORGANIZATION THAT:

(1) PROVIDES PHARMACY SERVICES;

(2) PROVIDES PRESCRIPTION DRUG OR DEVICE SERVICES; OR

(3) MANUFACTURES, SELLS, OR DISTRIBUTES PRESCRIPTION DRUGS, BIOLOGICS, OR MEDICAL DEVICES.

(C) A PHARMACY SERVICES ADMINISTRATIVE CONTRACT SHALL REQUIRE A PHARMACY SERVICES ADMINISTRATIVE ORGANIZATION TO NOTIFY AN INDEPENDENT PHARMACY IN WRITING WITHIN 5 CALENDAR DAYS AFTER ANY MATERIAL CHANGE IN ITS OWNERSHIP OR CONTROL RELATED TO ANY COMPANY, SUBSIDIARY, OR OTHER ORGANIZATION DESCRIBED UNDER SUBSECTION (B) OF THIS SECTION.

15–2014.

(A) BEFORE ENTERING INTO A CONTRACT WITH A THIRD–PARTY PAYER OR PHARMACY BENEFITS MANAGER, A PHARMACY SERVICES ADMINISTRATIVE ORGANIZATION SHALL PROVIDE TO THE THIRD–PARTY PAYER OR PHARMACY BENEFITS MANAGER A WRITTEN DISCLOSURE OF OWNERSHIP OR CONTROL.

(B) THE DISCLOSURE REQUIRED UNDER SUBSECTION (A) OF THIS SECTION SHALL INCLUDE THE EXTENT OF ANY OWNERSHIP OR CONTROL BY ANY PARENT COMPANY, SUBSIDIARY, OR OTHER ORGANIZATION THAT:
(1) PROVIDES PHARMACY SERVICES;

(2) PROVIDES PRESCRIPTION DRUG OR DEVICE SERVICES; OR

(3) MANUFACTURES, SELLS, OR DISTRIBUTES PRESCRIPTION DRUGS, BIOLOGICS, OR MEDICAL DEVICES.

(C) A CONTRACT WITH A THIRD-PARTY PAYER OR PHARMACY BENEFITS MANAGER SHALL PROVIDE THAT A PHARMACY SERVICES ADMINISTRATIVE ORGANIZATION SHALL NOTIFY THE THIRD-PARTY PAYER OR PHARMACY BENEFITS MANAGER IN WRITING WITHIN 5 CALENDAR DAYS AFTER ANY MATERIAL CHANGE IN ITS OWNERSHIP OR CONTROL RELATED TO ANY COMPANY, SUBSIDIARY, OR OTHER ORGANIZATION DESCRIBED IN SUBSECTION (B) OF THIS SECTION.

15–2015.

A CONTRACT BETWEEN A PHARMACY BENEFITS MANAGER AND A PHARMACY SERVICES ADMINISTRATIVE ORGANIZATION THAT AUTHORIZES A PHARMACY BENEFITS MANAGER TO CONDUCT AUDITS OF INDEPENDENT PHARMACIES FOR WHICH THE PHARMACY SERVICES ADMINISTRATIVE ORGANIZATION PROVIDES SERVICES AS A PHARMACY SERVICES ADMINISTRATIVE ORGANIZATION SHALL CONTAIN SPECIFIC LANGUAGE THAT AUTHORIZES THE PHARMACY BENEFITS MANAGER TO OBTAIN INFORMATION FROM THE PHARMACY SERVICES ADMINISTRATIVE ORGANIZATION REGARDING THE INDEPENDENT PHARMACY FOR PURPOSES OF THE AUDIT.

15–2016.

A PHARMACY SERVICES ADMINISTRATIVE CONTRACT SHALL:

(1) REQUIRE ALL REMITTANCES FOR CLAIMS SUBMITTED BY A PHARMACY BENEFITS MANAGER OR THIRD-PARTY PAYER ON BEHALF OF AN INDEPENDENT PHARMACY TO BE PASSED BY THE PHARMACY SERVICES ADMINISTRATIVE ORGANIZATION TO THE INDEPENDENT PHARMACY WITHIN A REASONABLE AMOUNT OF TIME; AND

(2) SPECIFY THE REASONABLE AMOUNT OF TIME IN WHICH THE PHARMACY SERVICES ADMINISTRATIVE ORGANIZATION IS REQUIRED TO PASS THE REMITTANCES RECEIVED FROM THE PHARMACY BENEFITS MANAGER OR THIRD-PARTY PAYER TO THE INDEPENDENT PHARMACY.

(A) A pharmacy services administrative organization that provides, accepts, or processes a discount, concession, or product voucher to reduce, directly or indirectly, an out-of-pocket expense for the order, dispensing, substitution, sale, or purchase of a prescription drug shall submit to the Commissioner an annual report that includes:

(1) An aggregated total of the amount received by the independent pharmacy for prescription drugs that were subject to a discount, concession, or product voucher and ordered, dispensed, substituted, sold, or purchased by the independent pharmacy; and

(2) An aggregated total of any payments received by the pharmacy services administrative organization for providing, accepting, or processing discounts, concessions, or product vouchers on behalf of an independent pharmacy.

(B) The Commissioner shall make the reports submitted under subsection (A) of this section available to the public.

15–2018.

(A) A pharmacy services administrative organization that owns or is owned by, in whole or in part, an entity that manufactures, sells, or distributes prescription drugs, biologics, or medical devices may not require, as a condition of entering into a pharmacy services administrative contract, that an independent pharmacy purchase any drugs, biologics, or medical devices from the entity.

(B) A pharmacy services administrative organization that owns or is owned by, in whole or in part, any entity that manufactures, sells, or distributes prescription drugs, biologics, or medical devices shall disclose to the Commissioner any agreement with an independent pharmacy under which the independent pharmacy purchases prescription drugs, biologics, or medical devices from the entity.


All disclosures made under this subtitle shall comply with the privacy standards established in federal and State law.

15–2020.
A PHARMACY SERVICES ADMINISTRATIVE ORGANIZATION SHALL ESTABLISH APPROPRIATE POLICIES AND PROCEDURES TO IMPLEMENT THE REQUIREMENTS OF THIS SUBTITLE.

15–2021.

(A) A PHARMACY SERVICES ADMINISTRATIVE ORGANIZATION MAY NOT:

(1) MISREPRESENT PERTINENT FACTS OR POLICY PROVISIONS THAT RELATE TO AN ISSUE IN A COMPLAINT OR AN APPEAL OF A DECISION REGARDING A COMPLAINT;

(2) REFUSE TO PAY OR REIMBURSE AN INDEPENDENT PHARMACY OR A PHARMACY BENEFITS MANAGER FOR AN ARBITRARY OR CAPRICIOUS REASON BASED ON ALL AVAILABLE INFORMATION;

(3) FAIL TO SETTLE A DISPUTE PROMPTLY WHENEVER LIABILITY IS REASONABLY CLEAR UNDER ONE PART OF A POLICY OR CONTRACT, IN ORDER TO INFLUENCE SETTLEMENTS UNDER OTHER PARTS OF THE POLICY OR CONTRACT; OR

(4) FAIL TO ACT IN GOOD FAITH.

(B) IF THE COMMISSIONER DETERMINES THAT A PHARMACY SERVICES ADMINISTRATIVE ORGANIZATION HAS VIOLATED ANY PROVISION OF THIS SUBTITLE OR ANY REGULATION ADOPTED UNDER THIS SUBTITLE, THE COMMISSIONER MAY ISSUE AN ORDER THAT REQUIRES A PHARMACY SERVICES ADMINISTRATIVE ORGANIZATION TO:

(1) CEASE AND DESIST FROM THE IDENTIFIED VIOLATION AND FURTHER SIMILAR VIOLATIONS;

(2) TAKE SPECIFIC AFFIRMATIVE ACTION TO CORRECT THE VIOLATION;

(3) MAKE RESTITUTION OF MONEY, PROPERTY, AND OTHER ASSETS TO A PERSON THAT HAS SUFFERED FINANCIAL INJURY BECAUSE OF THE VIOLATION; OR

(4) PAY A FINE IN THE AMOUNT DETERMINED BY THE COMMISSIONER.

(C) (1) AN ORDER OF THE COMMISSIONER ISSUED UNDER THIS SECTION
MAY BE SERVED ON A PHARMACY SERVICES ADMINISTRATIVE ORGANIZATION THAT IS REGISTERED UNDER § 15–2002 OF THIS SUBTITLE IN THE MANNER PROVIDED IN § 2–204 OF THIS ARTICLE.

(2) An order of the Commissioner issued under this section may be served on a pharmacy services administrative organization that is not registered under § 15–2002 of this subtitle in the manner provided in § 4–206 or § 4–207 of this article for service on an unauthorized insurer that does an act of insurance business in the State.

(3) A request for a hearing on any order issued under this section does not stay that portion of the order that requires the pharmacy services administrative organization to cease and desist from the conduct identified in the order.

(4) The Commissioner may file a petition in the circuit court of any county to enforce an order issued under this section, whether or not a hearing has been requested or, if requested, whether or not a hearing has been held.

(5) If the Commissioner prevails in an action brought under this section, the Commissioner may recover, for the use of the State, reasonable attorney’s fees and the costs of the action.

(D) In addition to any other enforcement action taken by the Commissioner under this section, the Commissioner may impose a civil penalty not exceeding $10,000 for each violation of this subtitle.

(E) The Commissioner may adopt regulations:

(1) to carry out this section; and

(2) to establish a complaint process to address grievances and appeals brought in accordance with this section.

(F) This section does not limit any other regulatory authority of the Commissioner under this article.

SECTION 2. AND BE IT FURTHER ENACTED, That this Act shall take effect October 1, 2020.