NEW YORK STATE DEPARTMENT OF FINANCIAL SERVICES
PROPOSED

FIRST AMENDMENT TO 11 NYCRR 6
(INSURANCE REGULATION 195)
ELECTRONIC FILINGS AND SUBMISSIONS

NEW 11 NYCRR 452
(INSURANCE REGULATION 222)
GENERAL DUTIES, ACCOUNTABILITY, AND TRANSPARENCY PROVISIONS FOR PHARMACY BENEFIT MANAGERS

I, Adrienne A. Harris, Superintendent of Financial Services, pursuant to the authority granted by sections 102, 201, 202, 301, 302, and 306 of the Financial Services Law, sections 301 and 316 of the Insurance Law, and section 280-a of the Public Health Law, after consultation with the Commissioner of Health, do hereby promulgate the following first amendment to Part 6 of, and the addition of a new Part 452 to, Title 11 of the Official Compilation of Codes, Rules, and Regulations of the State of New York, to take effect upon the filing of the Notice of Emergency Adoption with the Secretary of State, to read as follows:

(All of the following material is new)

A new paragraph (11) is added to section 6.2(a) as follows:

(11) *Pharmacy benefit manager documents.* The information and documents required by Insurance Law Article 29, Public Health Law section 280-a and Chapter XXI of this Title.

A new Part 452 is added to this Title as follows:

PART 452
(INSURANCE REGULATION 222)

GENERAL DUTIES, ACCOUNTABILITY, AND TRANSPARENCY PROVISIONS FOR PHARMACY BENEFIT MANAGERS

Sec.

Section 452.1 Application.

(a) Pursuant to the authority granted to the superintendent by Public Health Law section 280-a(2)(g) to make regulations defining, limiting, and relating to the duties, obligations, requirements, and other provisions relating to pharmacy benefit managers under Public Health Law section 280-a(2), the duties, obligations, and

requirements contained in Public Health Law section 280-a(2)(b), (c), (d), and (e) shall be applied as set forth in this Part.

(b) Safe Harbor. Except as provided in subdivision (c) of this section, each pharmacy benefit manager shall come into compliance with the provisions of this Part by December 31, 2023, provided, however, that no application for licensure under Insurance Law section 2906 submitted on or before December 31, 2023 shall be accepted by the superintendent unless the pharmacy benefit manager certifies that it is in compliance with the provisions of this Part.

(c) Notwithstanding subdivision (b) of this section, a pharmacy benefit manager shall comply with section 452.3 of this Part on and after June 1, 2023.

(d) A pharmacy benefit manager may submit the information and documents requested under this Part electronically to the health plan to an email address provided by the health plan for purposes of this Part.

Section 452.2 Health plan right to an accounting.

(a) Pharmacy benefit managers that provide pharmacy benefit management services only for health plans that provide workers' compensation insurance are exempt from the requirements listed in Public Health Law section 280-a(2)(b) and (c).

(b) Upon written request of any health plan for which the pharmacy benefit manager provides pharmacy benefit management services, a pharmacy benefit manager shall provide an accounting of all funds received by the pharmacy benefit manager for pharmacy benefit management services attributable to the health plan sufficient to demonstrate that such funds were used or distributed only pursuant to the pharmacy benefit manager's contract with the health plan or applicable law.

(c) Each pharmacy benefit manager shall have in place accounting measures, practices, and procedures that will permit such an accounting to each health plan for which it performs pharmacy benefit management services.

(d) A pharmacy benefit manager shall have a commercially reasonable time of not more than 60 days to produce the accounting to the health plan.

Section 452.3 Terms and conditions of contract relating to pharmacy benefit management services provided to health plans.

(a) The disclosures provided for by Public Health Law section 280-a(2)(d) shall:

(1) be made by the pharmacy benefit manager within 30 days from receipt of a written request from the health plan, but such request shall not be made by the health plan more than once every six months;

(2) require that the contracts or arrangements requested be provided to the health plans in full and unredacted; and

(3) not apply to health plans that provide workers' compensation insurance.

(b) In the event that a health plan requests disclosure of a contract or arrangement that the pharmacy benefit manager determines is not related to the pharmacy benefit management services provided to the health plan, or that the pharmacy benefit manager determines contains information that is confidential, the pharmacy benefit manager may appeal to the department for a determination on disclosure.

(1) Application for a determination on disclosure. A pharmacy benefit manager shall file a letter setting forth all the relevant facts and circumstances that the department should consider in making the determination within 30 days from receipt of the written request from the health plan by sending such letter by electronic mail to the department at the address listed on the website of the department for such purpose. Such application shall also contain a copy of the unredacted contract that is at issue.

(2) Stay of obligation. Upon the filing of a complete application for a determination on disclosure, the obligation to respond to the health plan is stayed until a determination is rendered. An incomplete application shall have no such effect.

(3) Determination on disclosure. Upon receipt of a complete application, the department may seek additional information from the pharmacy benefit manager, the health plan, or any other party. Once the department determines that the department has sufficient information to render a determination, such determination shall be made in writing to the pharmacy benefit manager, and may direct the pharmacy benefit manager:

(i) to make the disclosure;

(ii) that it is not required to make the disclosure and to instead send a copy of the department's determination to be transmitted to the health plan; or

(iii) to make the disclosure with specific redactions.

(4) Information obtained by the department under this section shall be treated as information obtained under Insurance Law section 2904.

Section 452.4 Conflicts of interest.

(a) Any of following activities, policies, practices, contracts, or arrangements shall be considered conflicts of interest for purposes of Public Health Law section 280-a(2)(e) and therefore the following information shall be disclosed to a health plan, upon written request by the health plan, within 30 days of such request:

(1) Where there is a difference in the amount charged to the health plan for a prescription drug's ingredient cost or dispensing fee and the amount the pharmacy benefit manager reimburses a pharmacy for the same prescription drug's ingredient cost or dispensing fee:

(i) the pharmacy benefit manager shall disclose to the health plan the actual total reimbursement amounts for each drug the pharmacy benefit manager paid to each network pharmacy after all direct and indirect administrative and other fees that have been retrospectively charged to the pharmacies are applied; and

(ii) the pharmacy benefit manager shall disclose to the health plan the actual total reimbursement amounts for each drug the pharmacy benefit manager pays each and every pharmacy benefit manager's owned or affiliated mail order or specialty pharmacy after all direct and indirect administrative and other fees have been retrospectively charged to the pharmacies are applied;

(2) Where the pharmacy benefit manager or any owned or affiliated entity receives any renumeration, including, any rebates, fees, discounts, reimbursements, payments, or other funds received by the pharmacy benefit manager from a manufacturer for a prescription drug, where such renumeration is not fully passed through to the health plan:

(i) the pharmacy benefit manager shall disclose to the health plan the total dollar amount and percentage of all rebates, fees, discounts, reimbursements, payments, or other funds received from any manufacturer by the pharmacy benefit manager for each drug on the pharmacy benefit manager's formularies, including any rebates, fees, discounts, reimbursements, payments, or other funds paid to or received from an owned or affiliated entity, which includes any rebate aggregator or group purchasing organization; and

(ii) the pharmacy benefit manager shall also disclose its relationship with each rebate aggregator or group purchasing organization, including whether and how the rebate aggregator or group purchasing organization is owned or affiliated with the pharmacy benefit manager;

(3) Where the pharmacy benefit manager has any ownership interest in, or affiliation with, any retail, specialty, or mail order pharmacy, including in-network pharmacies and out-of-network pharmacies, the pharmacy benefit manager shall disclose to the health plan:

(i) each and every ownership interest in, or affiliation with, each and every retail, specialty, or mail order pharmacy that claims were paid to by the pharmacy benefit manager on behalf of the health plan in the past calendar year;

(ii) the total dollar amount and the percentage of total claims that were paid to each owned or affiliated pharmacy by the pharmacy benefit manager on behalf of the health plan in the past calendar year; and

(iii) the total dollar amount and the percentage of total claims that were paid to non-affiliated pharmacies by the pharmacy benefit manager on behalf of the health plan in the past calendar year;

(4) Where the pharmacy benefit manager solicits or incentivizes, either directly or indirectly, any covered individual to use a pharmacy benefit manager-owned or affiliated dispensing entity, including a pharmacy benefit manager-owned or affiliated retail pharmacy, specialty pharmacy, mail order pharmacy or other dispensing entity in lieu of a non-pharmacy benefit manager-affiliated pharmacy, the pharmacy benefit manager shall disclose to the health plan:

(i) each and every communication made by the pharmacy benefit manager to each and every covered individual that could be seen by a reasonable person as a solicitation or incentivization to that covered individual to utilize a pharmacy benefit manager-owned or affiliated dispensing entity;

(ii) the contents of each and every communication that was made by the pharmacy benefit manager to each and every covered individual that could be seen by a reasonable person as a solicitation or incentivization to that covered individual to use a pharmacy benefit manager-owned or affiliated dispensing entity;

(iii) the method by which, and the number of times, each and every communication was made by the pharmacy benefit manager to each and every covered individual that could be seen by a reasonable person as a solicitation or incentivization to that covered individual to use a pharmacy benefit manager-owned or affiliated dispensing entity; and

(iv) any communications by a pharmacy benefit manager to any covered individual that mentions a pharmacy benefit manager's wholly owned pharmacy in any way;

(5) Where the prescription of a claim originating in one pharmacy is transferred to another pharmacy that the pharmacy benefit manager has an ownership interest in or affiliation with, the pharmacy benefit manager shall disclose to the health plan:

(i) each claim originating in a pharmacy where a prescription was transferred for any reason to another pharmacy that the pharmacy benefit manager has an ownership interest in or affiliation with;

(ii) to and from which pharmacy the prescription was transferred;

(iii) whether the pharmacy benefit manager contacted the covered individual, prescriber, or both in an effort to promote the transfer or obtain the prescription;

(iv) the reason why the prescription was transferred; and

(v) if the prescription was transferred for any reason related to a prior authorization, whether efforts were made to obtain the prior authorization at the originating pharmacy, and if so, whether the prescription was still transferred and the reason for the transfer;

(6) Where the pharmacy benefit manager conducts audits of pharmacies, the pharmacy benefit manager shall disclose to the health plan:

(i) each pharmacy for which the pharmacy benefit manager has conducted an audit in the past 12 months;

(ii) the number of audits that were or are currently being conducted on each individual pharmacy;

(iii) whether such pharmacy is owned or affiliated with the pharmacy benefit manager or whether such pharmacy is an independently owned pharmacy; and

(iv) the amount of any and all monetary fees of any kind paid to the pharmacy benefit manager in connection with such audit for each pharmacy as well as the reasons for the fees for each pharmacy;

(7) Where the pharmacy benefit manager or any entity owned or affiliated with the pharmacy benefit manager is responsible for managing, coordinating, or facilitating, in whole or in part, any program that restricts in any way a manufacturer's contributions to copay discount cards or copay coupons from applying to the health plan's beneficiaries' cost-sharing requirements under the health plan, the pharmacy benefit manager shall disclose to the health plan:

(i) the name of the entity responsible for managing, coordinating, or facilitating, in whole or in part, any program that restricts in any way a manufacturer's contributions to copay discount cards from applying to the health plan's cost-sharing requirements under the plan;

(ii) the relationship between the pharmacy benefit manager and the entity managing, coordinating, or facilitating, in whole or in part, any program that restricts in any way a manufacturer's contributions to copay discount cards from applying to the health plan's cost-sharing requirements under the plan; and

(iii) the percentage or amount of the manufacturer's contributions to copay discount cards or copay coupons applies to the health plan's beneficiaries' cost-sharing requirements under the plan;

(8) Where the pharmacy benefit manager or any entity owned or affiliated with the pharmacy benefit manager shares any data obtained from a non-affiliated pharmacy with the pharmacy benefit manager's own or affiliated pharmacy or pharmacies, the pharmacy benefit manager shall disclose to the health plan:

(i) how the non-affiliated pharmacy data was obtained from the pharmacy; and

(ii) the precise data obtained from the non-affiliated pharmacy that the pharmacy benefit manager shares with the pharmacy benefit managers' own affiliated pharmacy or pharmacies; and

(9) Where the health plan reasonably views any other activity, policy, practice, contract, or arrangement of the pharmacy benefit manager not otherwise listed above as directly or indirectly presenting a conflict of interest with the pharmacy benefit manager's relationship with or obligation to the health plan, the pharmacy benefit manager shall disclose such activity, policy, practice, contract, or arrangement to the health plan upon request by the health plan.