Regulatory Impact Statement for the First Amendment to 11 NYCRR 451 (Insurance Regulation 221)

1. Statutory authority: Financial Services Law sections 102, 201, 202, 301, 302, and 306; Insurance Law section 301; and Public Health Law section 280-a.

Insurance Law Article 29 and Public Health Law section 280-a authorize the Superintendent of Financial Services ("Superintendent") to regulate pharmacy benefits managers ("PBMs") and provides the Superintendent with broad independent regulatory authority over PBMs, including the promulgation of regulations regarding the registration, annual reporting, and licensing of PBMs.

Financial Services Law Section 202 establishes the office of the Superintendent.

Financial Services Law Section 302 and Insurance Law Section 301 authorize the Superintendent to effectuate any power accorded to the Superintendent by the Financial Services Law, Insurance Law, or any other law, and to prescribe regulations interpreting the Insurance Law.

Financial Services Law Section 102 consolidates the Departments of Insurance and Banking into the Department of Financial Services ("Department").

Financial Services Law Section 201 authorizes the Superintendent to take actions as necessary to eliminate financial fraud or other criminal abuse or unethical conduct in the industry.

Financial Services Law Section 306 provides the authority to the Superintendent, or the person authorized by the Superintendent, to conduct a hearing to subpoena witnesses, compel the attendance of witnesses, administer oaths, examine any person under oath and to compel any person to subscribe to his or her testimony, and to require the production of any books, papers, records, correspondence, or other such documents that the Superintendent deems necessary.

Insurance Law Section 301 authorizes the Superintendent to prescribe regulations governing the practices of the Department.

Public Health Law Section 280-a authorizes the Superintendent to make regulations defining, limiting, and relating to the duties, obligations, requirements, and other provisions relating to pharmacy benefit managers.

2. Legislative objectives: In accordance with Insurance Law Article 29 and Public Health Law section 280-a, the legislative objectives are to empower the Superintendent to establish, by regulation, registration requirements for a PBM, including the methods and procedures for facilitating and verifying compliance with those requirements, and to establish licensing standards for PBMs, including the broad regulatory authority to implement minimum standards for the issuance of licenses to PBMs.

3. Needs and benefits: This amendment is being promulgated as an emergency measure to be effective immediately upon filing with the Secretary of State because of the expiration of the moratorium imposed by 11 NYCRR 451 (Insurance Regulation 221) on the duties, obligations, and requirements contained in Public Health Law section 280-a(2)(b), (c), (d), (e), and (f). The Department is in the process of proposing such detailed regulations; however, taking into consideration the importance of providing clear yet thorough guidance and assurances to the industry, the Department requires more time to promulgate these regulations. This amendment maintains the status quo and does not add to or subtract from any substantive provisions within 11 NYCRR 451 (Insurance Regulation 221).

4. Costs: This amendment does not impose any additional costs on PBMs or any other party and merely seeks to maintain the current status quo until detailed regulations can be fully promulgated.

5. Local government mandates: The amendment does not impose any program, service, duty, or responsibility upon a county, city, town, village, school district, fire district, or other special district.

6. Paperwork: This amendment does not impose any additional reporting, recordkeeping, or other compliance requirements on PBMs or any other party and merely seeks to maintain the current status quo until detailed regulations can be fully promulgated to provide permanent clarity to the industry.

7. Duplication: The amendment does not duplicate or conflict with any existing state or federal regulations or other legal requirements.

8. Alternatives: The Department considered not promulgating this amendment. However, the amendment is required to maintain the status quo while the Department works to fully promulgate clear and permanent regulations. Without the amendment, PBMs would be left with unclear guidance on the application of, and how to comply with, the requirements contained in Public Health Law section 280-a. Therefore, the alternative of not promulgating the amendment was rejected.

9. Federal standards: The amendment does not exceed any minimum standards of the federal government for the same or similar subject areas.

10. Compliance schedule: The amendment will take effect immediately upon the filing of the Notice of Emergency Adoption with the Secretary of State.

Statement Setting Forth the Basis for the Finding that the First Amendment to 11 NYCRR 451 (Insurance Regulation 221) Will Not Have a Substantial Adverse Impact on Small Businesses and Local Governments

Small businesses: This amendment, being promulgated as an emergency measure, should not have any adverse impact on small businesses. This amendment merely maintains the status quo of 11 NYCRR 451 (Insurance Regulation 221) and provides certainty to the industry while the Department works to promulgate permanent regulations.

Local governments: This amendment does not apply to local governments. No local government will have to undertake any reporting, recordkeeping, or other affirmative acts to comply with this amendment. Therefore, the amendment will not have any impact, including any adverse impact, on any local government.

Statement Setting Forth the Basis for the Finding that the First Amendment to 11 NYCRR 451 (Insurance Regulation 221) Will Not Have a Substantial Adverse Impact on Rural Areas

This amendment, being promulgated as an emergency measure, should not have any adverse impact on pharmacy benefit managers or any other party in a rural area. This amendment merely maintains the status quo of 11 NYCRR 451 (Insurance Regulation 221) and provides certainty to the industry while the Department works to promulgate permanent regulations.

Statement Setting Forth the Basis for the Finding that the First Amendment to 11 NYCRR 451 (Insurance Regulation 221) Will Not Have a Substantial Adverse Impact on Jobs and Employment Opportunities

The Department of Financial Services ("Department") has determined that the emergency measure should not adversely impact jobs or employment opportunities in New York State. The amendment merely maintains the status quo of 11 NYCRR 451 (Insurance Regulation 221) and provides certainty to the industry while the Department works to promulgate permanent regulations.