

Regulatory Impact Statement for the Proposed Fiftieth Amendment to 11 NYCRR 52 (Insurance Regulation 62).

1. Statutory authority: Financial Services Law (“FSL”) sections 202 and 302; Insurance Law (“IL”) sections 301, 3201, 3216(l), 3217, 3221(h), 3221(l)(7-a), 4303(l-1) and (ll), 4304(l), 4308(a), and 4328(b)(1), and Article 49; Public Health Law (“PHL”) Article 49; and 45 C.F.R. section 156.122(c).

FSL section 202 establishes the office of the Superintendent of Financial Services (“Superintendent”). FSL section 302 and IL section 301, in pertinent part, authorize the Superintendent to prescribe regulations interpreting the IL and to effectuate any power granted to the Superintendent in the IL, FSL, or any other law.

IL sections 3201 and 4308(a) empower the Superintendent with discretion to approve policy and contract forms after ensuring that they conform to the requirements of the Insurance Law and are not inconsistent with the law.

IL section 3217 authorizes the Superintendent to issue regulations to establish minimum standards, including standards for full and fair disclosure, for the form, content and sale of accident and health insurance policies and subscriber contracts of corporations organized under IL Articles 32 and 43 and PHL Article 44.

IL sections 3216(l), 3221(h), 4303(ll), 4304(l), and 4328(b)(1) taken together require all individual and small group policies and contracts delivered or issued for delivery in New York to provide essential health benefits, as defined under the federal Affordable Care Act, which include coverage for medication for the detoxification or maintenance treatment of a substance use disorder approved by the federal Food and Drug Administration (“FDA”) for the detoxification or maintenance treatment of substance use disorder.

IL sections 3221(l)(7-b) and 4303(l-1) require that large group policies and contracts delivered or issued for delivery in New York provide coverage for medication for the detoxification or maintenance treatment of a substance use disorder approved by the FDA for the detoxification or maintenance treatment of substance use disorder.

IL Article 49 and PHL Article 49 provide the general structure of utilization review and the process for internal and external appeals of denials.

45 C.F.R. section 156.122(c) requires that all non-grandfathered individual and small group health plans provide an opportunity to request and gain access to any prescription drug that is not otherwise covered by the health plan.

2. Legislative objectives: IL sections 3216(l), 3221(h), 4303(l), 4304(l), and 4328(b)(1) require individual and small group health insurance policies and contracts to cover essential health benefits and by extension medications for the detoxification or maintenance treatment of a substance use disorder. IL sections 3221(l)(7-a) and 4303(l-1) specifically require policies and contracts delivered or issued for delivery in New York to provide coverage for medication for the detoxification or maintenance treatment of a substance use disorder approved by the FDA for the detoxification or maintenance treatment of substance use disorder. IL Article 49 and PHL Article 49 provide internal review and external appeals processes to the insurer when determinations are made that are adverse to the insured.

In accordance with the requirements in 45 C.F.R. section 156.122(c) that all non-grandfathered individual and small group health plans provide an opportunity to request and gain access to any prescription drug that is not otherwise covered by the health plan, individual and small group health plans provide internal review and external appeals in accordance with IL Article 49 or PHL Article 49, as appropriate.

This amendment accords with the legislative objectives of IL sections 3216(l), 3221(h), 3221(l)(7-a), 4303(l-1), 4303(l), 4304(l), 4328(b)(1), IL Article 49, and PHL Article 49 by codifying 45 C.F.R. section 156.122(c) in state law for individuals and small groups, and for large groups, to require that the plan provide a formulary exception process that allows an insured the opportunity to request an exception and gain access to medication for the detoxification or maintenance treatment of a substance use disorder not otherwise covered by the policy or contract when medically necessary. The amendment further accords with IL Article 49 and PHL Article 49 by

ensuring that the internal review and external appeals processes are followed for these medications, and by providing greater consumer protection where required under 45 C.F.R. section 156.122(c).

3. Needs and benefits: While 45 C.F.R. section 156.122(c) requires a formulary exception process for all prescription drugs in all non-grandfathered individual or small group health insurance policies and contracts, the federal regulation does not apply to large group policies or contracts. Pursuant to IL sections 3221(1)(7-a) and 4303(1-1), large group policies and contracts that provide coverage for medical, major medical or similar comprehensive-type coverage must provide coverage for medication for the detoxification or maintenance treatment of a substance use disorder. Without this amendment, and unless the policy or contract stated that off-formulary drugs were covered when medically necessary, requests by an insured covered under a large group health insurance policy or contract to access medications not on the insurer's list of covered drugs for substance use disorder treatment would be subject to the grievance process in IL section 4802 and PHL section 4408-a. This is a different and less-consumer protective process than the process granted to an insured covered under an individual or small group policy or contract, and would not include the right to an external appeal.

Accordingly, this amendment would require large group policies and contracts to comply with Article 49 of the IL or PHL, as applicable, with respect to medication for the detoxification or maintenance treatment of a substance use disorder, in the same way individual and small group policies and contracts must comply with those requirements by virtue of the federal regulation. Additionally, while the federal regulation requires all non-grandfathered individual and small group policies and contracts to provide a formulary exception process with an internal review and external appeal, this amendment codifies in state regulation that formulary exceptions for medication for the detoxification or maintenance treatment of a substance use disorder are subject to Article 49 of the IL or PHL, as applicable, while preserving any greater consumer protection offered by 45 C.F.R. section 156.122(c).

4. Costs: Insurers may incur costs to file with the Superintendent new policy and contract forms for large groups in order to provide coverage for a formulary exception process for medication for the detoxification or maintenance treatment of a substance use disorder. It is difficult to assess the potential costs to insurers for a number of reasons. Insurers in the regular course of their insurance business file new policy and contract forms in response to changes in law or regulation, and the Department of Financial Services (“Department”) developed model contract language for insurers to use that should mitigate any filing costs. Additionally, insurers may incur costs with respect to policies or contracts not subject to the federal regulation, which requires a formulary exception process, when providing the internal reviews and complying with the time frames contained in the amendment. These costs should be very limited or non-existent because the majority of insurers already have a formulary exception process in place for individual and small group policies and contracts due to the federal regulation. Further, large group insurers must comply with Article 49 of the IL or PHL, as applicable, in many other circumstances and insurers may leverage their existing processes to review requests for an insured to gain access to a medically necessary medication for the detoxification or maintenance treatment of a substance use disorder not otherwise covered by the policy or contract.

This amendment may impose costs on the Department because the Department will need to review amended policy and contract forms. However, any additional costs incurred by the Department should be limited because the need to refile forms will be a one-time only circumstance. In addition, as noted above, many insurers already have policies and contracts with such provisions in place. As such, the costs to the Department should be minimal and the Department expects to absorb the costs in its ordinary budget. The Department does not anticipate any need for revised rate filings for individual and small group coverage since the requirements to provide the formulary exception process are already applicable under the federal regulation and, with respect to large group coverage, any changes would be reflected in rating formulas based on the experience of the group.

This amendment will not impose compliance costs on any state or local government.

5. Local government mandates: This amendment imposes no new mandates on any county, city, town, village, school district, fire district or other special district.

6. Paperwork: As noted, insurers may need to file with the Superintendent new policy and contract forms for large groups in order to provide the processes that allow for a request for a formulary exception and the ability to gain access to clinically appropriate medication for the detoxification or maintenance treatment of a substance use disorder not otherwise covered by the policy or contract. However, the model contract language that the Department developed will greatly reduce any paperwork burden.

7. Duplication: This amendment, in part, overlaps with existing federal rules by codifying in state law current federal requirements and does not conflict with any existing state or federal rules or other legal requirements.

8. Alternatives: The Department considered not promulgating this amendment and thus retain the different standards for formulary exceptions for large group policies and contracts and individual and small group policies and contracts. As legislative policy clearly indicates a preference for uniform treatment of medications for the detoxification or maintenance treatment of a substance use disorder across all group sizes by requiring coverage of these medications in all individual, small group, and large group policies or contracts, it would be inconsistent with this legislative policy for the formulary exceptions processes to differ based on group size.

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 60 days after publication of the notice of adoption in the State Register.

Regulatory Flexibility Analysis for Small Businesses and Local Governments Statement for the Proposed Fiftieth Amendment to 11 NYCRR 52 (Insurance Regulation 62).

1. Effect of rule: This amendment to the regulation applies to insurers in New York State that provide hospital, surgical, or medical expense coverage. Although most insurers are not small businesses, industry has asserted previously that certain insurers, in particular mutual insurers, subject to the regulation are small businesses but has not provided the Department of Financial Services (“Department”) with specific insurers or the number of such entities. The amendment does not apply to local governments.

2. Compliance requirements: Since any insurer that is a small business is already required to comply with broader federal rules applying to prescription drugs for all individual and small group policies, any such insurer should not need to file new policy or contract forms with the Superintendent of Financial Services (“Superintendent”) with respect to those policies. Any insurer that is a small business may need to file new policy or contract forms for any large group product in order to comply with the amendment.

No local government will have to undertake any reporting, recordkeeping, or other affirmative act to comply with the regulation.

3. Professional services: The Department does not anticipate that any insurer that is a small business affected by this amendment will need to retain professional services to comply with this amendment.

4. Compliance costs: Since insurers that are small businesses already are required to comply with federal regulations with respect to individual and small group policies, insurers should not need to incur costs to file new policy or contract forms with the Superintendent for those policies. Insurers that are small businesses may incur costs to file with the Superintendent new policy and contract forms for large groups in order to provide coverage for a formulary exception process for medication for the detoxification or maintenance treatment of a substance use disorder. It is difficult to assess the potential costs to insurers for a number of reasons. Insurers in the regular course of their insurance business file new policy and contract forms in response to changes in law or regulation,

and the Department developed model contract language for insurers to use that should mitigate any filing costs. Additionally, insurers may incur costs with respect to policies or contracts that are not subject to the federal regulation, which requires a formulary exception process, when providing the internal reviews and complying with the time frames contained in the amendment. These costs should be very limited or non-existent because the majority of insurers already have a formulary exception process in place for individual and small group policies and contracts due to the federal regulation. Further, large group insurers must comply with Article 49 of the IL or PHL, as applicable, in many other circumstances and insurers may leverage their existing processes to review requests for an insured to gain access to a medically necessary medication for the detoxification or maintenance treatment of a substance use disorder not otherwise covered by the policy or contract.

5. Economic and technological feasibility: No insurer that is a small business affected by this amendment should experience any economic or technological impact as a result of the amendment.

6. Minimizing adverse impact: The Department considered the criteria in State Administrative Procedures Act (“SAPA”) section 202-b(1) but the Department could not design the amendment to minimize any adverse impact on insurers that are small businesses because: (1) as to all individual and small group policies, the Department is preempted by federal regulation, and (2) any such design would create the type of disparate treatment that this amendment seeks to remedy.

7. Small business and local government participation: The Department is in compliance with SAPA section 202-b(6) by publishing the proposed amendment in the State Register and posting the proposed amendment on the Department’s website.

Statement setting forth the basis for the finding that the Proposed Fiftieth Amendment to 11 NYCRR 52 (Insurance Regulation 62) will not impose any adverse impact on rural areas or reporting, recordkeeping or other compliance requirements on public or private entities in rural areas.

The Department of Financial Services finds that this regulation, which sets forth a required formulary exception process for medication for the detoxification or maintenance treatment of a substance use disorder, does not impose any additional burden on persons located in rural areas, and will not have an adverse impact on rural areas. This regulation applies uniformly to insurers that do business in both rural and non-rural areas of New York State. This regulation will not impose any additional costs on rural areas.



Statement setting forth the basis for the finding that the Proposed Fiftieth Amendment to 11 NYCRR 52 (Insurance Regulation 62) will not have a substantial adverse impact on jobs and employment opportunities.

The Department of Financial Services finds that this rule should have little or no negative impact on jobs and employment opportunities in this state. The rule applies directly to insurers authorized to do business in New York State and provides that every insurer that delivers or issues for delivery in this state an accident and health insurance policy that provides hospital, surgical, or medical expense coverage and provides coverage for medication for the detoxification or maintenance treatment of a substance use disorder shall include in the policy processes that allow a formulary exception and access to clinically appropriate medication for the detoxification or maintenance treatment of a substance use disorder not otherwise covered by the policy.