

Assessment of Public Comments on the Revised Proposed Fifty-Fourth Amendment to 11 NYCRR 52 (Insurance Regulation 62)

The New York State Department of Financial Services (the “Department”) received comments from associations that represent health plans and health maintenance organizations (hereinafter, “insurers”) and from advocacy organizations, including an organization that represents entities that provide primary and preventative sexual and reproductive health care services, an organization that represents obstetricians and gynecologists, and an organization that works to protect and advance the progress of women and their families (the “commenters”). Most of the comments supported the amendment. However, some of the commenters requested changes to the amendment or clarifications regarding the law on which the amendment is based.

Comment: The proposed amendment implements Chapter 25 of the Laws of 2019 and Part M of Chapter 57 of the Laws of 2019 (“Chapters 25 and 57”) by establishing time frames and other standards regarding an insured’s request for coverage of a contraceptive drug, device, or product that is not covered by the insurer (the “exception process”). Two commenters suggested requiring insurers to clearly communicate, in both plan materials and on their websites, directions for submitting an exception request.

Response: The Department expects insurers to provide information regarding the exception process to insureds, including making the standard exception form readily available. The Department does not think it is currently necessary to revise the amendment to explicitly require an insurer to provide information about the exception process in plan materials and on its website. Thus, the Department did not make any changes in response to this comment.

Comment: The amendment requires insurers to accept the standard exception form that is developed by the Superintendent of Financial Services (the “Superintendent”) if the insurer requires requests to be made in writing. Three commenters requested clarification that the phrase “in writing” applies to electronic communications. The commenters also requested clarification that the only method of communication that

would not require use of the standard exception form is verbal communication. They also requested that insurers implementing a verbal process have adequately trained staff to process such requests.

Response: A request “in writing” includes requests submitted by U.S. mail or electronically, including through the internet, by e-mail, or by fax. Thus, the standard exception form applies to all written requests, including when submitted electronically. Additionally, if an insurer implements a verbal process, the Department expects that the insurer’s staff will be adequately trained to handle such requests.

The Department did not make any changes in response to this comment.

Comment: Two commenters requested that the Department engage a range of stakeholders to provide input on the standard exception form before it is implemented.

Response: The Department intends to engage stakeholders to obtain feedback on the standard exception form before it is finalized and did not make any changes in response to this comment.

Comment: One commenter suggested that since the Department has not yet released a draft standard exception form, the Department provide for a transitional period for insurers to comply with the amendment.

Response: The Department intends to finalize the standard exception form as soon as possible and will work with insurers on implementation. Thus, the Department did not make any changes in response to this comment.

Comment: Two commenters requested that the Department require insurers to provide notification of receipt of the standard exception request and confirm its processing to mitigate delays in coverage.

Response: The amendment requires insurers to provide coverage within 72 hours for a standard exception request or 24 hours for an exception request based on exigent circumstances. Due to these short time frames, an acknowledgement to confirm receipt may not be timely. However, if an insurer receives an incomplete exception request or an exception request in a format other than the standard exception form promulgated by the Superintendent, the Department expects the insurer to immediately notify the submitting party of any missing

information and provide the correct standard exception form. Therefore, the Department did not make any changes to the amendment in response to this comment.

Comment: One commenter requested clarification that if the insurer requires a written request, it may require use of the standard exception form by health care providers and insureds.

Response: An insurer may require that an exception request be submitted in writing. If the insurer requires that the request be submitted in writing, the insurer must use the standard exception form prescribed by the Superintendent pursuant to new Section 52.74(b)(1). Since insurers must use the form prescribed by the Superintendent, this means that this is the only form health care providers and insureds may use to submit their written requests. Thus, the Department did not make any changes to the amendment in response to this comment.

Comment: One commenter requested clarification that the term “attending health care provider”, as used in the amendment, has the same meaning as the term “attending provider” used in federal guidance.

Response: The term “attending health care provider”, as used in the amendment, is intended to have the same meaning as the term “attending provider” used in federal guidance. “Attending health care provider” is read to mean an appropriately licensed, registered, or certified health care provider that is recommending the treatment requested pursuant to the exception request. It does not include insurers. The term “attending health care provider” was used in this amendment for consistency with terms used in the Insurance Law and regulations promulgated thereunder. The Department did not make any changes to the amendment in response to this comment.

Comment: Two commenters noted that Chapters 25 and 57 require coverage for contraceptive drugs, devices, and products without a deductible, coinsurance, copayment, or any other cost-sharing requirement. These commenters allege that the Department is interpreting Chapters 25 and 57 to mean that all contraceptive drugs, devices, or products covered by the insurer must be covered without cost-sharing and that such

interpretation goes beyond the letter of the law. Both commenters noted that because the regulation requires coverage for all covered contraceptive drugs, devices, or products without cost-sharing, insurers may remove certain contraceptive drugs, devices, or products from their formularies. Additionally, one commenter noted that insurers with formularies that cover all drugs may move to formularies that cover only a limited list of drugs.

Response: The Department disagrees with the commenters' interpretation. Chapters 25 and 57 specifically require coverage for all U.S. Food and Drug Administration ("FDA")-approved contraceptive drugs, devices, or products. Where the FDA has approved one or more therapeutic and pharmaceutical equivalent(s), the insurer is not required to cover all therapeutic and pharmaceutical equivalents on its formulary, so long as one is included and covered without cost-sharing. Further, in Chapters 25 and 57, it clearly states that policies or contracts subject to Chapters 25 and 57 shall not impose a deductible, coinsurance, copayment, or any other cost-sharing requirement on the coverage provided pursuant to the law. Thus, under a plain reading of Chapters 25 and 57, any contraceptive drug, device, or product covered by an insurer must be covered without imposition of a deductible, coinsurance, copayment, or any other cost-sharing requirement. The intent of Chapters 25 and 57 was to provide broad access to contraceptive drugs, devices, or products and eliminate barriers to coverage, such as cost-sharing requirements. Further, if insurers with formularies that cover all drugs limit access to contraceptive drugs, devices, or products by establishing a formulary that covers only a limited list of drugs, they must provide coverage for all therapeutic and pharmaceutical non-equivalent contraceptive drugs, devices, or products, and permit an insured to access a non-covered contraceptive drug, device, or product through the exceptions process.

Thus, the Department did not make any changes to the amendment in response to this comment.

Comment: One commenter noted that insurers should only be required to cover one of each of the FDA-approved 18 methods for contraception without cost-sharing as required by federal law and regulation.

Response: The Insurance Law, even before Chapters 25 and 57, required broad coverage of contraceptives; however, cost-sharing could be imposed on additional contraceptives beyond one in each of the FDA-approved 18 methods. The commenter's interpretation is not consistent with Chapters 25 and 57, which specifically provide that where the FDA has approved one or more therapeutic and pharmaceutical equivalents, the insurer is not required to cover all therapeutic and pharmaceutical equivalents on its formulary, so long as one is included and covered without cost-sharing. The Chapters 25 and 57 requirement for coverage of all therapeutic and pharmaceutical non-equivalent contraceptive drugs, devices, or products without cost-sharing exceeds the 18 FDA-approved methods of contraception required to be covered without cost-sharing pursuant to federal law and regulation.

Thus, the Department did not make any changes to the amendment in response to this comment.

Comment: One commenter suggested that the Department revise Section 52.74(b)(3) to clarify that the insurer makes the determination regarding whether a covered contraceptive drug, device, or product is medically inadvisable for the insured.

Response: The suggested change is not consistent with Chapters 25 and 57. Chapters 25 and 57 state that if the covered therapeutic and pharmaceutical equivalent versions of a contraceptive drug, device, or product are not available or are deemed medically inadvisable, the policy or contract shall provide coverage for an alternative therapeutic and pharmaceutical equivalent version of the contraceptive drug, device, or product without cost-sharing. Chapters 25 and 57 further provide that if the attending health care provider, in his or her reasonable professional judgment, determines that the use of a non-covered therapeutic or pharmaceutical equivalent of a drug, device, or product is warranted, the health care provider's determination shall be final. The attending health care provider, not the insurer, makes the determination whether the covered therapeutic and pharmaceutical equivalent versions of a contraceptive drug, device, or product are not available or are deemed medically inadvisable.

Therefore, the Department did not make any changes to the amendment in response to this comment.

Comment: One commenter requested clarification that the health condition that may seriously jeopardize the insured's life, health, or ability to regain maximum function in the definition of "exigent circumstances" must benefit from or relate to the contraceptive drug, device, or product request.

Response: The intent of the amendment is to implement the exceptions process contemplated by Chapters 25 and 57. That law establishes coverage for contraceptive drugs, devices, or products. Therefore, it would be expected that the health condition that may seriously jeopardize the insured's life, health, or ability to regain maximum function in the definition of "exigent circumstances" benefit from or relate to the contraceptive drug, device, or product that is the subject of the exception request. As a result, the Department did not make any changes to the amendment in response to this comment.

Comment: One commenter suggested deleting a reference to "therapeutic and pharmaceutical equivalent versions" in Section 52.74(a) because it is confusing and unnecessary and adding the "specific" before "non-covered" in Section 52.74(b)(2) for clarification.

Response: The Department made the edits because they are non-substantive and clarified the language of the amendment.