

Assessment of Public Comment for New Insurance Regulation 219 (11 NYCRR 450).

The Department of Financial Services (“Department”) received comments from one entity that represents pharmaceutical manufacturers.

Comment

The commenter expressed concerns about the protection of highly-sensitive confidential information and requested that the Department amend the proposed regulation to include additional process safeguards to protect confidential and proprietary data from being publicly disclosed.

Response

Section 450.3 references a “Code of Conduct” that individuals are required to sign in order to be appointed to the Drug Accountability Board (“DAB”). The Code of Conduct sets strict ethical protocols and responsibilities for DAB members. The Code of Conduct includes provisions specifically addressing conflicts of interest, confidential information and a recusal process. DAB Members are required to complete a financial disclosure and may access information only through the Department’s secure platform. DAB members are required to attend an ethics training session.

Notably, Insurance Law Section 111 requires that any information obtained in an investigation shall be confidential and shall not be subject to disclosure by the Department, except to the drug accountability board, which may review the information and, as necessary, include any such information in its report. Section 202 also provides that information reviewed by the DAB is subject to confidential treatment. The Department finds that including additional confidentiality protections to the regulation is unnecessary given the protections already provided by statute and the Code of Conduct. Finally, DFS will perform outreach to the commenter inviting discussions on the contents of the Code of Conduct to ensure any concerns they have are adequately addressed. Thus, no changes are necessary in response to these comments.

Comment

The commenter commented on the Department's recusal authority being vested in the Chairperson of the Board.

Response

The Department's decision to provide the Chairperson with ultimate recusal authority provides a check on the self-recusal requirements contained in the Code of Conduct. While DAB members are required to recuse themselves, the Chairperson has final authority on recusal of a member. Providing the Chairperson with final authority to determine whether and when recusal is required is consistent with the governing rules for similar state drug review boards. This measure prevents abuses that could occur under an unchecked self-recusal policy. Thus, no changes are necessary in response to this comment.

Comment

The commenter requested that the regulation include more detail on the processes by which the Office of Pharmacy Benefits (OPB) and the DAB operate.

Response

Insurance Law Sections 111 and 202 provide the mechanism by which the OPB and DAB operate. This regulation establishes rules to operate the OPB and the DAB and includes provisions for, among other things, the adoption of by-laws related to the conduct of board operations, which can provide additional details about the internal operations of the DAB. Given the confidential deliberations provided for in the statute, the Department has determined this is the appropriate manner to handle detailed operational questions. Thus, no changes were necessary in response to this comment.

Comment

The commenter suggested that the subject of an investigation should have access into the information reviewed and presentations to the DAB or Department and an opportunity to respond.

Response

Providing the subject of an investigation an opportunity to respond to anticipated conclusions of the board will ensure the DAB members have balanced input. Such an opportunity to comment is consistent with the Department's intent in proposing the rule. The final rule contains a provision that will enable the subject of an investigation to respond to a set of anticipated findings of the DAB before the report is finally adopted.