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What Drug Cos. Must Know About NY Price Transparency Law

By **Elizabeth Bierut and Angie Garcia** (August 29, 2024, 6:27 PM EDT)


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At present, at least 24 states have adopted drug price transparency laws, many of which impose advance notice reporting requirements on drug manufacturers for qualifying price increases.[1]

On June 19, New York joined these states with the implementation of New York Insurance Law Section 111-A, which authorizes the New York State Department of Financial Services to require manufacturers to self-report certain qualifying drug price increases.[2]

It is important for drug manufacturers to understand the contours of Section 111-A, including which entities must comply, their reporting obligations and the possible penalties for noncompliance.

Who Must Comply

Section 111-A applies to any manufacturer of prescription drugs that are purchased or reimbursed in New York by any number of different entities including, but not limited to, insurance companies, municipal cooperative health benefit plans and pharmacy benefit managers.[3]

What Triggers the Reporting Obligation

A drug manufacturer that falls within the ambit of Section 111-A(a) must report to the NYDFS any price increase in excess of 16% for a prescription drug with a wholesale acquisition cost, or WAC, of more than $40 for a course of therapy. The 16% threshold includes the proposed WAC increase and any cumulative increases in the 24 months preceding the planned effective date of the proposed increase.

"Course of therapy" refers to U.S. Food and Drug Administration-approved daily dosage units equal to either (1) the daily dosage units of a prescription drug under its prescribing label for 30 days, or (2) the daily dosage units of a prescription drug under its prescribing label for a normal course of treatment that is less than 30 days.

What Must Be Reported to the NYDFS and When

If required by Section 111-A(b), notice to the NYDFS must be submitted in writing at least 60 days before the planned effective date of the price increase. The NYDFS maintains a drug price increase reporting

form on its website and instructs drug manufacturers to submit the necessary information using this form.[4]

The notice should include:

- Information about the drug, including the national drug code, manufacturer name, drug product name, strength, dosage form and package size;
- The date of the submission;
- The prescription drug's current WAC;
- The effective date of the price increase;
- The dollar amount of the planned increase in the prescription drug's WAC;
- The percentage of the planned WAC increase;
- The cumulative percentage of the proposed price increase, including any price increases over the preceding 24 months;
- A statement regarding whether the effective date of the increase is within 60 days of the reporting date;
- A statement regarding "whether a change or improvement in the drug necessitates the price increase" and, if so, an explanation of such change or improvement;[5]
- A statement regarding whether any information is reasonably designated as a trade secret, and, if so, an explanation of why; and
- Contact information for the reporting manufacturing company.

If a manufacturer's notice is submitted to the NYDFS less than 60 days before the effective date of the proposed price increase, the manufacturer must explain why.

Confidentiality

Drug manufacturers should be aware that all submitted notices will be published on the NYDFS website within five days of receipt. However, any information included within the submissions fairly identified as trade secrets, including information related to changes or improvements in a drug necessitating the proposed price increase, should be protected from disclosure.

The reporting form asks whether any information submitted is a trade secret, and, if so, asks a drug manufacturer to specify which information it is designating as a trade secret.

Section 111-A offers protections for information submitted by a drug manufacturer that is "reasonably designated as a trade secret," and such information will not be disclosed directly or indirectly by the NYDFS superintendent.[6]

Such information, however, may be publicly disclosed in an aggregated format, if the aggregated information "cannot directly or indirectly be used to identify trade secret information related to a specific manufacturer or the manufacturer's prescription drug[.]"[7]

The reporting form also allows a manufacturer to upload additional information with a submission. It may be prudent for a manufacturer not only to identify the trade secret information using the space indicated on the reporting form, but also to submit a separate document that explains why such information meets the definition of a trade secret under New York law.[8]

Penalties for Noncompliance

The New York Insurance Law grants broad powers to the NYDFS superintendent in the event of noncompliance with its provisions. Section 111-A also specifically authorizes the NYDFS superintendent to impose a fine of up to $5,000 for every day the information is not reported after the reporting period begins.

Challenges to Similar Laws in Other States

Notably, states with similar advance notice laws have faced constitutional challenges by trade groups on First Amendment, Fifth Amendment and commerce clause grounds.

Most recently, in 2019, the Pharmaceutical Research and Manufacturers of America brought a successful lawsuit challenging an Oregon law that contained extensive advance reporting requirements for manufacturers seeking to increase drug prices.[9]

The Oregon law further required the director of the Oregon Department of Consumer Business Services to publish on its website all information that a manufacturer submits as part of its price increase and new drug reports unless (1) the information was a trade secret under Oregon law and (2) the DCBS determined that "the public interest [did] not require disclosure of the information."[10]

Thus, the Oregon law permitted the DCBS to publish a manufacturer's trade secrets whenever the agency found that disclosure was in the public interest.

The PhRMA sought a declaratory judgment that the Oregon law violated three provisions of the U.S. Constitution: the commerce clause, by imposing penalties on manufacturers related to a product's national list price; the First Amendment, because it compelled manufacturers to explain price increases in a manner that endorsed Oregon's preferred message that manufacturers are solely responsible for drug price spikes; and the Fifth Amendment, because the forced publication of trade secrets would constitute a taking without just compensation.

On Feb. 16, the U.S. District Court for the District of Oregon granted summary judgment in favor of the PhRMA on First and Fifth Amendment grounds.[11] The court concluded that the public interest exception amounted to a regulatory taking under the Fifth Amendment, and that the law's reporting requirement constituted compelled speech in violation of the First Amendment because it was not narrowly tailored to serve the governmental interests asserted by Oregon.

New York's law arguably provides for greater protection of a manufacturer's trade secrets than the Oregon law because it allows a manufacturer to designate information it submits as a trade secret and does not sanction publication of trade secrets simply because NYDFS finds it to be in the "public

interest." Time will tell whether Section 111-A will face legal challenges and whether those challenges will succeed in the Empire State.

Best Practices for Drug Manufacturers

Drug manufacturers should take steps to ensure compliance with Section 111-A, including:

- Establishing an internal pricing committee to determine whether, when and how much to increase the WAC of a product;
- Documenting the rationale for and timing of any planned WAC increase;
- Submitting timely notices of qualifying WAC increases to the NYDFS at least 60 days prior to the planned effective date of the planned increase;
- Identifying any trade secret information that may potentially need to be disclosed to the NYDFS, and explaining why such information qualifies as a trade secret under New York law; and
- Tracking legal challenges or other developments with respect to Section 111-A.

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[1] State Laws Passed to Lower Prescription Drug Costs: 2017-2024 ("Transparency"), National Academy for State Health Policy (Updated July 19, 2024), https://nashp.org/state-tracker/state-drug-pricing-laws-2017-2024/.

[2] For the full text of the statute, see N.Y. Ins. Law § 111-A; see also Overview - Prescription Drug Manufacturer Filings, N.Y. State Dep't of Fin. Servs., https://www.NYDFS.ny.gov/apps_and_licensing/drug_manufacturers (last visited Aug. 15, 2024); N.Y. Ins. Law § 111.

[3] § 111-A(a) (defining which drug manufacturers must comply).

[4] Drug Price Increase Reporting, N.Y. State Dep't of Fin. Servs., https://www.NYDFS.ny.gov/form/drug-price-increase-reporting (last visited Aug. 22, 2024).

[5] § 111-A(b)(3)(ii).

[6] § 111-A(b)(4).

[7] Id.

[8] Under New York law, "[a] trade secret is 'any formula, pattern, device or compilation of information which is used in one's business, and which gives [one] an opportunity to obtain an advantage over competitors who do not know or use it." E.J. Brooks Co. v. Cambridge Sec. Seals, 31 N.Y.3d 441, 453 (2018) (second alteration in the original) (quoting Ashland Mgmt. Inc. v. Janien, 82 N.Y.2d 395, 407 (1993)).

[9] Pharm. Rsch. & Mfrs. of Am. v. Stolfi, No. 6:19-cv-01996-MO, -- F. Supp. 3d -- , 2024 WL 1177999 (D. Or. Mar. 19, 2024).

[10] Id. at *2.

[11] The full opinion on the ruling was published on March 19, 2024. Stolfi, 2024 WL 1177999.