# Revised Draft Regulations for California's Drug Transparency Law (SB-17)

On September 17, California's Office of Statewide Health Planning and Development (OSHPD) released a revised set of proposed regulations to implement the California Drug Transparency Law (SB-17) passed in 2017. SB-17 mandates when drug manufacturers must report information to purchasers and to OSHPD, specifically 60 days prior to increasing the price of a drug product more than 16%[1] and when releasing a new drug to the market with a price that exceeds the threshold of a specialty drug under Medicare.[2] (For more details on SB-17 and the lawsuit filed against it by the Pharmaceutical Research and Manufacturers of America, see The Source's coverage in a blog post from October 2017, the California Legislative Beat, our recent article in Health Affairs[3] or the litigation roundup blog.)

OSHPD is the agency tasked with promulgating regulations to implement SB-17. The regulations dictate both the content of the disclosures SB-17 requires and the process for making them. Specifically, the regulations detail how the information required by SB-17 is collected from manufacturers and insurers and disseminated to purchasers and the public including: the process for drug manufacturers to submit required data, the process for purchasers to register with OSHPD to obtain notifications from manufacturers required by SB-17, the deadlines for required quarterly reports, and the process by which civil penalties are assessed including prehearing provisions and an appeals process. In the past year, OSHPD held public workshops, hearings, and public comment periods about the proposed regulations. The revised regulations are nearly identical to the draft regulations OSHPD issued in May 2018.[4] The public comment period on the revisions ends on October 2, 2018 and The Source expects the final regulations to mirror this revised version.

In April 2018, The Source attended a workshop at OSHPD intended to give data submitters, i.e. drug manufacturers, a chance to comment on the regulations. At the workshop, most of the regulations appeared to implement the provisions of SB-17 in

a straightforward manner. The concerns that drug manufacturers presented at the meeting centered on how OSHPD would define a "drug product". In both the initially proposed and revised regulations, OSHPD defines a "drug product" as "the finished dosage form of a prescription drug that…in association with other active or inactive ingredients…has a unique [National Drug Code,] NDC."[5] The Food and Drug Administration (FDA) uses NDCs to track all drugs manufactured, prepared, propagated, compounded, or processed for commercial distribution.[6] The NDC is comprised of three sections that identify: 1) the labeler (i.e. the manufacturer, distributor, or repackager), 2) the product (including the amount of the drug and form – capsule, tablet etc.), and 3) the packaging (including the size of the carton or bottle). For example, a 2.5-mg delayed release granule of Nexium, a drug for acid reflux produced by AstraZeneca and sold in a 30-dose carton has the NDC code: 0186-4025-01. If the same 2.5-mg delayed release granule of Nexium is sold in a 5-dose carton, the NDC is 0186-4025-02; if the product is sold as a 10-mg delayed release granule in a 30-dose carton, the NDC is 0186-4010-01. Each of these packages has the same active ingredient, but because they are different packages, they have different NDC codes. The Source's search of the FDA's online database found 30 different NDCs for the drug Nexium, 17 of which are for the manufacturer AstraZeneca.

Why is this important? In the regulations, OSHPD requires advance reporting for any drug product (i.e. each unique NDC code) for which the manufacturer plans to increase the price above the 16% threshold. For example, if AstraZeneca wanted to raise the price of Nexium by 20% (i.e. above the threshold), OSPHD requires it to submit data for all 17 NDC codes or face penalties for each filing that it fails to submit (i.e. 17-times the $1,000-per-day penalty specified in SB-17 for failing to submit timely reports). For that reason, drug manufacturers had asked to submit one report for each active ingredient and not separately for each NDC. At the workshop, however, OSHPD maintained that it needed to track each NDC independently because it was possible that a company would only increase the price for one formulation, packaging, or strength. The revised regulations keep the same requirements for reporting price increases for each NDC.

Stay tuned to The Source for future updates about the implementation and litigation of SB-17.

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[1] The 16% is measured cumulatively and includes the current proposed wholesale acquisition cost increase and the sum of the wholesale acquisition cost increases that occurred in the current calendar year and the two previous calendar years. The reporting is limited to drugs with a list price over $40 per 30-day supply.

[2] For 2018, the threshold is $670 per 30-day supply or a course of treatment, if the course of treatment is less than 30 days. See https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2017.pdf.

[3] Gudiksen KL, Brown TT, Whaley CM, King JS. *California's Drug Transparency Law: Navigating The Boundaries Of State Authority On Drug Pricing*. **Health Affairs** (Project Hope). 2018;37(9):1503-8. Available from: https://www.healthaffairs.org/doi/10.1377/hlthaff.2018.0424.

[4] OSHPD revised regulations have 3 minor changes that are closely related to the original text and 2 grammatical changes.

[5] OSHPD SB-17 proposed regulations: Article 1 § 96060(b). Available from: https://oshpd.ca.gov/ml/v1/resources/document?rs:path=/About-OSHPD/Documents/Laws-Regulations/CTRx-Regulations-15-Day-Comment-Period-Notice-20180917.pdf.

[6] https://www.fda.gov/drugs/informationondrugs/ucm142438.htm