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Federal Drug Pricing Transparency Efforts Outpace State Laws Requiring Drug Manufacturer Price Reporting for the First Half of 2019

By Merle M. DeLancey Jr.*

After a brief review of a variety of federal healthcare and drug pricing transparency initiatives, this article discusses state laws requiring drug manufacturers to report pricing and other related information. Thereafter, the article reviews previously enacted state laws imposing manufacturer price reporting obligations to assess the impact these laws have had on drug prices in the applicable state.

During 2017 and 2018, states took the reins in terms of enacting laws compelling drug manufacturers to disclose drug pricing. State activity has slowed during the first six months of 2019. Instead, during the first half of 2019, the federal government has led the way on a variety of healthcare and drug pricing transparency initiatives. After a brief review of these federal initiatives, this article discusses state laws requiring drug manufacturers to report pricing and other related information. Thereafter, the article reviews previously enacted state laws imposing manufacturer price reporting obligations to assess the impact these laws have had on drug prices in the applicable state.

FEDERAL GOVERNMENT ACTIVITY

Since the Trump administration's release of its Drug Pricing Blueprint in May 2018, the U.S. Department of Health and Human Services ("HHS") has floated several drug pricing transparency initiatives.[1] Many of HHS's initiatives, however, have failed (disclosure of wholesale acquisition costs ("WACs") in

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[1] This article focuses on drug manufacturer price reporting and transparency. To be fair, the Trump administration has successfully taken steps attempting to lower the prices paid for drugs including, for example, improving generic drug competition, expanding the use of prior authorization and step therapy under Medicare Managed Care and Part D, prohibiting gag clauses imposed by pharmacy benefit managers in pharmacy contracts restricting a pharmacy's ability to discuss with beneficiaries the availability of prescriptions at a lower cash price, and requiring Part D sponsors to implement a real-time benefit tool that allows prescribers to inform patients of lower cost drug alternatives.

television ads), been abandoned (requiring pharmacies to apply rebates and discounts at the point of sale to lower drug prices), or remain notional (aligning Medicare Part B drug reimbursements with the prices paid for drugs in other countries and the recently publicized policy allowing the importation of certain drugs from Canada and other countries).

HHS's most recent defeat came in July 2019 when the U.S. District Court for the District of Columbia vacated a final rule that would have required drug manufacturers to disclose WACs in their television commercials. Many critics of the final rule questioned how manufacturer disclosure of WAC prices would benefit consumers. WAC rarely, if ever, is related to the price consumers pay for drugs at their local or mail-order pharmacy. In addition, a consumer, armed with the WAC price of a medication, cannot negotiate the price he or she is willing to pay with his or her pharmacy, medical provider, or insurer. Thus, the final rule appeared to be nothing more than an effort at public shaming of drug manufacturers. Many also worried that requiring manufacturers to disclose WAC prices in their television commercials would only confuse the public. Regardless, the district court held that Congress had not granted HHS the authority to regulate drug marketing to require manufacturers to disclose WAC prices.[2]

Notwithstanding, numerous bills have been introduced in both houses of Congress which, among other requirements, include drug pricing transparency initiatives. For example, the proposed Prescription Drug Pricing Reduction Act of 2019 ("PDPRA") would allow the pricing manufacturers are required to disclose to Medicare Part D and Medicaid, which is currently considered confidential under federal law, to be shared with MedPAC[3] and MACPAC[4] and would require manufacturers to report detailed information supporting list prices for certain new drugs and biologics and list price increases exceeding certain thresholds for existing drugs and biologics.

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[2] One interesting note: even if the court had allowed HHS's final rule to stand, the Centers for Medicare and Medicaid Services ("CMS") had already made clear that neither it nor any other federal agency intended to enforce the rule and consumers do not have standing to enforce the rule. Rather, CMS intended to monitor manufacturer drug ads and publicize a list of violators.

[3] MedPAC is a nonpartisan legislative branch agency that provides the U.S. Congress with analysis and policy advice on the Medicare program.

[4] MACPAC is a non-partisan legislative branch agency that provides policy and data analysis and makes recommendations to Congress, the Secretary of the U.S. Department of Health and Human Services, and the states on a wide array of issues affecting Medicaid and the State Children's Health Insurance Program ("CHIP").

NEW STATE LAWS IN 2019

Thus far in 2019, five states have enacted drug price transparency laws that require drug manufacturers to disclose pricing and other information.

Colorado

In May 2019, Colorado enacted HB-19-1131. The Colorado law is not the typical state law requiring drug price disclosures. Rather, the law focuses on educating prescribers regarding drug prices and alternatives. Effective August 2, 2019, a manufacturer and/or its sales representative must provide a prescriber with the WAC for the drug being detailed and the names of at least three generic drugs or, if less than three generics exist, as many generics as available in the same therapeutic class. In May 2019, Colorado also passed HB 1216 capping the price of insulin for insured patients at $100 per month.

Maine

In May 2018, Maine enacted LD 1406 requiring the Maine Health Data Organization ("MHDO") to produce to the legislature an annual prescription drug report that includes:

- The 25 most frequently prescribed drugs in the state;
- The 25 costliest drugs as determined by the total amount spent on those drugs in the state; and
- The 25 drugs with the highest year-over-year cost increases as determined by the total amount spent on those drugs in the state.

A year later, in June 2019, Maine enacted LD 1162 expanding its drug price transparency efforts beyond state purchasing to include drug manufacturer reporting obligations. Beginning January 30, 2020, and annually thereafter, drug manufacturers are required to report to the MHDO if:

- The WAC of a brand-name drug increased by more than 20 percent in the prior calendar year;
- The WAC of a generic drug that costs more than $10 increased by more than 20 percent in the prior calendar year; or
- A new drug was introduced with a WAC greater than the amount that would cause the drug to be considered a specialty drug under Medicare Part D (currently $670 per month).

In addition, within 60 days of an MHDO request information regarding a specific drug, a manufacturer must report the "pricing component data" for the smallest dispensable dosage of the drug. "Pricing component data" is data that evidences the manufacturer's cost to make a prescription drug available to

consumers and the payments received by the manufacturer to make a prescription drug available to consumers, taking into account any price concessions.

Manufacturer-reported information will be considered "confidential," but MHDO is permitted to share the information with the Bureau of Insurance and in the aggregate, so long as an individual manufacturer cannot be identified based on the released information. Manufacturers are required to "certify" to the accuracy of the information reported. A manufacturer can be fined $30,000 per day for violating the reporting requirements. Further, the new law permits MHDO to audit the data submitted by a manufacturer and the manufacturer is responsible for the cost of the audit.

Beginning November 1, 2020, and annually thereafter, MHDO will make publicly available a report based upon the manufacturer-reported data. The annual report will include prescription drug cost trends, an analysis of manufacturer prices and price increases, the major components of prescription drug pricing along the supply chain and the impacts on insurance premiums and cost sharing, and any other information MHDO determines is relevant to providing greater consumer awareness of the factors contributing to the cost of prescription drugs in the state.

Maryland

In May 2019, shortly after having its anti-gouging law struck down as unconstitutional, Maryland enacted HB 768 that created a Prescription Drug Affordability Board. The Board is to work with a newly-created Prescription Drug Stakeholder Council to protect Maryland residents from high drug costs.

Interestingly, the new law does not create a manufacturer price reporting obligation as its first source for pricing data. Rather, the Board hopes to collect drug pricing information from other states that require such reporting. Based on that data, the Board will create a list of:

- Brand drugs or biologics that have a WAC of $30,000 or more per year or course of treatment at launch;
- Brand drugs or biologics that have a WAC increase of $3,000 or more in any 12-month period, or course of treatment if less than 12 months;
- Biosimilar drugs that have a WAC that is not at least 15 percent lower than the reference brand biologic at launch;
- Generic drugs that have a WAC of $100 or more for a supply lasting 30-days or fewer, or for one unit of the drug; and
- Generic drugs whose WAC increased by 200 percent or more during

the immediately preceding 12-month period.

After identifying these drugs, the Board may conduct a cost review of a drug or drugs. If publicly available information is not available for a drug's cost review, the Board may request information from, among others, the drug's manufacturer. Information and data that is not publicly available is considered confidential and proprietary information that will not be released to the public and perhaps even certain Board members.

To determine whether a drug has led or will lead to an affordability challenge, the Board is to consider such factors as:

- A drug or biologic's WAC or comparable pricing;
- The average price concession, discount, or rebates provided or to be provided to health plans and pharmacy benefit managers ("PBMs") in the state;
- The WAC, concessions, discounts, and rebates to the same entities for alternative drugs or biologics;
- Patient access issues; and
- Patient copays or coinsurance.

If the Board cannot determine whether a drug or biologic creates an affordability challenge based upon the above factors, the Board can consider the following additional factors: a manufacturer's research and development costs from public filings; direct-to-consumer marketing costs for the applicable drug; and gross and net manufacturer revenues for the drug. Each of the foregoing are to be apportioned based upon the manufacturer's sales of the applicable drug to the state.

If the Board determines that spending on a drug leads to an affordability challenge, the Board is to develop a plan that includes setting an upper payment limit for the applicable drug. Before an upper payment limit for a drug is implemented, the Board's plan must be approved by, among others, the governor and attorney general.

The Board has several obligations to complete on or before December 31, 2020. First, the Board, in consultation with a newly-created Stakeholder Council, is to provide a report to the Senate Finance and House Health and Government Operations Committees covering the entire pharmaceutical distribution and payment system in the state and systems used by other states and Countries to lower the list price of drugs, including setting upper payment limits, reverse auctions, and bulk purchasing.

On or before December 31, 2020, the Board also is to submit a report to the above Committees that covers, among other information: prescription drug

price trends; the number of drugs subject to Board review and the results of the review; and Board recommendations for legislation necessary to make drugs more affordable in the state.

Texas

In June 2019, Texas enacted HB 2536 requiring certain drug manufacturers to submit reports to the Texas Health and Human Services Commission ("HHSC") before January 1, 2020. Reports are required for drugs with a WAC of at least $100 for a 30-day supply. Under the new law, drug manufacturers are required to disclose when a drug's WAC increases:

- 15 percent or more compared to the previous year, or
- 40 percent or more over the past three calendar years.

Among other information, manufacturers are required to report the company-wide research and development costs and provide a statement identifying the factor(s) that caused the increase in WAC and the role of each factor's impact on cost. The law provides that the information submitted to the HHSC shall be made public.

Washington

In May 2019, Washington State enacted a law requiring drug manufacturers to report and provide justification for certain launch prices and price increases associated with a "covered drug." The new law defines covered drugs to include:

- A new drug that will be introduced to the market at a WAC of $10,000 or more for a course of treatment lasting less than one month or a 30-day supply, whichever is longer; or
- A drug that is currently on the market, has a WAC of more than $100 for a course of treatment lasting less than one month or a 30-day supply, and the WAC increased at least 20 percent over the prior calendar year, or 50 percent over the prior three calendar years.

A manufacturer's reporting obligation begins October 1, 2019. For each covered drug, a manufacturer is required to report, among other information:

- A description of the specific financial and nonfinancial factors used to make the decision to set or increase the WAC. For a WAC increase, the manufacturer must provide the amount of the increase and an explanation of how these factors explain the increase;
- Itemized cost for production and sales, including manufacturing costs, annual marketing and advertising costs, total research and development costs, total costs of clinical trials, and total cost for acquisition of the drug;

- Total financial assistance given through assistance programs, rebates, and coupons; and
- A schedule of WAC increases for the past five years, if applicable.

Reports must be submitted 60 days in advance of a price increase or within 30 days after launch of a new covered drug to the market. Drug manufacturers also are required to submit written notice within 60 days after receiving Food and Drug Administration ("FDA") approval for a new drug application or biologics license application. The state may request additional information from a manufacturer if it expects the drug to have a significant impact on state expenditures.

Finally, beginning October 1, 2019, a manufacturer of a covered drug must notify the state of a price increase in writing at least 60 days prior to the planned effective date of the increase. The notice must include the date of the increase, the current WAC, the dollar amount of the future WAC increase, and a statement regarding whether a change or improvement in the drug necessitated the price increase. The state will provide recommendations on how manufacturers should provide advance notice of price increases by December 1, 2020. The law specifies that information submitted by manufacturers is not subject to public disclosure.

REVIEW OF EXISTING STATE LAWS

California

In October 2017, California enacted one of the first drug manufacturer pricing disclosure laws. However, nearly two years after passage, California's law is still the subject of litigation with a trade group representing drug manufacturers.

Effective January 1, 2019, drug manufacturers are required to notify the California Office of Statewide Health Planning & Development ("OSHPD") within three days of introducing a new drug with a WAC that exceeds the Medicare Part D specialty drug cost threshold (currently $670). Within 30 days of its notification, manufacturers must submit additional information such as drug launch marketing and pricing plans. Further, after January 1, 2019, drug manufacturers are required to submit to OSHPD information on the rationale for cost increases for existing drugs when the increase is greater than 16 percent for the previous three years. OSHPD has stated that it will publish the above information on its website on a quarterly basis. According to OSHPD's website, it was to publish information on new drugs beginning in spring 2019 and beginning in June 2019 it was to begin publishing WAC price increase information.

On August 8, 2019, OSHPD published its first report of new drugs introduced with a WAC that exceeds $670. The report reveals that approxi-

mately 40 drug manufacturers introduced 153 drugs from January 1, 2019, through March 30, 2019, with a WAC that exceeds $670. The overwhelming majority of manufacturers did not disclose their marketing or pricing plans; instead, they relied on the safe harbor that any non-public information is not required to be reported. A report with WAC price increase information could not be located on OSHPD's website.

Connecticut

The Connecticut Office of Health Strategy was tasked with preparing a list of drugs that have WACs exceeding certain thresholds and for which manufacturers will be required to report certain publicly-available information. The Office of Health Strategy has until March 1, 2020, to prepare its list; thus, manufacturers have not yet been required to report any information to the state.

Louisiana

In June 2017, Louisiana enacted a law requiring drug manufacturers to report current WAC prices to the Louisiana Pharmacy Board on a quarterly basis. Although the Louisiana law requires the Pharmacy Board to make manufacturer-reported WAC prices publicly available, no such information appears on the Board's website. The Board's Pharmaceutical Cost Transparency webpage has not been updated since September 2017.

Nevada

Since 2017, Nevada has required manufacturers of "essential" drugs for the treatment of diabetes that have experienced certain increases in pricing to report additional information justifying such increases. On May 30, 2019, Nevada passed new legislation (SB 262) expanding manufacturer reporting requirements to manufacturers of asthma drugs.

In May 2019, the Nevada Department of Health and Human Services ("DHHS") released its 2019 Drug Transparency Report. The Report notes that the most frequent justifications for price increases provided by manufacturers were:

- Research and development investments (26 percent);
- The drug has more competitive value (12 percent);
- Changes in marketplace dynamics (11 percent);
- Rebates provided to PBMs, insurers, and others (11 percent); and
- Investment in manufacturing (eight percent).

Since reporting the aggregated manufacturer price increase justification data, it does not appear that DHHS nor any other Nevada government office has

taken any action with respect to drug pricing. DHHS held two public meetings in 2018. Its second and most recent meeting was in May 2018 for the purpose of hearing public comments on proposed drug pricing transparency reporting.

New York

The New York Medicaid Drug Utilization Review ("DUR") Board can require a manufacturer to report certain cost and price information for drugs with high Medicaid utilization (projected spend over five million dollars), significant increases in cost or utilization, and other outlier drugs. In February 2019, the DUR Board looked at one drug that it considered had pierced the Medicaid Drug Cap but took no action in terms of requesting information from the drug's manufacturer.

Oregon

Beginning March 15, 2019, like in California, manufacturers are required to report the WAC and other information regarding a drug introduced with a WAC that exceeds $670—the Medicare Part D specialty drug cost. On July 31, 2019, Oregon's Division of Financial Regulation published its new drug pricing report. However, like in California, the report has little to no value. Other than identifying the name of the drug and its manufacturer, there is no substantive information. For example, for Marketing Description and Pricing Methodology, most manufacturers did not report any information, relying on the trade secret exemption. The Division's website indicates that all information that manufacturers have claimed to be trade secrets is under review.

Vermont

In accordance with the state's Prescription Drug Cost Transparency Act,[5] the Vermont Attorney General ("AG") identified 10 drugs and requested that the applicable drug manufacturers submit justifications for price increases no later than November 5, 2018. The AG's list was compiled from the drug lists provided by two sources: (i) the Department of Vermont Health Access ("DVHA") and (ii) insureds with more than 5,000 covered lives in Vermont. The lists provided consist of drugs for which the payor's net cost increased by 50 percent or more over the past five years or 15 percent or more over the past calendar year.

All of the manufacturers the AG contacted submitted information. On February 23, 2018, the AG in turn submitted a report to the legislature. However, the AG was statutorily precluded from publicly disclosing information that allows the identification of a specific drug or manufacturer or

[5] 18 V.S.A. § 4635.

information that could cause financial, competitive, or proprietary harm to a manufacturer. Thus, the AG reported that, as was the case in 2016, drug manufacturers' price increase justification reports had three common themes:

- Pricing analyses should be based upon actual prices paid as opposed to WAC, which is a manufacturer's undiscounted list price for wholesalers;
- Manufacturers do not determine the prices patients pay and WAC does not typically reflect the price a patient pays; and
- Manufacturers set prices based on a variety of factors and no specific percentage is assigned to any individual factor.

EFFICACY OF STATE LAWS REQUIRING REPORTING

During 2019, federal government drug pricing transparency efforts outpaced such state efforts. Most of these efforts, thus far, have not been successful, but that has not deterred the federal government. Recently, the HHS announced it is still committed to implementing an international-pricing-index-based reimbursement system for Medicare Part B. HHS also recently appealed the federal district court ruling that struck down its plan to compel drug manufacturers to disclose WAC prices in television advertisements.

State efforts for drug pricing transparency based upon manufacturer reporting appear to be waning. In the first six months of 2019 only five states passed new laws requiring drug manufacturers to disclose prices and related information. These laws generally apply when initial pricing or price increases cross certain dollar thresholds. Since most state legislatures are in session earlier in the calendar year, it is unlikely that there will be much additional state action during 2019.

A review of state reports under existing laws compelling manufacturers to disclose prices and other related information shows little to no tangible benefit to the states or its consumers. Several states passed legislation and enjoyed the resulting positive media coverage but have since gone silent. Other states that have implemented regulations regarding reporting are receiving reports from manufacturers, but the reports are of little value. States have been stymied by state laws prohibiting the disclosure of drug manufacturer trade secrets. Thus, such reporting defaults to the disclosure of WAC prices and very general statements regarding a drug's launch pricing or price increases.

Based on the foregoing, one has to ask whether state laws requiring drug manufacturers to report information justifying price increases is working. Some argue that pricing disclosure requirements have had a positive impact as manufacturers want to avoid public shaming. For example, it was recently reported that in the first seven months of 2019, drug manufacturers raised list

prices for brand-name drugs by a median of five percent—down from approximately nine percent or 10 percent over those months the prior four years. Whether this reduction was coincidental or caused by state requiring drug manufacturers to disclose pricing is unknown. However, to date, no state can point to its drug pricing disclosure law as the basis for the state or its consumers paying less for prescription medications.

DRUG MANUFACTURERS MUST REMAIN VIGILANT

With approximately a dozen different state laws requiring pricing disclosures, drug manufacturers must ensure compliance with these laws. While many of the laws are similar, each has its own nuances. Each law requires disclosures based on crossing different dollar thresholds, with different information reporting requirements, with different marking requirements and processes for protecting confidential and proprietary trade secrets, and different reporting deadlines. While there are no enforcement mechanisms for initial price setting or price increases, there is the potential for significant penalties for late or false reporting.