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Government Contracts

MARCH 2021 • NO. 1

Under Biden Administration, Will Federal Drug Pricing Transparency Efforts Continue to Outpace State Laws?

During 2019 and 2020, states enacted fewer laws requiring drug manufacturers to disclose pricing and related information. Initially, the slowdown may have been due to federal actions to rein in drug prices through the Trump administration's multiple executive orders.[1] Thereafter, states were focused on responding to the pandemic and drug pricing was understandably placed on the back burner.

Circumstances have since changed. We now have a new president and administration, and the country is hopefully turning the corner on the COVID-19 pandemic. Inevitably, the federal government and states will again turn their focus to drug prices. While the Trump administration's executive orders made for good public sound bites, they had little to no actual impact on drug prices. At the end of the day, most of the Trump administration's initiatives never made it to the regulatory rulemaking phase and those that did were met with legal challenges.

Only a month in, the Biden administration has issued multiple executive orders and memoranda reversing prior executive orders and freezing pending regulations and enforcement policies with respect to existing regulations.

After a brief discussion of what we have seen in the early days of the Biden administration in terms of drug pricing, this article reviews new and existing state laws requiring drug manufacturers to report pricing and other information. Thereafter, we again question the efficacy of the state price transparency efforts and what manufacturers should be doing in terms of compliance.

BIDEN ADMINISTRATION

Beginning on its first day, the Biden administration took action, impacting drug prices, and potentially signaled, directly or indirectly, the polices we may see over the next four years. The new administration's actions have continued at a rapid pace.

First, on January 20, President Biden issued a "regulatory freeze" memorandum halting the previous administration's "midnight regulations" and revoking certain executive orders. The memo instructed agencies to withdraw any last-minute rules not yet published and postpone for 60 days the implementation of published rules that had not yet taken effect. With respect to drug prices, the memo:

1. *See* Recent and Possible Executive Orders on Drug Pricing: What You Need to Know (*Government Contracts Navigator,* September 17, 2020); and Administration Issues Executive Order Tying Medicare Drug Costs to International Prices (*Government Contracts Navigator,* July 30, 2020).

- Delayed implementation of a Department of Health and Human Services ("HHS") Office of Inspector General regulation issued pursuant to Executive Order 13939 that prohibited drug manufacturers from providing rebates to pharmacy benefit managers and insurers. 84 FR 2340. The regulation encouraged drug companies to provide discounts directly to patients at the pharmacy counter. This would have been a radical change in the way most drugs are priced and reimbursed under Medicare and Medicaid. The regulation was not revoked; rather, its implementation delayed until 2023.

- Paused an HHS regulation requiring Federally Qualified Health Centers, which primarily treat underserved communities, to pass on discounts they receive on insulin and epinephrine products to their patients. 85 FR 83822. Based on Executive Order 13937, the rule would have only affected insulin and epinephrine product prices purchased through the Public Health Service 340B drug discount program, not the prices of these drugs for the general public. The effective date of the rule was delayed 60 days until March 22.

Second, although not covered by the regulatory freeze memo, the Biden administration is expected to abandon two drug pricing related policies implemented through prior executive orders.

- In November 2020, HHS issued a final rule that would have tied the reimbursement amount for certain drugs under Medicare Part B to foreign pricing indices. 85 FR 76180. The final rule was based on Executive Order 13948, the so-called "Most Favored Nations" Rule. Attempted implementation of the regulation has been enjoined by no less than three federal courts. Rather than revoking the rule, the Biden administration's Department of Justice is expected to withdraw opposition to the injunctions.

- Pursuant to Executive Order 13938, in September 2020, HHS published a final rule establishing a path for, among other entities, states to set up drug importation programs. 85 FR 62094. In November 2020, the Pharmaceutical Research and Manufacturers of America ("PhRMA") moved to block implementation of the final rule. While the Biden administration, including new HHS Secretary Xavier Becerra, have supported lower drug prices through importation, it remains to be seen whether the Biden administration will defend a "Trump policy" or whether the administration will withdraw the rule and issue a new Biden importation rule.

Other drug pricing issues are sure to arise during the Biden term, such as whether to reverse the existing law that prohibits Medicare from negotiating lower prices with drug manufacturers. Similarly, whether the federal government should use "march-in rights," also known as "compulsory licensing," as a tool to lower drug prices, which is supported by Secretary Becerra and Senator Elizabeth Warren.[2]

Everyone should stay tuned to see if or how the Biden administration tackles drug pricing. Will it take a hard-nosed, antagonistic approach, like that of the Trump administration, which ultimately was not successful? Alternatively, will the Biden administration seek to establish a more cordial relationship with the pharmaceutical industry in the hopes of implementing some form of pricing controls? Only time will tell.

STATE DRUG PRICE REPORTING LAWS

Regardless of federal efforts, state drug price reporting programs are alive and well. In 2020, only one state, Utah, enacted a new drug pricing disclosure law. Below is an update on existing and new state transparency programs.

California

California enacted one of the first drug manufacturer pricing disclosure laws in October 2017. Beginning January 1, 2019, drug manufacturers began reporting certain data and information on existing drugs with a wholesale acquisition cost ("WAC") that exceeds $40 for a course of therapy and whose WAC increased more than 16 percent, and for new drugs with a WAC that exceeds the Medicare Part D specialty drug cost threshold (currently $670). Rather than being known as an innovative tool to reduce drug prices, California's law is better known because it has been under constant legal attack.

In December 2020 (on summary judgment), and again on January 4, 2021 (on the merits), a federal district court denied PhRMA's claims that California's law violates the Constitution's First Amendment right to free speech and the dormant Commerce Clause. The unfavorable California decisions do not bode well for similar challenges filed by PhRMA to Oregon's drug reporting law.

2. *See* What Could a DHHS Secretary Becerra Mean for the Pharmaceutical Industry? (*Government Contracts Navigator*, December 9, 2020).

Notwithstanding the legal challenges, most manufacturers complied with the state's reporting requirements. California published two reports in 2019 and one in 2020, identifying newly introduced drugs with a WAC that exceeds $670. California also has issued two reports covering drugs with WAC increases that triggered a reporting obligation and a report showing a five-year history of a drug's WAC increases. These reports cover 2019 and the first two quarters of 2020. The reports include very general manufacturer explanations for the WAC increases and note that most manufacturers consider multiple factors when determining to raise WACs.

In the first six months after the California reporting law became effective, the state fined 12 manufacturers a total of $17.5 million for failing to report drug price increases. The fines were based on the number of days the manufacturers failed to timely report price increases. In 2020, California reportedly collected nearly $11 million from manufacturers for failing to comply with reporting obligations.

Connecticut

Connecticut's reporting requirements are unlike other states. Effective January 1, 2020, drug manufacturers that have filed a new drug application or biologics license application for a pipeline or a biosimilar drug with the Food and Drug Administration ("FDA") are required to notify the Connecticut Office of Health Strategy ("OHS") within 60 days of FDA approval.

After January 1, 2020, OHS is permitted to study a drug manufacturer of a pipeline drug that may have a significant impact on state expenditures for outpatient prescription drugs. The manufacturer will be required to provide (a) the primary disease, condition, or therapeutic area studied in connection with such drug, and whether such drug is therapeutically indicated for such disease, condition, or therapeutic area; (b) each route of administration studied for such drug; (c) clinical trial comparators, if applicable, for such drug; (d) the estimated year of market entry for such drug; (e) whether the FDA designated such drug as an orphan drug, a fast track product, or a breakthrough therapy; and (f) whether the FDA designated such drug for accelerated approval and, if such drug contains a new molecular entity, for priority review.

On or before March 1, 2020, and annually thereafter, OHS will prepare a list of up to 10 outpatient prescription drugs that are provided at substantial cost to the state, considering the net cost of such drugs, or critical to public health. The list is to include outpatient prescription drugs from different therapeutic classes and at least one generic. To be included on the list, a drug's WAC, less all rebates paid to the state for the drug during the immediately preceding calendar year, must have increased by at least 20 percent during the immediately preceding calendar year, or 50 percent during the immediately preceding three calendar years, and was not less than $60 for a 30-day supply of the drug or course of treatment of the drug lasting less than 30 days.

For drugs on the OHS list, a manufacturer must provide (i) a description, suitable for public release, of all factors that caused the increase in the drug's WAC; and (ii) aggregate, company-level research and development costs, and such other capital expenditures deemed relevant. Such information shall be of the quality and type available in a manufacturer's publicly available SEC 10-K or any other public disclosure. OHS intends to release its first list identifying drugs on which manufacturers will be required to report the foregoing information in March 2021.

Louisiana

In June 2017, Louisiana enacted a law requiring drug manufacturers to report current WACs to the Louisiana Pharmacy Board on a quarterly basis. The board's Pharmaceutical Cost Transparency webpage now includes a searchable database with a drug's information including, in most cases, its WAC.

Maine

Beginning January 30, 2020, and annually thereafter, drug manufacturers are required to report WAC for a brand-name drug increased by more than 20 percent in the prior calendar year, a generic drug that costs more than $10 increased by more than 20 percent in the prior calendar year, and a new drug introduced with a WAC greater than the Medicare Part D specialty drug limit (currently $670 per month). In addition, the Maine Health Data Organization ("MHDO") is permitted to request information on specific drugs.

Beginning November 1, 2020, and annually thereafter, MHDO will publish an annual report based upon the manufacturer reported data. Among other reasons, the purpose of the annual report is to provide greater consumer awareness of the factors contributing to the cost of prescription drugs in the state.

On October 12, 2020, MHDO provisionally adopted rules covering manufacturer price submissions. If adopted, such rules will require a manufacturer to register or update an existing registration online each year by January 30. In addition, by January 30 of each year, a manufacturer will

be required to report whether, during the prior calendar year, it: (1) increased the WAC of a brand-name drug by more than 20 percent; (2) increased the WAC of a generic drug that costs at least $10 by more than 20 percent; or (3) introduced a new prescription drug for distribution in the state with a WAC greater than the Medicare Part D specialty drug amount (currently $670).

A manufacturer also will be required to submit data for any of its drugs that are included in one of MHDO's three annual reports: (i) the 25 Costliest Drugs (determined by the total amount spent in the state); (ii) the 25 Most Frequently Prescribed Drugs in the State; and (iii) the 25 Drugs with the Highest Year-Over-Year Cost Increases (determined by the total amount spent in the state).

Further, a manufacturer will be required to provide data for any drug in the same drug product family as a drug requiring reporting for increases in WAC set forth above. On or before February 15 of each year, MHDO intends to post a list of drug product families for which it intends to request pricing data. 30 days after posting the list, MHDO will notify, via e-mail, manufacturers that will be required to report pricing information within 60 days of such notification.

For each drug satisfying one of the tests above or appearing on an MDHO list, a manufacturer will be required to report sales volume, acquisition volume, revenue, acquisition amount, and rebates (all net of returns). Other required information includes the national drug code of the drug; the estimated number of patients in the United States for the drug; a baseline WAC; the total WAC change amount; the WAC after changes; U.S. sales volume; gross U.S. revenue; total rebate payable amount; and a code(s) identifying the reason for increasing the drug's WAC.

For drugs acquired within the previous five years, a manufacturer will be required to report the acquisition date and the name of the company from which the drug was acquired, the acquisition purchase price, and the WAC at the time of acquisition.

With its reporting, a manufacturer will be required to include a signed certification of the report's accuracy. With a 30-day notice, MHDO may audit the finalized data submitted by a reporting entity, and that entity shall pay for the costs of the audit.

Nevada

Since 2017, Nevada has required manufacturers of "essential" drugs for the treatment of diabetes that have experienced certain price increases to report information justifying such increases. In May 2019, Nevada expanded manufacturer reporting to include asthma drugs.

The Nevada Department of Health and Human Services ("DHHS") issued Drug Transparency Reports in 2019 and 2020. The reports demonstrate that drug prices continue to increase and manufacturers' justifications for such increases are multiple and general—*e.g.,* research and development, competitive value of the drug, and market changes.

Since reporting the aggregated manufacturer price increase justification data, it does not appear that DHHS nor any other Nevada government office has taken any substantive action concerning drug pricing.[3] In total, DHHS held three public meetings—two in 2018 and one in December 2020. At the December 2020 meeting, drug pricing transparency was not discussed; rather, the entire meeting appears to have been devoted to adopting regulatory amendments concerning hearing procedures for manufacturers that fail to timely file required price transparency reports.

Thus far, it does not appear that Nevada's Drug Transparency Reporting Program has had any effect on drug prices paid by Nevadans or the state. Rather, the most notable headline about the program is the announcement in November 2019, that DHHS imposed $17.4 million in fines on 21 drug manufacturers for failing to timely file reports. Penalties assessed against the manufacturers ranged from $735,000 to $910,000.

Oregon

In March 2018, Oregon began requiring drug manufacturers to submit annual reports for each drug that has a WAC of $100 or more for a one-month supply or for a course of treatment lasting less than one month, and that had a net increase of 10 percent or more in the price over the course of the previous calendar year. The Oregon law also requires drug manufacturers to report pricing and other information for new prescription drugs within 30 days after introducing a drug for sale in the United States at a price that exceeds the threshold for specialty drugs set by the Medicare Part D program ($670 in 2020).

3. In January 2020, Nevada enacted a law capping monthly insulin costs at $100 for people covered by state-regulated commercial health insurance plans. Among other bases for the law, the fact that three manufacturers control 90 percent of the global insulin market and that the corresponding absence of competition has led to incredible price inflation for insulin products—nearly 600 percent from 2001 to 2015.

Subsequently, in June 2019, Oregon expanded reporting by requiring manufacturers to report price increases at least 60 days before an increase in: (i) the price of a brand-name drug that will result in a cumulative increase of 10 percent or more, or an increase of $10,000 or more, in the price of the brand-name drug within a 12-month period; or (ii) the price of a generic drug that will result in a cumulative increase of 25 percent or more and an increase of $300 or more in the price of the generic drug within a 12-month period. Manufacturer reporting must include the date and dollar amount of the increase, and a statement of whether the increase is necessitated by a change or improvement in the drug, and, if so, a description of the change or improvement.

In December 2019, PhRMA filed a lawsuit challenging the Oregon laws as it had with similar laws in California and Nevada. PhRMA alleged the Oregon laws violate the First Amendment and the dormant Commerce Clause. The lawsuit is pending. Both parties have moved for partial summary judgment. The court heard oral argument on January 14, 2021, and took the motions under advisement.

PhRMA's lawsuit, however, was filed after the March 2019 manufacturer reporting requirement for new drugs and the July 2019 reporting requirement for price increases. As a result, manufacturers made such submissions and, on July 31, 2019, Oregon's Division of Financial Regulation ("DFR") published its Prescription Drug Price Transparency Results and Recommendations. Thereafter, based upon manufacturer data submitted as of October 15, 2020, Oregon released its second annual report. Notably, between its first and second report, DFR held no public meetings or hearings.

The second annual report is comprehensive, but it remains to be seen how the report will assist the state or consumers in achieving or accessing lower drug prices. The report's findings do not provide "new" or startling information. For example, one finding states that "all of the most expensive drugs reported are brand names" and "[c]ancer drugs were consistently the most expensive drugs in Oregon." Similarly, the reports states that "[h]igh prices for new drugs appear to be driven, in part, by the relative cost of established drugs that treat the same condition." The report goes on to state that:

> "drug manufacturers submitted 70 percent fewer price increase reports to the state in 2020, compared to 2019. The reasons for this trend are unclear, but do not seem to be related to reduced compliance with reporting requirements. One explanation suggested by the data is that manufacturers are spreading price increases more widely across their portfolio of drugs to avoid triggering transparency requirements."

On December 16, 2020, DFR held its second annual public hearing regarding prescription drug price transparency. The hearing was allotted two hours. The hearing recording has not been made available as of the date of this article.

Texas

In June 2019, Texas enacted a law 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, for drugs satisfying one of the tests above, manufacturers are required to report the company-wide research and development costs, and 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.

HHSC is implementing the drug cost reporting requirements in phases to allow drug manufacturers time to gather and submit the required information. The first phase of the implementation, annual WAC reporting by manufacturers, is complete. HHSC collected the January 1, 2020 WACs on all FDA-approved drugs sold in or into Texas by drug manufacturers. Hopefully, HHSC staff did not spend too much time or money on the first phase since WACs are readily available for a modest fee from several commercial companies.

In August 2020, HHSC released two reports from its second phase: (i) Price Increase Report, and (ii) Manufacturer Activity Report. The reports actually are searchable data sets on HHSC's webpage. The accuracy or completeness of these reports is questionable. For example, the Price Increase Report, which covers drugs with a WAC of at least $100 for a 30-day supply and which had an increase of 15 percent in one year or 40 percent over three years, includes a total of

14 manufacturers and 50 drugs. In comparison, the Annual WAC Report includes hundreds of manufacturers and more than 18,000 drugs. Similarly, only 13 manufacturers submitted Manufacturer Activity Reports. These reports provide the rationale for WAC increases reflected in the Price Increase Reports. However, the manufacturers submitting Manufacturer Activity Reports do not match those reporting WAC increases.

Utah

In August 2020, Utah supplemented its Prescription Drug Price Transparency Act by requiring drug manufacturers to submit reports to the Utah Insurance Department. The department is creating a reporting template and an administrative rule that will provide guidelines for drug manufacturers to submit the reports, which will be required beginning January 1, 2022.

Vermont

Since 2018, manufacturers have been required to report drug pricing information if the manufacturer's drug appears on one of two lists prepared by the State Attorney General's Office ("AGO"). The first list is comprised of 10 prescription drugs (at least one generic and one brand name) on which the state "spends significant health care dollars" and for which the WAC has increased by 50 percent or more over the past five calendar years or by 15 percent or more during the previous calendar year. The second list is comprised of 10 prescription drugs (at least one generic and one brand name) on which the state "spends significant health care dollars" and for which the Department of Vermont Health Access' ("DVHA") net cost has increased by 50 percent or more over the past five years or 15 percent or more during the previous calendar year. For an identified drug, a manufacturer must report the justification for the increase in the net cost of the listed drug, together with all relevant information and supporting documentation.

In compliance with Vermont law, the AGO has submitted annual reports to the legislature with the drugs identified based upon information submitted by drug manufacturers. The 2019 and 2020 reports are remarkably similar. The reports identify factors manufacturers have provided justifying price increases. Such factors are very general and, among others, include the value of innovative medicines; cost effectiveness (meaning the economic value to patients given the effectiveness of the drug, compared to other drugs in the same class); the size of the patient population for the drug; investments made (including in research and development) and risks undertaken; cost of ingredients; and competition, including for drugs in the same class.

Perhaps most notable in the AGO reports is the conclusion:

> "Pharmaceutical drug pricing is extraordinarily complicated. Each party in the drug distribution chain (which includes manufacturers, wholesalers, pharmacy benefit managers, pharmacies, and health plans/payers) is governed by myriad requirements, and they also have a variety of interests. While it is clear there are ongoing sizeable drug price increases, the process of preparing this report—including communications with DVHA and the health insurers over many months—has demonstrated the challenges to providing the public with useable information about pharmaceutical pricing."

This language accurately describes pharmaceutical pricing and underscores whether reported pricing information is truly useful to consumers.

Manufacturers also must report to the AGO if it is introducing a drug to market at a WAC that exceeds the threshold set for a specialty drug under the Medicare Part D program (currently $670). For drugs meeting this threshold, a manufacturer must submit a "notification" to the AGO within three calendar days following the release of the drug in the commercial market. Thereafter, within 30 calendar days following the notification, the manufacturer must provide: (1) a description of the marketing and pricing plans used in the launch of the new drug in the United States and internationally; (2) the estimated volume of patients who may be prescribed the drug; (3) whether the drug was granted breakthrough therapy designation or priority review by the FDA prior to final approval; and (4) the date and price of acquisition if the drug was not developed by the manufacturer. Manufacturers' reports are available on the AGO website.

Washington

Washington delayed a manufacturer's obligation to report pricing information by one year until October 2020. The Washington law requires manufacturers to report information on three categories of drugs:

- New Covered Drug—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;

- Qualifying Price Increases—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; or

- New Drug Application—new drug applications or biologic license applications for pipeline drugs submitted on or after October 16, 2020, within 60 days of the manufacturer receiving the FDA approval date.

Manufacturer reporting obligations began on October 16, 2020. The data requested by the Washington Health Care Authority ("HCA") is perhaps the most comprehensive of any other state transparency program. Manufacturer reports for New Covered Drugs must be submitted within 30 days after launch. Reports for Qualifying Price Increases must be submitted 60 days in advance of a price increase. Reports for New Drug Applications must be submitted within 60 days of the manufacturer receiving the applicable FDA approval date.

For New Covered Drugs and those with a Qualifying Price Increase, a manufacturer must report: (a) a description of the specific financial and nonfinancial factors used to make the decision to set or increase the WAC of the drug. In the event of a price increase, a covered manufacturer must also submit the amount of the increase and an explanation of how these factors explain the increase in the WAC of the drug; (b) the patent expiration date of the drug if it is under patent; (c) whether the drug is a multiple source drug, an innovator multiple source drug, a noninnovator multiple source drug, or a single source drug; (d) the itemized cost for production and sales, including the annual manufacturing costs, annual marketing and advertising costs, total research and development costs, total costs of clinical trials and regulation, and total cost for acquisition of the drug; and (e) the total financial assistance given by the manufacturer through assistance programs, rebates, and coupons.

For Qualifying Price Increases of existing drugs, a manufacturer also must submit the year the drug was introduced to market and the WAC of the drug at the time of introduction. If a manufacturer increases the price of an existing drug it has manufactured for the previous five years or more, it must submit a schedule of wholesale acquisition cost increases for the drug for the previous five years. If a manufacturer acquired the drug within the previous five years, it must submit: (a) the WAC of the drug at the time of acquisition and in the calendar year prior to acquisition; and (b) the name of the company from which the drug was acquired, the date acquired, and the purchase price.

For New Drug Applications, within 60 days of receiving FDA approval, a manufacturer must submit a "notice" to HCA stating it has filed with the FDA: (a) a new drug application or biologics license application for a pipeline drug; or (b) a biologics license application for a biological product.

HCA may request additional information from the manufacturer if it believes the drug will have a significant impact on state expenditures. Such information includes: (a) the primary disease, condition, or therapeutic area studied in connection with the new drug, and whether the drug is therapeutically indicated for such disease, condition, or therapeutic area; (b) each route of administration studied for the drug; (c) clinical trial comparators for the drug; (d) the date at which the FDA must complete its review of the drug application pursuant to the federal Prescription Drug User Fee Act of 1992; (e) whether the FDA has designated the drug an orphan drug, a fast track product, or a breakthrough therapy; and (f) whether the FDA has designated the drug for accelerated approval, priority review, or if the drug contains a new molecular entity.

Notwithstanding the above data and information requests, a manufacturer may limit the information reported to that which is otherwise in the public domain or publicly reported. HCA will submit an annual report to the legislature based upon the data received from, among others, drug manufacturers.

ARE STATE DRUG PRICE TRANSPARENCY PROGRAMS WORKING?

It appears that only a select few of state legislators, when seeking to enact a drug pricing transparency law, assert that requiring drug manufacturers to report prices for purposes of transparency works. They argue that the pricing information is useful to consumers in making purchasing decisions and rein in manufacturer price increases.

However, the facts argue otherwise:

FACT: Notwithstanding state drug transparency programs, drug prices continued to rise in 2019 and 2020. According to GoodRx, the list prices on 457 brand name drugs increased by an average of 5.1 percent in 2020, similar to the 5.2 percent average price increase in 2019.

FACT: No state that has implemented a drug transparency program has or can reasonably assert that its drug transparency program has caused drug manufactures to forego price increases. Indeed, as Oregon's most recent annual report stated, manufacturers are now spreading out their price increases to avoid reporting thresholds.

FACT: With the exception of certain state insulin pricing programs, no state legislature has used a report from its agency collecting pricing data from manufacturers to lower drug prices or alter buying patterns in his or her state.

FACT: WACs are of no use to consumers. WACs do not accurately reflect the prices consumers pay. And, regardless of whether a consumer is armed with a drug's WAC or some other price or information, consumers do not have the ability to negotiate prices for their drugs.

It appears that the applicable data collecting agencies in states with drug pricing transparency programs spend a significant amount of time collecting manufacturer pricing information, analyzing such information, and drafting comprehensive reports. However, with no disrespect to the state government employees performing this work, the reports have little to no value to the states or its consumers. Several states passed legislation and enjoyed the positive media coverage but have since gone silent. In numerous states, reports have been filed with legislatures, but no action has been taken based on the reports. Other states that have implemented regulations regarding reporting and are receiving reports from manufactures, but because the information in the reports is so general and vague, the reports have no value. States have been stymied by laws and lawsuits 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 drug prices and information justifying price increases are working.

DRUG MANUFACTURERS MUST REMAIN VIGILANT

The number of states with drug transparency programs continues to grow. The state programs are not consistent. Many of the programs have different reporting deadlines, different drug price thresholds triggering a reporting requirement, and different price increase percentages triggering reporting. Manufacturer price reporting has become its own industry. The multi-million dollar fines imposed on manufacturers in Nevada and California for failing to timely submit price reports show that manufacturers can no longer dabble in price reporting. All of the divergent requirements mandate that drug manufacturers build the internal structure to responsibly submit price reports to states. 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.

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