Complying With Colorado's New Drug Price Transparency Law

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Executive Summary

Much has been written about the continued back-and-forth between the federal government and pharmaceutical manufacturers regarding the issue of drug pricing and price transparency. In early July, a year after the Department of Health and Human Services (HHS) first proposed including drug prices in television commercials, a *federal judge* ruled that HHS did not have the authority to impose these *new rules*; rather, the judge stated, that is the job of Congress.

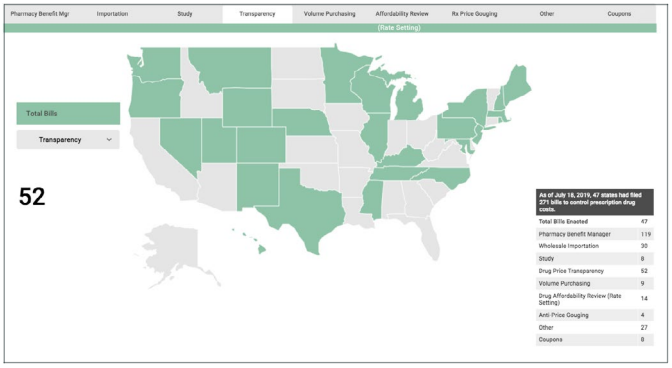
At the time of this writing, the pharmaceutical industry has gained a reprieve, but only at the federal level. Meanwhile, the earth has moved at the state level — most recently in Colorado — and the result is nothing short of uncertainty and confusion.

This POV describes the new Colorado *House Bill 19-1131* and how it could affect pharma marketers. The bill requires that any one-to-one communications between pharmaceutical representatives (or anyone communicating on their behalf) and prescribers must include written information about the wholesale cost of a drug, as well as the names of at least three generic equivalents. The law goes into effect on August 2, 2019.

What Is the New Colorado Law?

According to the *National Academy of State Health Policy* — as of July 18, 2019 — 47 states had filed a total of 271 bills to control prescription-drug costs; many of those bills didn't become laws or are still in legislative limbo. In 2019 alone, 29 states passed a total of 47 new laws to curb prescription costs. Of the 52 pricing transparency bills introduced so far in 2019, only four have been signed into law.

The latest piece of state legislation on pricing transparency comes in the form of Colorado *House Bill 19-1131*, a four-page document that requires drug manufacturers to provide — in writing — the wholesale acquisition cost (WAC) of a prescription drug to the prescriber with whom the drug manufacturer is sharing information concerning the drug.



Interactive map from National Academy of State Health Policy.

Beginning August 2, 2019, when a "drug manufacturer or pharmaceutical representative, agent, or employee of the manufacturer" engages in prescription-drug promotion with a Colorado healthcare prescriber, they will be required to not only provide information on the FDA-approved language on drug efficacy and safety, but also the wholesale acquisition cost of the drug.

The *law also requires* drug manufacturers to provide the name of at least three generic prescription drugs in the same therapeutic class, if available. If there are not three generic prescription drugs available, the manufacturer is to provide the names for as many as are available for prescription use. If more than three generics are available, the law does not describe how manufacturers should select the three they mention. The law covers some forms of both personal promotion and non-personal promotion.

Specifically, the law states:

"'Prescription drug marketing' means any activity that does not include conversations at scientific conferences and that may include in-person meetings, physical mailings, telephonic conversations, video conferencing, electronic mailing or texting, or facsimile transmissions that provides educational or marketing information or materials regarding a prescription drug."

While not specifically stated in the law, digital sales aids and sample distribution programs also fall under this purview, and use of them requires providing pricing and generic-equivalent information.

Worth noting, the price disclosure requirement only applies when the sales rep (or other representative of the manufacturer, as noted above) "provides information concerning the drug to the prescriber." This excludes emails about scheduling, CME events, miscellaneous news, and non-substantive emails/texts. For example, sales staff should distinguish between when they are "providing information" about a drug versus when they are developing rapport with a prescriber, and act accordingly.

Digital media campaigns targeted 1:1 to an HCP based on his or her NPI number are considered person-to-person interactions, so they do fall within the scope of the statute (since NPIs are targeted, this is arguably comparable to a group email or mailing).

Additional Legal and Regulatory Concerns

Intouch consulted with legal and regulatory experts and learned that the following points from Colorado's new law are particularly noteworthy:

- The requirement to provide information about generic alternatives only requires the disclosure of the name of the generic(s) in the same class. Pricing information is not required for generic alternatives.
- House Bill 19-1131 did not create new penalties for noncompliance, but under existing law the state could fine the manufacturer or wholesaler up to $500,000. See the Penalty section under *Colorado Revised Statute 12-42.5-307* concerning pharmacists, pharmacy businesses and pharmaceuticals wholesalers.

Recommendations

Based on guidance from Intouch's experts and legal advisors and review of pricing disclosure addenda used to comply with *Vermont's* (more broad) 2016 pricing law about communications with prescribers, absent a legal challenge, we recommend that pharma marketers:

01. **Prepare, as soon as is feasible, the basic information that must be disclosed** – i.e., WAC price and which generics will be provided as alternatives. This should be made available in print and digital formats.

02. **Plan to prepare**, *review, and post the information online*, similar to what manufacturers have done for Vermont prescribers (see examples from *Pfizer*, *Allergan*, *AstraZeneca*, and *Celgene*). This provides a destination link for compliance for electronic communications such as email and SMS text messaging.

03. **Plan to "comply with context"**: While the law lays out what information must be provided, manufacturers reserve the right to provide additional context, and we recommend that they plan to do that by providing, for example, language around what patients may typically pay and context around an implied comparison of the branded versus generic drugs.

Example 1 – WAC Price Context

One of the major industry concerns about the HHS proposal was that the WAC price misrepresented what most patients would ultimately pay once discounts, co-pays and insurance were applied. That concern applies to the new Colorado law as well; simply listing the WAC price without context is confusing and potentially even misleading.

Though Johnson & Johnson's Xarelto TV commercials are directed toward consumers, they set a solid industry standard for "compliance with context." The spot provides the list price (as was expected to be required by HHS), but then goes several steps further to provide more clarity, including:

- Potential out-of-pocket costs for patients
- A visual representing the list price — $448, vis-à-vis what "most patients pay" — $0-$47
- Direction to a *website* for more specific pricing information, providing typical costs for patients on Medicare, Medicaid, or private or employer insurance, and for the uninsured or those whose insurance doesn't cover the drug.

Screenshot of the Xarelto TV ad via JanssenUS YouTube

Example 2 – Generics "Equivalent" Context

Generic equivalents are not always truly "equivalent," and the branded manufacturer cannot be held responsible for the viability of generic medications in treatment. For example, prescribers who specialize in treating patients with epilepsy have often noted different outcomes in those treated with generics compared to those treated with branded medications.

A disclaimer, such as this one *provided by Daiichi Sankyo, Inc.* in response to Vermont's 2016 similar pricing law, may help provide this context:

> *"This list does not imply that the products on this chart are interchangeable or have the same efficacy or safety. Please refer to each product's FDA-approved label and indication for further information."*

Manufacturers can refer to their own language used for Vermont prescribers for additional reference.

04. **Provide training ASAP.** Colorado sales reps — as well as marketing teams and their agencies who market directly to Colorado prescribers — will need to be trained immediately on the proper use of this new information according to the law, and begin compliance by August 2.

05. **If marketing teams and their partners** *are not prepared to comply by August 2*, they should cease branded communications in Colorado, including emails, until proper preparations and approvals are complete.

Conclusion

Colorado House Bill 19-1131 goes into effect on August 2, 2019, and will require that when a "drug manufacturer or pharmaceutical representative, agent, or employee of the manufacturer" engages in prescription-drug promotion with a Colorado healthcare prescriber, they will be required to not only provide information on the FDA-approved language on drug efficacy and safety, but also the wholesale acquisition cost of the drug as well as the names of three generic equivalents, if available.

If marketers feel the law and its pending deadline snuck up on them, they're not alone. In addition, we are seeing widely different interpretations by manufacturers' legal counsel.

While it's possible that there may be a future legal challenge, mitigation steps can likely be taken quickly, and Intouch recommends immediate action. We will continue to monitor this issue. Reach out to your account team today with any questions.

For more information on state actions to control drug costs, visit the National Academy for State Health Policy *at nashp.org.*

Disclaimer: Intouch is not a law firm, and the authors of this POV are not lawyers. The legal information provided in this POV is not intended to be taken as legal advice; if you have additional legal questions, please seek the advice of a licensed attorney.

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