Professional Perspective

Pharma & Med Device Bidding, State-Mandated Disclosures, & Public Records Laws

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Pharmaceutical and medical device manufacturers often participate in requests for proposals (RFPs) or other bidding processes initiated by states and localities seeking to procure important treatments and services. These processes typically call on manufacturers to disclose an array of information about their products and offerings and to offer pricing information that is as competitive as possible.

All this information helps differentiate manufacturers from their competitors and, ideally, allows them to win a partnership with the government entity. But this information is often proprietary and competitively sensitive, and once it is disclosed to a state or other public entity, it also is often subject to the state's public records disclosure laws.

Given this dynamic, it is critical for manufacturers to understand how to maximize the protections available for their proprietary information prior to disclosing it in a competitive process, or pursuant to a state law, and how to navigate a third party's public records request for that private information once in the hands of a state or local government.

Detailed below are several strategies that manufacturers can use to protect proprietary information submitted to government entities, both before the manufacturer submits information in a bidding process and after a third party makes a public records request for that information from the applicable state agency. These strategies also may be effective in connection with state-mandated drug pricing disclosures.

Disclosure Risks Flowing From Submissions to States

Manufacturers frequently make voluntary submissions to state and local governments while participating in a competitive bidding process for contracts to supply products and services—for example, bulk, long-term orders of certain drugs or devices. When bidding on RFPs for state contracts, manufacturers must disclose confidential business information, including proposed pricing and pricing terms, as well as details regarding their proprietary ancillary services and capabilities. And in blind bidding processes in particular, manufacturers are strongly incentivized to disclose their most competitive pricing information and other proprietary information that will aid the authority in evaluating their bids and win the contract.

Separately, manufacturers also at times are required to submit sensitive information to government authorities outside the bidding context. For instance, states are increasingly passing drug pricing transparency laws that require manufacturers to disclose detailed cost, profit, and price increase information. The Nevada legislature, for example, passed SB No. 539 in 2017, which requires Nevada's Department of Health and Human Services to collect information about wholesale acquisition cost (WAC), and planned increases in WAC, from manufacturers of diabetes drugs deemed "essential." In 2019, the Nevada legislature expanded that law to require reporting from manufacturers of asthma drugs.

Once a manufacturers' information is in a state agency's possession—whether obtained through RFP responses, mandatory reports, or otherwise—it becomes the potential subject of a disclosure request by the public under the state's public records laws. However, in order to compete effectively in the marketplace—while maintaining confidentiality of pricing and other proprietary information—manufacturers must be mindful of all the tools in the toolkit to maintain confidentiality over their proprietary information.

Public Records Law Overview

Public Records Laws Typically Favor Disclosure

Public records laws are typically codified by legislation in each state, and can vary widely. However, these statutes are typically designed to provide the public with access to state records and thus often skew in favor of disclosure to varying degrees. For example, the public records law in Florida states that "It is the policy of this state that all state, county, and municipal records are open for personal inspection and copying by any person." Fla. Stat. Ann. § 119.01.

Similarly, the Washington public records law provides that the law "shall be liberally construed and its exemptions narrowly construed to promote [the] public policy" of keeping the public informed "so that they may maintain control" over the government. Wash. Rev. Code Ann. § 42.56.030. While Vermont's statute provides that "[a]ll people … have a right to privacy in their personal and economic pursuits," it also establishes by law that the right to privacy ends if "specific information is needed to review the action of a governmental officer." Vt. Stat. Ann. tit. 1, § 315.

The federal Defend Trade Secrets Act of 2016 (18 U.S.C. 1836) offers some baseline uniformity, but many states have adopted "mini-DTSAs," which, again, provide varying degrees of protection. For example, most state versions of the DTSA provide that "[a]ctual or threatened misappropriation may be enjoined," and "in appropriate circumstances, affirmative acts to protect a trade secret may be compelled by court order." See, e.g., Del. Code Ann. tit. 6, § 2002; Mass. Gen. Laws Ann. ch. 93, § 42A. But states differ in their criteria for "appropriate" circumstances. States also vary in their standards for awarding damages for misappropriation. Compare, e.g., Ala Code Ann. § 8-27-4 with Cal. Civ. Code § 3426.3.

Exemptions and Other Law Protecting Information From Disclosure

Although public records laws often structure their statutes in favor of disclosure as the default, these state statutes also recognize that certain types of information should be exempted from disclosure. Such exemptions are typically enumerated in the public records statutes themselves, and may also be included as part of other statutes.

It is therefore imperative for manufacturers to understand ex ante what exemptions are available to protect submissions of pricing and other information to state agencies and how clearly the agency, and a court, will deem the exemption to apply to such circumstances. Some states' public records laws include exemptions that are specifically targeted to protect manufacturer information.

For example, Washington's public records law specifically exempts "[p]roprietary data, trade secrets or other [unique] information," that is "submitted by any vendor to … the health care authority for purposes of the development, acquisition, or implementation of state purchased health care." Wash. Rev. Code. Ann. 42.56.270(11). Such information may include "a vendor's unique methods of conducting business" or how a vendor "determine[s] prices or rates to be charged for services."

Similarly, in Louisiana, certain information may be exempted from disclosure if submitted to state Department of Health for reimbursement or research purposes. See La. Stat. Ann. § 44:4(36) (exempting from public records disclosure manufacturer information related to "supplemental rebate negotiations for prescription drug coverage by the Medicaid Program"); La. Stat. Ann. § 40:3.1(a) (exemption materials gathered for "statistical, scientific, and medical research purposes" relating to health).

Even in the absence of exemptions specific to proprietary health care provider information, state public records laws often include a more general exemption for "proprietary" or "trade secret" information. See, e.g., La. Stat. Ann. § 44:3.2; Idaho Code Ann. § 74-107. The issue then becomes how state case law and administrative precedent has treated such broader exemptions. A state may have case law supportive of a protective reading of the exemption, while other state courts may read exemptions especially narrowly.

Compare, e.g., Sargent v. Seattle Police Dep't, 179 Wash.2d 376, 386 (2013) ("Like all exemptions to the PRA, this exemption is to be construed narrowly.") with US W. Commc'ns, Inc. v. Office of Consumer Advocate, 498 N.W.2d 711, 714 (Iowa 1993) (construing "trade secret" beyond the eight enumerated statutory examples). In some jurisdictions, the public records case law can be quite scant, leaving it especially uncertain how a court would rule on the applicability of a broadly worded exemption.

In many instances, state courts will also look to the state's decisional law on trade secret protections to determine whether a particular submission is subject to protection from public disclosure. State ex rel. Besser v. Ohio State Univ., 2000-Ohio-475, 87 Ohio St.3d 535, 539, 721 N.E.2d 1044, 1048 (finding that "trade secrets, as defined by the Ohio Uniform Trade Secrets Act, are not public records … A contrary holding would afford no protection for an entity's trade secrets that are created or come into the possession of an Ohio public office and would render the remedies [exempting certain information from public disclosure] meaningless").

Generally, trade secret protections apply where the information is not generally known, derives value from being secret, and the manufacturer has taken steps to protect the secrecy of the information. For example, in Michigan, courts have

found information to be protected trade secret where there was evidence that "plaintiff expended time, money and effort to develop the processes and equipment, that the processes and equipment gave plaintiff a competitive edge, that plaintiff took measures to keep the processes and equipment secret, and that it would take someone with normal skill in the industry four years of hard work to develop similar equipment and processes." Hayes-Albion v. Kuberski, 421 Mich. 170, 182-83 (1984).

In Utah, a response to a competitive bid was considered trade secret because the data "were not generally known or readily ascertainable and that they derived independent economic value, actual or potential from this status." USA Power, LLC v. PacifiCorp, 372 P.3d 629, 655 (Utah 2016).

Apart from the list of enumerated exemptions typically found in the public records statutes themselves, states sometimes also provide for agency-specific carve-outs from public records disclosure, which may be contained in totally unrelated state statutes. For example, Washington State's statutory code covering its health care authority requires the director of that authority, upon written request by a bidder in an RFP process, to "exempt from public inspection and copying such proprietary data, trade secrets, or other information contained in the bidder's proposal that relate to the bidder's unique methods of conducting business or of determining prices or premium rates to be charged for services under terms of the proposal." RCWA 41.05.026. Examples like these underscore the importance of reviewing any potentially relevant sources of law, beyond the public records statute itself, that may protect proprietary bidding information.

Adding to the statutory and decisional law that often protects against public disclosure, strong public interest considerations are also often at play. From a purely economic perspective, states and their taxpayers and beneficiaries benefit from blind competitive bidding that incentivizes manufacturers to offer their best pricing, and to tailor proposals to specific states' needs, without the risk that competitors will obtain that information.

In other words, disclosure risks undermining manufacturers' incentives for price competition and innovation. And forced public disclosure of competitively sensitive information to competitors may even implicate antitrust policy by having the effect of aligning pricing as among competitors. Federal regulators like the Centers for Medicare and Medicaid Services and the Federal Trade Commission have emphasized this concern in stressing the importance of maintaining confidentiality of manufacturer information. See, e.g., Medicaid Program; Covered Outpatient Drugs, 81 FR 5170-01.

Third-Party Public Records Requests

In general, members of the public can submit a request to the relevant state agency, usually via letter or email, for any records that the requestor believes constitute public records.

Requesters come with a wide range of potential motivations: they might be journalists, competitors, consumers, lawyers, or other interested parties. And whether the manufacturer or other owner of the information can learn the requester's identity can also vary from state to state. Some states' public records laws expressly protect requestors' right to remain anonymous. See, e.g., Ohio Rev. Code Ann. § 149.43. In other jurisdictions, the state agency at issue may disclose the requester's identity. However, in many cases, the requester is an attorney or other representative, such that the actual requester can remain anonymous, even if the agency is permitted to disclose the requester's identify.

Once the state agency receives a request, it generally must promptly notify the manufacturer or other owner of the requested information. The agency will likely notify a business person at the manufacturer, typically the person who is designated as the contact in the manufacturer's RFP response or drug pricing report. However, it is not guaranteed that the agency will notify the owner of the information.

Because notification requirements vary in different jurisdictions—and indeed may not be required at all in some instances—clearly designating all submission materials as confidential and expressly invoking the applicable public records exemptions remains the best practice and increases the likelihood of state notification to the manufacturer. Since the public records process typically imposes tight deadlines, often requiring a state response within a certain number of days, it is imperative for the business contact to notify internal or outside counsel as quickly as possible.

For example, the Washington public records law provides that a government representative must respond to a public records request within five business days of receipt. Wash. Rev. Code Ann. § 42.56.520. The Kentucky, Louisiana, and New Mexico public records laws require a response within three business days. Ky. Rev. Stat. Ann. § 61.880; La. Stat. Ann. §

44:32; N.M. Stat. Ann. § 14-2-8. So the turnaround time for the owner of the information to object or take other required action is thus even shorter in many cases.

In turn, the action required to prevent or postpone disclosure can also vary considerably by state. For example, in some states, agencies are required to disclose the requested information by default, unless a court order to the contrary is obtained. In other states, the burden is reversed, requiring the requester to obtain a court order requiring disclosure if the owner of the information has objected to disclosure. For example, the Washington public records regime requires the manufacturer challenging disclosure to obtain an injunction to block disclosure. In contrast, a Pennsylvania state court has ruled that "the burden of proving that a requested piece of information is a 'public record' lies with the requester." Barkeyville Borough v. Stearns, 35 A.3d 91, 94 (Pa. Commw. Ct. 2012).

In this process, the role of the state attorney general's (AG) office, as counsel for the agency at issue, also varies by state. In many states, the AG's office at least nominally has the authority to oppose the public records request on the owner's behalf. See, e.g., Wash. Rev. Code Ann. § 42.56.540 (granting agencies and their representatives the authority to enjoin disclosure). AGs offices rarely do so, however, because states frequently face steep statutory penalties for inappropriately opposing a public records request. See, e.g., Wash. Rev. Code Ann § 42.56.550 (imposing fines up to $100 for each day that public records are wrongfully withheld).

Protective Actions

Against this legal backdrop, there are steps and considerations for manufacturers to bear in mind both when initially disclosing sensitive information to a state agency, and when confronted with a third party's public records request for that information.

Precautions

To reduce the risk of disclosure, manufacturers can take a number of precautions prior to, or concurrent with, submission of their confidential business information to state agencies. To begin, manufacturers can request state representatives to sign non-disclosure agreements before providing sensitive information. Manufacturers can also explain why certain information in their submissions warrants protection from disclosure by submitting confidential treatment request letters or forms, which are sometimes included as part of the standard package requested by a state RFP.

Indeed, some bidding processes expressly call for the submission of a version of the RFP or other bid response that redacts any sensitive information. This redacted version would be the "public" version, subject to disclosure under a public records request, whereas the unredacted version would be considered protected. Whether the agency's process calls for these measures or not, a manufacturer can preemptively request these kinds of protections and seek the agency's agreement to such terms.

Defenses

If a third party makes a public records request, a manufacturer has a number of avenues for recourse. Again, however, the manufacturer must act fast. As an initial matter, the manufacturer can negotiate with the state agency to request a deadline extension to allow it time either to reach negotiated resolution with the requester or, if necessary, seek relief from the courts.

In the course of these negotiations, the manufacturer should also gauge the state's position on whether the requested information is exempted from disclosure and its willingness to protect the manufacturer's information or at least postpone disclosure. Second, the manufacturer can negotiate with the requestor to prevent or minimize disclosure. Such negotiations may involve alerting the requestor to applicable exemptions and protections, and potentially proposing a "lesser-redacted" version that may satisfy the requestor's needs.

Finally, the manufacturer may have to pursue litigation to block disclosure. In states where disclosure is automatic absent a court order, the manufacturer will likely have to submit a complaint and motion for temporary restraining order or preliminary injunction prior to any automatic disclosure deadline. If the burden is on the requestor, the manufacturer typically can wait to see if the requester files an action to compel disclosure.

In either scenario, the manufacturer should ascertain whether the state will take a position in the litigation or if they will act as a neutral party in the dispute. No matter what litigation strategy the manufacturer uses, a full legal analysis of the

strengths of the applicable exemptions and related law, coupled with an evaluation of the potential harm from disclosure, will be important in formulating a legal plan and negotiating a possible resolution.

Manufacturers may also keep in mind that the public records request might impact other manufacturers who submitted response to the same RFP, so collaboration with common interest counsel may be appropriate under some circumstances.

Conclusion

Despite the unwelcome prospect of public records requests for their competitively sensitive information, manufacturers can prepare themselves to mitigate those risks by understanding the applicable legal and practical landscape and negotiating the best protections available, while they pursue government partnerships and comply with reporting requirements.