States May Be Moving To Expand The Federal Sunshine Law

Law360, New York (July 11, 2014, 10:42 AM ET) -- Although it has been over a year since the Centers for Medicare and Medicaid Services released the final rule implementing the federal Physician Payment Sunshine Act, states continue to analyze the extent to which existing laws are preempted and, in some instances, have even sought to impose new reporting requirements that avoid preemption by focusing on health care providers other than physicians and teaching hospitals.

Some states with disclosure laws predating the Affordable Care Act, like Vermont and Massachusetts, declared early on that preemption prohibits state agencies from requiring manufacturers to disclose information that has already been reported to the federal government under the Sunshine Act. Minnesota, on the other hand, repealed its pre-ACA disclosure statute and subsequently instituted new requirements. And now, for the first time since the Sunshine Act went into effect, one state has passed a new disclosure law that avoids preemption altogether.

This article provides an overview of recent changes and clarifications to state transparency laws following passage of the Sunshine Act.

The most significant state disclosure development since the ACA is in Connecticut, a state which, prior to the Sunshine Act, had not instituted a payment reporting requirement applicable to pharmaceutical and device manufacturers. On May 8, 2014, Connecticut Gov. Dannel Malloy signed into law a new statute requiring U.S. pharmaceutical and medical device manufacturers to disclose on a quarterly basis payments or other transfers of value to advanced practice registered nurses practicing in the state. The disclosure law was enacted as part of a broader bill that provides greater practice independence to certain APRNs who have been licensed and practicing in collaboration with a physician for at least three years.

Specifically, the new Connecticut law requires applicable manufacturers to report, with respect to payments to APRNs, the same information as that required under the Sunshine Act for payments or transfers of value to physicians and teaching hospitals and uses similar terminology such as “applicable manufacturer” and “payments or other transfers of value.” However, because the law applies to payments to APRNs, and not physicians or teaching hospitals, it is not preempted.

The new law takes effect on Oct. 1, 2014, with the first report due by Jan. 1, 2015. However, there is a Connecticut bill, HR 5597, which could delay this deadline to July 1, 2015, if signed into law. It remains to be seen whether implementing regulations will be promulgated under the new statute. A different but related Connecticut law requiring pharmaceutical and device manufacturers to implement codes of conduct by Jan. 1, 2011, has yet to be implemented by regulation.

In states with pre-ACA disclosure laws in place, the key challenge for manufacturers has been understanding the extent to which preemption applies and which state requirements, if any, remain in place. For example, the Minnesota Board of Pharmacy undertook two important actions to interpret the impact of the Sunshine Act’s preemption provision on its state reporting requirements. On Jan. 8, 2013, the board stated that drug wholesalers and manufacturers would

not be required to file annual reports identifying compensation provided to health care practitioners in Minnesota for the 2012 calendar year "since the vast majority of data that has been reported under our state law is information covered by the [Sunshine Act]." The board also requested that the state legislature repeal the statutory provision that required such annual reports. While the Minnesota legislature subsequently repealed the disclosure requirements, it then enacted a new provision requiring annual reporting of certain research-related and conference payments paid to health care practitioners in Minnesota, "[u]nless prohibited by" the Sunshine Act. Shortly thereafter, the board released a memorandum, stating that "the clear legislative intent this session was for the board to continue collecting data concerning payments made to practitioners other than 'physicians.'" In other words, the state affirmed its ability to collect confirmation information related to health care practitioners where preemption does not apply.

Similarly, Massachusetts has clarified that its disclosure law is only partially preempted. Under the Massachusetts law, both pharmaceutical and device companies must disclose to the state's Department of Public Health all economic benefits with a value of at least $50 to any person or entity authorized to prescribe, dispense or purchase drugs in the commonwealth. Just prior to publication of the final rule, Massachusetts' regulations were amended to explain that manufacturers were no longer required to report to the state Department of Public Health "information ... that has been disclosed to a federal agency pursuant to a federal law" (i.e., payments or transfers of value to physicians and teaching hospitals reported to CMS under the Sunshine Act).

Massachusetts has also attempted to harmonize its disclosure requirements with those set by the federal government, but with limited success. For example, the Sunshine Act's reporting obligations are limited to manufacturers of "covered" products, and CMS has provided a grace period of 180 days for first-time manufacturers to begin complying with the final rule's data collection and reporting requirements. The Massachusetts Department of Public Health adopted a similar position for research-stage companies, stating that "[t]he department's regulation applies only to companies that have at least one commercially available product. The regulations do not apply do research-stage companies that do not manufacture or market any FDA approved or cleared devices." However, the department failed to address whether Massachusetts will afford the same 180-day grace period to new manufacturers as provided under the final rule. Thus, the question remains whether payments or transfers of value to Massachusetts physicians need to be reported to the state during this 180-day period, despite not being required by CMS.

Connecticut's recent statutory addition demonstrates that the number of state disclosure laws may still be growing, particularly with respect to payments or benefits conferred to nonphysician health care practitioners. For example, the New York Legislature has introduced a bill that would require drug manufacturers and wholesalers to disclose all gifts with a value of $75 or more to health care practitioners authorized to prescribe drugs, subject to certain exceptions. Although it is unclear whether states like New York will ultimately follow Connecticut's lead, manufacturers should nonetheless position themselves to adapt quickly by maintaining flexibility in their internal payment tracking systems and rigorously monitoring federal and state transparency law developments.

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