The Final Sunshine Rule's Impact on Teaching Hospitals

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On February 1, 2013, the Centers for Medicare & Medicaid Services (CMS or the Agency) released the long-awaited Physician Payment Sunshine Rule (Sunshine Rule), which implements Section 6002 of the Affordable Care Act (Sunshine Act).[1] The Sunshine Rule will require manufacturers of drugs, devices, and other medical supplies (Applicable Manufacturers) to track and report certain payments that they make to physicians and teaching hospitals (Covered Recipients). In addition, the rule will make available to the public information about physicians' (and physicians' immediate family members') ownership and investment interests in Applicable Manufacturers and group purchasing organizations (GPOs).

CMS issued the proposed rule on December 14, 2011, and received 373 comments from the public.[2] In May 2012, CMS anticipated that it would release the final rule no later than the end of 2012, and indicated in its official blog that it would not require Applicable Manufacturers or GPOs to collect data until January 2013.[3] Because of the Agency's continued delay, Senator Charles Grassley (R-IA) and former Senator Herb Kohl (D-WI), the Sunshine Act's co-authors, and stakeholders put pressure on the Obama Administration in recent months to issue final regulations. Many of those stakeholders continued to be critical of CMS' proposals; however, many also wanted to see the final rule so that they would have adequate time to prepare for implementation. The Agency responded by releasing the final rule at the beginning of February.

The final rule represents CMS' attempt to meet several primary objectives. For example, the Agency wanted to increase the transparency of financial ties between industry, teaching hospitals, and physicians and to reduce conflicts of interest that "may influence research, education, and clinical decision-making in ways that compromise integrity and patient care, and might lead to increased health care costs."[4] In addition, the Agency wanted to educate patients about the nature and scope of their caregivers' financial relationships with industry. At the same time, CMS did not want to discourage stakeholders from collaborating in ways that have previously had a positive impact on the provision of healthcare, including improvements in patient care, new drugs and medical devices to diagnose and treat diseases, and increased education about products. This article highlights some of the ways in which CMS' decisions will affect teaching hospitals (and to some extent, physicians) and considers the real impact that the rule will have on healthcare going forward.

Impact on Teaching Hospitals

Teaching hospitals have a long history of collaborating with industry on clinical research, educational matters, and other matters, and likely will be subject to stricter public scrutiny for that collaboration once data about payments and transfers of value they receive becomes publicly available under the Sunshine Rule. While some stakeholders are concerned that this increased scrutiny may chill the relationships between teaching hospitals and industry, others are fairly supportive of the goals the rule aims to achieve. For example, the Association of American Medical Colleges (AAMC), a nonprofit association representing all 136 U.S. medical schools and nearly 400 teaching hospitals and health systems, has commented that a "critical component of these principled relationships [between academic medical centers and industry] is the transparency of their interactions."[5] AAMC also suggested that the posting of information about these relationships in a place where it can be viewed by the public will help to increase patients' understanding of the scope of these relationships, but warned that the information posted must be accurate and include sufficient context for it to be meaningful.[6]

CMS appears to have been fairly responsive to comments from teaching hospitals in certain areas in the final rule, as the Agency finalized a number of provisions that will have a positive impact on these institutions going forward. One can see the Agency's willingness to compromise in a number of areas, including: (1) CMS' clarification that teaching hospitals will not be considered "Applicable Manufacturers"; (2) the Agency's willingness to identify teaching hospitals that will be subject to this rule; and (3) the Agency's agreement to simplify the process related to reporting research payments. At the same time, CMS was less accommodating in other areas, such as the time that teaching hospitals and physicians will have to review and correct data submission before it is published. Each of these areas is described below.

Definition of "Applicable Manufacturer"

During the comment period, stakeholders expressed concerns that the definition of "Applicable Manufacturer" found in Section 1128G of the Social Security Act[7] might inadvertently capture teaching hospitals, hospital-based pharmacies, and laboratories because they engage "in the production, preparation, propagation, compounding, or conversion of covered drugs and devices."[8] In such case, it appeared that teaching hospitals would be responsible for collecting and reporting data about payments and other transfers of value to physicians in the same way as drug and device manufacturers. This responsibility would have imposed a tremendous administrative burden on teaching hospitals, but would not have enabled CMS to achieve the rule's stated goals.

In the final rule, CMS agreed to revise the definition of Applicable Manufacturer so that it does not include hospitals, hospital-based pharmacies, and laboratories that manufacture a covered product "solely for use by or within the entity itself or by an entity's own patients."[9] The Agency reasoned that the statute did not intend

to include these entities since the statute did not specifically identify them in its list of manufacturers. Because of this revision, teaching hospitals will be relieved of having to collect and report any data for purposes of the Sunshine Act—a big "win" for these institutions under the final rule.

List of Teaching Hospitals

In the proposed rule, CMS proposed to publish a list of teaching hospitals on its website. Stakeholders, including AAMC, generally supported this proposal, and CMS appears to have finalized it without hesitation. In addition, CMS agreed to update the list annually and include on the list hospital Taxpayer Identification Numbers "to provide more specific information on hospitals with complex corporate identities."[10]

The posting of a list of teaching hospitals will benefit both teaching hospitals *and* non-teaching hospitals. Under the final rule, teaching hospitals are defined as hospitals that receive Medicare direct graduate medical education or indirect medical education payments. First and foremost, the list will provide sufficient clarity to identify which institutions are covered by this final rule during an applicable reporting year. Therefore, hospitals will be put on notice about exactly when their financial relationships will be made available to the public in some manner and when they will need to participate in the post-submission review process to confirm that reportable data is accurate. Additionally, hospitals that are not considered to be teaching hospitals for purposes of this rule will not have to worry that Applicable Manufacturers will report payments to those institutions for public viewing. Given that many Applicable Manufacturers might conservatively have reported information about payments to more than just teaching hospitals if they not had a clear way to discern which institutions were "Covered Recipients," this appeared to be a possibility.

Reporting Research Payments

Teaching hospitals were particularly concerned that the way in which CMS proposed to account for research payments would cause reports to be misleading, excessive, and out of context. Under the proposed rule, both the institutions that received a payment related to research *and* the principal investigator (PI) responsible for conducting the research would be credited as having received the full amount of payment. If PIs were viewed as personally receiving significant lump sum payments from industry (more than the amount necessary to cover their own time and expenses), they might become concerned that their patients would have reasons to question the integrity of the clinical decisions and ultimately be discouraged from participating in research. If this happened, teaching hospitals would suffer because fewer physicians would be available to run their research programs.

AAMC, one of the strongest proponents for clarification in this area, was especially concerned that this proposal would "mischaracterize the relationship between the manufacturer and the physicians conducting the research."[11] In its comments to the proposed rule, the advocacy group contended that research-related payments made only to academic medical centers should be attributed to those institutions and should not simultaneously [and in full] be attributed to individual PIs.[12] The advocacy group also noted that when an industry sponsor provides funding to an academic institution for research purposes, the payment covers many expenses in addition to compensation for the PI, including equipment, support and research staff, and facility overhead cost, and suggested that the PI does not always have control over all of those funds.[13]

CMS was responsive to these comments by "simplifying" the way in which research-related payments will be reported and calling for a separate template for research-payment data. The Agency's willingness to compromise was another "win" for teaching hospitals. Applicable Manufacturers must list the entire research payment, along with the institution and the lead physician researcher, but will not be required to name each doctor who worked on a study. They will also have the option of listing additional contextual information on, or the objectives of, the research. These modifications should ease concerns that the rule would discourage physicians from engaging in clinical research.

Post-Submission Review Period

Teaching hospitals and other stakeholders, such as physicians, have expressed concerns that their reputations could be damaged if reports of payments they have received are not accurate or are otherwise misleading. Section 1128G(c)(1)(D) of the Social Security Act[14] requires that CMS provide a minimum of 45 days to allow Covered Recipients to review and correct data that has been submitted to the Secretary of the U.S. Department of Health & Human Services (HHS) before it is published. In the proposed rule, CMS suggested implementing a 45-day period and allowing Covered Recipients to review and amend data from the current and previous years.

During the comment period, Covered Recipients requested an extended review period (perhaps 60 or 90 days), as well as the chance to restrict the public's access to disputed information. In addition, stakeholders asked CMS not to publish data that was disputed or, alternatively, to publish the recipient's data alongside the manufacturer's data when the parties disagreed over the correct amount or context of a payment. CMS accommodated some of these comments and declined to adopt others.

Under the final rule, Covered Recipients will only have 45 days to review and dispute payment information that Applicable Manufacturers submit to CMS. Once they review the information, CMS will allow them to have the remainder of that 45-day period and the subsequent 15-day period to agree with the party that made the payment upon the correct payment amount. Thereafter, the data will be published. In the event that Covered Recipients and Applicable Manufacturers agree upon corrected data following this 60-day period, it is unlikely that the public version of the data will be corrected until the following year. This leaves teaching hospitals and physicians with little control over what information is actually published about them. CMS also declined

to restrict the public's access to disputed data or to publish both parties' data when it was being disputed. However, the Agency will flag data that is in dispute, which is positive for stakeholders.

Both teaching hospitals and physicians are concerned about the accuracy of data that is made publicly available, especially given that their reputations are at stake and they have limited control over what data is ultimately posted on the public website. However, they should rest assured that Applicable Manufacturers have incentives to ensure that data is accurate when it is published. For example, under the final rule Applicable Manufacturers are required to attest in good faith to the accuracy and completeness of their original submissions. If the data is later disputed and corrected, they must re-attest after the submission of updated or new data. They may face a civil monetary penalty for "failure to report information in a timely, accurate, or complete manner."[15] In addition, both CMS and the HHS Office of Inspector General will be authorized to investigate Applicable Manufacturers and GPOs for failures to report timely, accurate, or complete data.

Overall Impact

Many policymakers supported the enactment of the Sunshine Act as part of healthcare reform and the implementation of the Sunshine Act through subsequent rulemaking. In the end, however, it remains unclear what the Sunshine Act and final rule will really accomplish. For example, many question whether the final rule will meet the objectives it was designed to achieve; whether it will impede continued collaboration between industry, teaching hospitals, and physicians; and how the rule will interplay with other laws, rules, and polices that are already in place to discourage inappropriate financial relationships and to require the reporting of appropriate ones.

CMS intends that this final rule will put patients in a better position to evaluate relationships between physicians, teaching hospitals, and industry. However, there are valid questions about whether patients are familiar enough with these types of relationships to interpret the data and determine whether their physicians or hospitals actually could be biased toward one Applicable Manufacturer or another (and, as such, whether they may unnecessarily lose faith in their physicians' clinical judgment). There are also valid questions about whether any patients will ever choose to review the data. Perhaps patient education is necessary to best ensure that they benefit from the collection and reporting of data under this rule.

There are also questions about how the final rule will impact teaching hospitals and physicians, including whether the rule will discourage these parties from collaborating with industry and how the rule will ultimately impact patient care. It is possible that the final rule will cause bias in the clinical setting to be reduced significantly and lead to further improvements in quality of care. At the same time, it is possible that Applicable Manufacturers will be less likely to provide certain resources to hospitals and physicians for fear of how their own reputations will be affected by required disclosures. This will force recipients to provide those resources internally or obtain them from a different type of organization. Perhaps the final rule will have no material impact in any of these areas at all.

Finally, given that there are other enforcement mechanisms and policies in place to restrict improper financial relationships and conflicts of interests, there are questions about whether this final rule is really necessary at all. For example, the federal Anti-Kickback Statute prohibits the exchange (or the offer to exchange) of anything of value in an effort to induce or reward the referral of federal healthcare business and, in effect, already limits the size and scope of payments between industry and Covered Recipients.[16] In addition, many teaching hospitals already have in place internal conflicts-of-interest policies that help to maintain the integrity of financial relationships involving the institution. Many states also have their own sunshine rules that require the collection and reporting of certain payment data. While CMS is clear that the federal rule will preempt the states' rules, there are circumstances when this preemption will not occur (such as when there are public health purposes behind the state law). Therefore, adding another layer of reporting obligations might simply add burden to, or cause confusion for, stakeholders, rather than create an independent and positive impact.

Conclusion

Applicable Manufacturers must begin collecting reportable data on August 1, 2013, and must submit data from 2013 to CMS by March 31, 2014. This data will be available to the public by September 30, 2014. Therefore, regardless of what impact the Sunshine Rule might have on healthcare going forward, it is clear that affected stakeholders will need to begin putting certain internal protocols in place now so that they will be prepared to meet the myriad of new obligations that are here to stay.

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1 Medicare, Medicaid, Children's Health Insurance Programs; Transparency Reports and Reporting of Physician Ownership or Investment Interests; Final Rule, 78 Fed. Reg. 9458 (Feb. 8, 2013).

2 Medicare, Medicaid, Children's Health Insurance Programs; Transparency Reports and Reporting of Physician Ownership or Investment Interests; Proposed Rule, 76 Fed. Reg. 78742 (Dec. 19, 2011).

3 *Available at* http://blog.cms.gov/2012/05/03/information-on-implementation-of-the-physician-payments-sunshine-act/.

4 78 Fed. Reg. at 9459.

5 Letter from Ass'n of Am. Med. Coll. to Acting Adm'r Marilyn Tavenner (Feb. 17, 2012) (on file with author).

6 *Id.*

7 42 U.S.C. § 1320a-7h(e)(1).

8 *See* 78 Fed. Reg. at 9461.

9 *Id.*

10 78 Fed. Reg. at 9470.

11 Letter from Ass'n of Am. Med. Coll. to Acting Adm'r Marilyn Tavenner, *supra* note 5.

12 *Id.*

13 *Id.*

14 42 U.S.C. § 1320a-7h(c)(1)(C)(ix).

15 78 Fed. Reg. at 9506.

16 *See* 42 U.S.C. § 1320a-7b.