



The Honorable Marilyn Tavenner
Administrator
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

August 31, 2014

Re: Revisions to the Sunshine Act Under the Medicare Physician Fee Schedule for CY 2015, CMS-1612-P

Dear Administrator Tavenner:

It is our pleasure to submit these comments on behalf of Rockpointe, Inc. (www.rockpointe.com) regarding the proposed changes to the February 8, 2013 Final Rule to implement Section 6002 of the Affordable Care Act (the Physician Payments Sunshine Act). Specifically, we have tailored our comments to address CMS's proposal to remove 42 C.F.R. § 403.904(g)(1), the accredited-continuing medical education (CME) exemption, from the Final Rule.

Founded in 1995, Rockpointe is a privately held business with twenty-nine employees located in Columbia, Maryland. Through its subsidiary company, Potomac Center for Medical Education (PCME), and other accredited organizations, Rockpointe/PCME plans and implements accredited CME activities for physicians, pharmacists, and nurses. Rockpointe/PCME is accredited by the Accreditation Council of Continuing Medical Education (ACCME) and the Accreditation Council for Pharmacy Education (ACPE).

Analysis of CMS's Proposal

We support the objective outlined in CMS's statement accompanying the proposed rule that "if an applicable manufacturer conveys 'full discretion' to the continuing education provider, those payments [should be] outside the scope of the rule," and thus not reportable. However, we are very concerned that the actual language being proposed by CMS could cause considerable confusion as written, and might be interpreted to *eliminate* the current reporting exemption for these programs for physician speakers, faculty, and attendees. Such an outcome would have devastating consequences for the practice of CME and patients.

CMS states that its motivation in eliminating the specific CME exemption is to “create a more consistent reporting requirement” and avoid the “apparent endorsement or support to organizations sponsoring continuing education events.” Its remedy, according to CMS, would result in an outcome whereby “payments... where an applicable manufacturer conveys ‘full discretion’ to the continuing education provider... [would be] outside the scope of the rule.”

Although this intended outcome seems to indicate CMS’s willingness to *expand* rather than *eliminate* the reporting exemption for CME payments, because the exemption would no longer be limited to programs accredited by the five enumerated bodies of § 403.904(g), we fear that the opposite outcome will result. Indeed, unless CMS explicitly states otherwise, CMS’s proposal to replace the CME exemption with the “indirect payment” carve-out at § 403.904(i)(1) would subject CME payments to reporting if a commercial supporter (manufacturer) becomes “aware” of the identity of the program’s speakers, faculty, or attendees within 18 months of its grant to the CME provider. Given the public nature of CME programs and the broad knowledge standard CMS has adopted, this is a virtual surety. In addition, since CMS is proposing to implement this change in 2015, it could retroactively force commercial supporters to report indirect payments made as long ago as Q3 2013, which would be a large administrative challenge and could even implicate constitutional concerns related to reasonable notice.

Without further clarification that specifically exempts accredited CME payments from the reporting requirement in the actual rule, rather than the preamble, we believe the decision to simply eliminate section 403.904(g) would have the following consequences:

1. Speakers/Faculty

CMS states that indirect payments to speakers at continuing education events will be exempt from reporting in its proposed *preamble*, not in the actual rule. This is unreliable from a legal standpoint. Accredited CME payments could easily be interpreted instead as a reportable “indirect payment.” CMS suggests that its intent is to consider these payments “indirect payments” in order to avoid redundancy. Under the current Final Rule, however, indirect payments must be reported if the applicable manufacturer becomes aware of the identity of the recipient within up to 18 months of the payment. CME presenters are always publicly listed. It is unreasonable to assume that a commercial supporter will remain unaware of their identity.

Reporting faculty payments has the potential to grossly misrepresent the relationships between CME providers, faculty, and manufacturers. Faculty are chosen exclusively by the accredited CME provider. When a manufacturer provides funding to an accredited provider, it has no say in which faculty the provider chooses or how much honoraria and related payments the provider gives to faculty. The Open Payments system would publicly link a physician to a manufacturer with whom they have no direct or financial relationship. In fact, faculty may never have heard of the manufacturer before the accredited CME provider informs them of the funding source, since the CME provider both seeks the CME funding and makes the payments to the faculty.

2. Attendees

Current CMS guidance provides that physician-attendees at CME programs are only exempt from reporting for the educational value (or ancillary items) provided at accredited CME events per Section §403.904(g). The new proposal brings into question the entire status of attendees. The educational value that physicians receive from these programs may have to be considered an “indirect payment.” CMS should clarify that this reporting exemption still exists for attendees or users of bona fide CME programming. Otherwise, it will be literally impossible for commercial supporters to attempt to accurately calculate, track, or report the “value” of the educational experience for any given physician participant. Further, forcing manufacturers to require accredited CME providers to track and report to the manufacturer specific physician information about their participation or attendance is generally prohibited under current standards for commercial support and otherwise blurs the strong firewalls CME providers have in place to ensure the integrity of their programs.

3. Unreasonable Burden on CME Providers in Conflict with ACCME Standards

Under current standards, accredited providers are not obligated to disclose any specific information on payments made to individual faculty. The proposed rules would require such reporting, and in doing so put upon Rockpointe and other providers of CME new and significant responsibilities to track payments based on applicable manufacturer reporting needs, not based on accrediting requirements. In fact, the proposed regulations are in direct conflict with the requirements of the ACCME Standards for Commercial Support as they would require accredited providers to report details of faculty relationships, an action that would cross the

line needed to maintain independence from applicable manufacturers providing a CME grant.

Rockpointe's Proposal

CMS's previous well-defined exemption sent a clear message to physicians that they could present at, and attend, accredited or certified CME programs without later finding themselves publicly reported in the Open Payments system as recipients of payments from applicable manufacturers. Without specific language pertaining to accredited CME events, the effect of the Sunshine Act on manufacturers, CME providers, and physicians remains unclear. This uncertainty will only serve to chill CME participation. We are very concerned that doctors will simply avoid CME events because they fear the stigma attached to having their name publicly reported as receiving "payment" from an industry sponsor.

Thus, we recommend that CMS explicitly define "accredited or certified continuing education program" to include all bona fide CME/CE programs. There are more than a dozen accrediting organizations that have adopted the ACCME Standards for Commercial Support word for word.

These standards require CME/CE providers to make all decisions regarding the disposition and disbursement of commercial support and prohibit applicable manufacturers from:

- **Selecting or paying the covered recipient speaker or faculty directly;**
- **Providing the CME provider with a distinct, identifiable set of covered recipients to be considered as speakers or faculty;**
- **Controlling the CME content; or**
- **Influencing, inviting, or selecting the covered recipient-attendees or otherwise conditioning its financial sponsorship on the participation of particular attendees.**

Perhaps most importantly, the **ACCME has extensive monitoring and enforcement powers**. If CME providers do not adhere to these rigorous standards, the ACCME will remove their accredited status and such providers will no longer enjoy exemption from Sunshine reporting.

Rockpointe urges CMS to modify their proposal to **exclude** from the Open Payments program any reporting where companies have embraced the standards outlined above. Alternatively, CMS could exclude continuing activities where the industry donor is unaware of the speakers and participants **before committing to**

fund the activity. As noted above, the 18-month retroactive awareness definition under CMS' proposed indirect payment standard is unduly burdensome.

Rockpointe/PCME's Mission and Current Policies

Our mission is to create clinically relevant and evidence-based educational interventions which are objective and balanced. These interventions seek to bridge professional practice gaps and enhance physician competence. Physicians must stay up to date with the latest medical research and medications so they can provide the most appropriate care to their patients. Each year, this research results in new treatment breakthroughs, medications, diagnostic procedures, and clinical guidelines. Continuing medical education is a vital way for physicians to stay informed about the latest, most-effective treatments.

As outlined in our discussion of the ACCME Standards for Commercial Support, the CME industry is heavily regulated to ensure the utmost compliance with all regulatory requirements and to ensure fair and balanced education. As an accredited provider, Rockpointe/PCME strictly adheres to all of the ACCME Standards when applying for and receiving grant funds, handling conflicts of interest, developing CME content and procedures, and reviewing programs. Rockpointe is not involved, directly or indirectly, with any promotional activities related to the sale of commercial products, or otherwise, for pharmaceutical or medical device companies. All Rockpointe/PCME-sponsored CME/CE activities are therefore objective, balanced, scientifically rigorous, and absent of commercial bias and influence

Many of the educational activities Rockpointe/PCME develops are supported by grants funded by pharmaceutical and medical device companies. To ensure impartiality, grants from applicable manufacturers (referred to as "commercial interests" by the ACCME) are obtained and implemented by a highly regulated, systematic, and structured process established by the ACCME that requires independence from industry influence, involvement, and control. Pursuant to these mandates, applicable manufacturers that fund grants have absolutely no involvement in the educational activity planning, implementation, and outcomes that are realized with awarded grant funds. This includes grant budgets, faculty honoraria, and expenses.

Educational grants are awarded to Rockpointe/PCME based on grant applications submitted to these commercial entities (pharmaceutical, medical device companies, and biologic companies). Grant applications are 30 to 35 page documents that

address specific educational needs of medical practitioners and patients and offer detailed logistical information concerning proposed educational activities. Each grant request includes a thoroughly researched and referenced assessment of the educational need developed by the science and medical staff of Rockpointe/PCME in consultation with practitioners, researchers, and educators utilizing government data and reports on patient and physician needs.

Grant requests are typically submitted to more than one company, and each request includes a budget for the proposed educational activity that details all of the professional service fees (staff time) and direct expenses necessary for the implementation of the proposed activity. Once an activity is approved for funding, in strict accordance with ACCME and government standards, Rockpointe/PCME does not allow commercial supporters to place any requirements or restrictions on program content. Letters of agreement between the grantor and grantee specify that funds must be used for the intended purpose and in accordance with all ACCME policies and practices. Many grantors require a financial reconciliation at the conclusion of each project.

Each agreement between an accredited CME provider and manufacturer must clearly acknowledge the provider's complete independence and control over every aspect of the supported CME activity. These agreements also state that there can never be any input, direction, or involvement of the supporting manufacturer in the selection of faculty, determination or creation of educational content, or educational design of the intended CME activity.

Conclusion

In its proposed change to the Final Rule, CMS states that replacing the CME exemption with the indirect payment standard "is consistent with our discussion in the preamble to the final rule, in which we explained that if an applicable manufacturer conveys 'full discretion' to the continuing education provider, those payments are outside the scope of the rule." However, as described above, Rockpointe is concerned that if these payments are indeed to be covered under the rules governing "indirect payment," they will, as a practical matter, *lose*, rather than *maintain*, their current reporting exemption.

Payments made by CME providers to faculty of CME programs should be exempt from publication because there are already sufficient industry guidelines in place that ensure transparency, independence, and accountability within the CME community. The publication of such payments would be detrimental to Rockpointe

and other CME providers in many ways, including finding sufficient subject-matter expert faculty, planning and budgeting high-cost and high-quality CME, and soliciting funding. Any benefit that might be gained from requiring the publication of these payments is simply not matched by the predictable, negative impact on this vital component of our healthcare system, and we urge you to protect or expand the CME reporting exemption in your final rule.

We thank you very much for this opportunity to share our comments.

Sincerely,

Thomas Sullivan
President

Jay Katz
CEO