INTRODUCTION

Founded in 2011, The Continuing Medical Education (CME) Coalition (cmecoalition.org) is a Washington-based organization comprised of CME providers, beneficiaries (including both educational institutions and professional societies), and supporters of CME (such as pharmaceutical manufacturers and device makers) that exists to advocate for the merits of continuing medical education. Additional partnerships and affiliations have also been extended to health policy thought leaders and other interested parties who share an appreciation for the mission of the organization.

THE MISSION

The mission of the CME Coalition is to: (1) educate federal, state and third-party policy makers on issues related to the provision of CME, (2) monitor policy initiatives of government and non-governmental actors that could impact CME, and (3) advocate for sensible federal, state, and non-governmental actors’ policies to advance its practice. The CME Coalition fulfills this mission by developing, managing, and implementing a comprehensive government affairs and public affairs strategy to promote the benefits of accredited CME.

The Coalition additionally serves as a vital informational, analytical, and legal resource for member organizations seeking assistance with understanding and implementing the myriad, and ever changing, rules and regulations that guide the CME enterprise. It is a recognized thought leader and participates in numerous activities, programs, and venues to better inform all CME stakeholders of the policy landscape and real world trends impacting the enterprise.

A BIG WIN IN 2016

While we can count many victories since our founding, none was bigger than securing a clarification from the Centers for Medicare & Medicaid Services (CMS) regarding the limitation of Open Payments reporting rules to only those activities where a commercial supporter “instructs, directs or otherwise causes” payment to be made to a specified physician. In September 2016, in response to its engagement with the CME Coalition, CMS posted sub-regulatory guidance on its Open Payments website regarding the reporting of CME-related payments. This outcome could not have been accomplished without the active support and cooperation of many other allies, including the Alliance for Continuing Education in the Health Professions, the American Medical Association, the Council of Medical Specialty Societies, the ACCME, and key Members of Congress.
The revised “FAQ 8165” replaces an earlier “Frequently Asked Question” on the same subject by providing greater specificity with regard to the exclusion of certain CME-related payments from Sunshine Act reporting that meet the standards outlined by CMS. This clarity has provided the CME community with a renewed confidence in CMS’ interpretation of the issue and has led to a broadening consensus among commercial supporters concerning their collection and reporting of CME related data.

However, there is still considerable work ahead in this regard if we are to succeed in driving complete consensus among CME stakeholders regarding the Open Payments rules. We must continue to explain, convince, and advocate. Towards that end, and along with the Coalition’s legal counsel, in 2016 we conducted numerous calls and hosted programs with stakeholders to review the new FAQ and what it means for the CME community. For reference, we have included the FAQ at the end of this document.

**Other 2016 Accomplishments**

**House Passes Legislation to Exempt CME and Journal Reprints, But We Come Up Just Short in the Senate:** Last year, the CME Coalition led the charge for congressional legislation to exempt payments related to CME and journal reprints from the Sunshine Act reporting requirements: H.R.293 was introduced in the House of Representatives by Rep. Peter DeFazio (D-OR) – one of the original authors of the Sunshine Act – and Rep. Michael Burgess (R-TX), while S.2978, The Protect Continuing Physician Education and Patient Care Act, was introduced by Sen. John Barrasso (R-WY). Although the House passed our bill as part of its version of the 21st Century Cures Act, the CME provisions were stripped from the final version that passed the Senate and went to the President (Obama) for his signature. As a result, commercial supporter–provided peer-reviewed journals, journal reprints, journal supplements, medical conference reports, and medical textbooks remain reportable to CMS, as before. In retrospect, the Coalition nearly took this legislation across the finish line the first time it was introduced – which represents a rare feat – and we remain confident that the political landscape in 2017 will prove even more favorable to our chances for success.

**Leading a Campaign for CME in MIPS/MACRA:** In 2016, the CME Coalition initiated a stakeholder campaign to drive CMS to define a specific role for continuing medical education in the context of the new Medicare physician quality measurement system, known as the Merit-Based Incentive Payment System or "MIPS." Both a proposed and final rule implementing the underlying statute – the Medicare Access and CHIP Reauthorization Act of 2015, or MACRA – was promulgated by CMS in the second half of the year. The CME Coalition led a stakeholder campaign that resulted in over 350 individual comments to CMS urging the creation of a role for CME, regularly convened a “MACRA working group” of leading accreditors, physician groups and others, and secured a commitment from the Agency to consider a comprehensive proposal for CME.
**Priority Issues for 2017**

As much as ever, the need for an organization to represent and promote the interests of CME among the nation’s policymakers is crucial. And while there are new opportunities to explain the importance of continuing medical education to our healthcare system to the new Administration and Congress, skeptics of commercially supported CME remain active. At both the federal and state levels, efforts continue to proscribe the traditional role of private industry in funding the ongoing education of medical professionals. At the core, most criticism of private sector support for CME has erroneously presumed that such funding constitutes an inherent conflict of interest and inappropriately influences the decisions of healthcare providers. So we must remain vigilant and continue to champion CME, promote its responsible use, and create opportunities to enhance policy maker support for CME.

We have identified the following priority issues that we will be working on in 2017:

1. **Cementing the Policy Outlined in FAQ 8165 by Driving a CMS Rulemaking:** In order to promote greater certainty around the Open Payment reporting rules, the Coalition will pursue a formal rulemaking through the Department of Health and Human Services to adopt, and supersede, the current FAQ's stated policy to exclude most independent CME support payments. A formal rulemaking, unlike an FAQ, requires an extensive public vetting and commenting process. As such, a determination cannot be easily undone without going through a similar process. As a practical matter, it would bring even greater clarity and certainty to the Open Payment rules, and would help to eliminate any doubts as to the law’s (Physician Payment Sunshine Act) actual requirements. We believe that the current Administration is likely to look favorably upon this request, and we intend to pursue it vigorously.

2. **Exempting Medical Textbooks and Medical Journal Reprints from Open Payments Reporting:** The CME Coalition was a leading force behind bipartisan legislation introduced during the last Congress (in both the House and the Senate) that would have exempted the provision of medical textbooks and peer-reviewed medical journal reprints from Open Payments reporting. We were successful in having this legislation included as part of the House-passed 21st Century Cures Act, but it was removed in conference with the Senate before being presented to the President. We believe that 2017 presents a ripe opportunity to revisit this issue, through both legislative and regulatory means, in order to encourage – rather than penalize – the sharing of medical science findings with healthcare providers as part of their continuing medical education.

3. **Educating the Larger CME Community on the Current CMS Open Payment Guidance:** Confusion within the larger CME community around the rules for reporting remains. While we have worked to educate all parties about the rules for reporting, and specifically about FAQ 8165, some companies are still not interpreting the rules in accordance with the current
guidance. Through individualized outreach when necessary, we will continue to advocate for an industry consensus recognition and interpretation of the Open Payment guidance.

4. **Continuing the Campaign to Include CME in MIPS/MACRA**: Although seemingly arcane and only tangentially related to CME, the development of the MIPS/MACRA system for physician reimbursement under Medicare presents an unprecedented growth opportunity for CME. If CMS explicitly designs a role for CME to play by recognizing relevant activities as “clinical practice improvement activities” within MIPS, it will create an entirely new incentive for physicians to utilize CME and allow CME to play an integral role in physician practice for decades to come. In 2017, the CME Coalition will continue to serve as the lead convener of a broad range of CME stakeholders that will drive an effort to work with CMS to develop and define a role for CME in MIPS. This campaign will necessitate the development of champions on Capitol Hill and within the Trump Administration, as well as a public information campaign to drive broad awareness of the implications and opportunities provided by MIPS.

**Benefits of Membership**

Membership on the Steering Committee offers a seat at the table in determining all Coalition policy and significant decisions (which are determined by consensus). Steering Committee Members are invited to participate in regular monthly calls and populate our task force work groups.

As part of the Coalition, Steering Committee members are often invited to participate in policy meetings and briefing with Administration officials and Members of Congress as issues warrant. Further, Steering Committee Members receive frequent email updates regarding Coalition activities, CME policy developments, and news reports related to CME. Members also have direct access to Coalition staff, which is housed at the Washington-based health policy firm of Thorn Run Partners, who are at their disposal for individualized regulatory and compliance counsel.

The CME Coalition also produces a continuous stream of useful materials for CME practitioners for use by its members, such as regularly updated Sunshine Act Compliance Guides, legal memoranda, FAQs, comments to CMS and ACCME, voluntary industry codes of conduct and press statements on CME related issues. As part of its role as the voice of CME, the CME Coalition is an oft-cited resource in both the trade and “Beltway” media on pressing issues of the day. All of this material may be found at the Coalition’s website, www.cmecoalition.org.

In addition to supporting the Coalition’s extensive advocacy efforts with Washington policymakers and the broader health care provider community, many members also find considerable value in receiving Thorn Run Partners’ regularized health policy updates and analysis, which is provided as an additional benefit.
**Cost of Membership**

With a reasonable rate structure that strives to attract both corporate and non-profit members to our Steering Committee, we are confident that our members enjoy significant benefits of membership and see a real return on their commitment. Annual dues among Steering Committee members range from $15,000 to $2,000 depending upon a member’s annual revenue or nonprofit status. The annual membership dues structure is as follows:

- Annual revenue is under $2.5M per year - annual dues are set at $2,000.00.
- Annual revenue is above $2.5M but under $10M per year - annual dues are set at $7,500.00.
- Annual revenue is above $10M per year - annual dues are $15,000 per year.

If you are interested in learning more about membership, please contact the Coalition’s Executive Director Chris Lamond ([clamond@thornrun.com](mailto:clamond@thornrun.com)) or Senior Advisor Andy Rosenberg ([arosenberg@thornrun.com](mailto:arosenberg@thornrun.com)), who can provide additional information on the next steps to secure your membership.
Q: “If an applicable manufacturer or group purchasing organization (GPO) provides a payment or transfer of value to a continuing education provider to support a continuing education program, but did not require, instruct, direct or otherwise cause (including, but not limited to, ‘encouraging’ or ‘suggesting’) the continuing education provider to provide payments or transfers of value to a specific or particular physician speaker or faculty, would the contribution be considered a reportable payment?

A: No. A payment or transfer of value as described above would not be subject to reporting under Open Payments for any covered recipient physician speakers or faculty. As explained in the Calendar Year 2015 Physician Fee Schedule Final Rule, when an applicable manufacturer or GPO provides funding to a continuing education provider, but does not: (1) select or pay the covered recipient speaker directly, or (2) provide the continuing education provider with a distinct, identifiable set of covered recipients to be considered as speakers for the continuing education program, CMS will consider those payments to be excluded from reporting under § 403.904(i)(1) [revised as § 403.904(h)(i)]. This approach is consistent with our discussion in the preamble to the final rule, where we explained that if an applicable manufacturer conveys ‘full discretion’ to the continuing education provider, those payments are outside the scope of the rule (79 Fed. Reg. 67759). We continued by saying ‘[t]his is the case even if the applicable manufacturer or applicable GPO learns the identity of the covered recipient during the reporting year or by the end of the second quarter of the following reporting year.’ (79 Fed. Reg. 67760).”

The FAQ is posted here: https://questions.cms.gov/faq.php?id=5005&faqId=8165.