



STATEMENT ON PASSAGE OF 21ST CENTURY CURES ACT, MAINTENANCE OF OPEN PAYMENTS REPORTING EXEMPTION FOR INDEPENDENT, INDIRECT CME PAYMENTS

FOR IMMEDIATE RELEASE

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December 8, 2016 – On Tuesday, December 6, the Senate [approved](#), by a vote of 94-5, a wide-ranging biomedical innovation bill called the 21st Century Cures Act ([H.R. 34](#)), which will provide about \$4.8 billion over 10 years in medical research funding, make changes to the FDA's review of medical products, and advance mental health reforms. The bill now heads to the desk of President Obama, who is expected to sign the measure into law. The bill passed the House of Representatives last week.

An earlier version of the bill included language, supported by the CME Coalition, that would have revised the Physician Payments Sunshine Act by declaring that certain transactions to doctors from pharmaceutical and medical device companies would no longer need to be reported through Open Payments as currently required. 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.

At the urging of Senator Charles Grassley (R-IA), the original architect of the Sunshine Act, other language creating a relatively broad exemption for the reporting of “non-promotional” education activities was also removed from the final bill before passage. For CME Coalition members, this decision was of low consequence, however, since the Sunshine Act already excludes reporting for education related payments where a commercial supporter provides a payment to a continuing education provider but “does 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.” Thus, most independent CME support for physicians was, and remains, already exempt from Open Payments reporting.

The current reporting exemption for certain CME payments is described in CMS sub-regulatory guidance [FAQ 8165](#), which is provided below. The FAQ applies to all CME-related transfers of value in 2016.

FAQ 8165

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).”

About the CME Coalition

The CME Coalition represents a broad collection of continuing medical education provider companies, in addition to other supporters of CME and the vital role it plays in the US health care system. Its member organizations provide, manage and support the development of healthcare continuing education programs that impact more than 500,000 physicians, nurses and pharmacists annually. Graduation from medical school and completion of residency training are the first steps in a career-long educational process for physicians. To take advantage of the growing array of diagnostic and treatment options, physicians must continually update their technical knowledge and practice skills. CME is a mainstay for such learning.

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