GODFREY & KAHN S.C.

Health Care Flash

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Thomas N. Shorter
608.284.2239
tshorter@gklaw.com

Sean O'D. Bosack
414.287.9431
sbosack@gklaw.com

Wendy K. Arends
608.284.2659
warends@gklaw.com

340B Drug Pricing Program Omnibus Guidance Withdrawn

Last week, on Jan. 30, 2017, the Office of Management and Budget (OMB) withdrew the U.S. Department of Health and Human Services (HHS) Health Resources and Services Administration's (HRSA) 340B Drug Pricing Program Omnibus Guidance (Omnibus Guidance). The Omnibus Guidance was originally published on Aug. 28, 2015.

The intent of the Omnibus Guidance was to clarify and further define many aspects of the 340B Program, including, most significantly, the definition of a 340B eligible patient. Other proposed changes and clarifications were around Child Site eligibility and registration requirements, Disproportionate Share Hospital eligibility, outpatient status, manufacturer requirements, contract pharmacy requirements and record retention requirements, among others. However, this is not the first time HRSA's proposed guidance regarding the 340B Drug Pricing Program has been quashed. In 2014, HRSA both published and withdrew its "mega rule" after it was questioned as to its rulemaking authority. Therefore, in 2015, HRSA chose to issue guidance regarding the 340B Drug Pricing Program rather than a rule.

As we previously alerted our clients, on Jan. 20, 2017, the Trump administration suspended all new and pending federal regulations. Godfrey & Kahn suspects HRSA's recently finalized rule on 340B Drug Pricing Program calculations and Civil Monetary Penalties for drug manufacturers will also be delayed or otherwise affected by the Trump administration's regulatory freeze.

Godfrey & Kahn's Health Care Practice Group will continue to monitor HRSA guidance around the 340B Drug Pricing Program.

If you have questions, please contact:

- Tom Shorter at 608.284.2239 or tshorter@gklaw.com,
- Sean Bosack at 414.287.9431 or sbosack@gklaw.com,
- Wendy Arends at 608.284.2659 or warends@gklaw.com, or
- Your regular Godfrey & Kahn attorney.