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June 29, 2017

Mabel Echols
The Office of Management and Budget
725 17th Street, NW
Washington, DC 20503

Dear Ms. Echols:

During Dexcom's meeting with OMB (0938-AT04) for rule CMS-1674-P, OMB requested follow-up information on the health and economic outcome evidence supporting the use of continuous glucose monitoring, as well as the costs of regulatory approval. Dexcom commissioned Dr. Michael O'Grady, who served as the HHS Assistant Secretary for Planning and Evaluation from 2003 to 2005, to summarize the available evidence. Since leaving HHS, Dr. O'Grady has focused his work on health economic analysis of clinical trials in diabetes; particularly Type 1 diabetes. He is the author of eleven peer-reviewed journal articles, including four on the economic impact of continuous glucose monitoring. He concludes that the available evidence for CGM use in Medicare beneficiaries points to positive outcomes in both clinical improvement and cost-effective care.

With regard to the cost of regulatory approval, a report from Stanford University in 2010 estimated the costs of a PMA device approval to be $94 million, with $75 million spent specifically on FDA clearance. A copy of this study is attached. This is generally consistent with Dexcom's experience in obtaining FDA approval.

Dexcom is happy to answer any further questions you might have that would aid in your analysis, please do not hesitate to contact me at cgraham@dexcom.com or (858) 200-0248. Thank you again for your time and we look forward to reviewing the proposed rule.

Sincerely,

Claudia Graham

Claudia Graham
Senior Vice President, Global Access
Dexcom, Inc.