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**DATE:** January 5, 2018  
**TO:** All Part D Plan Sponsors  
**FROM:** Jennifer R. Shapiro, Acting Director  
Medicare Drug Benefit and C&D Data Group  
**SUBJECT:** Medical Supplies Associated with the Injection of Insulin

We are issuing this guidance regarding Part D coverage of products used for the delivery of insulin for the treatment of diabetes. With the introduction of new insulin delivery devices to the market, questions have arisen about Part D coverage for these products. Specifically, we have been asked whether newer insulin delivery devices that are not covered under Medicare Part B meet the Part D definition of “medical supplies associated with the injection of insulin.”

Section 1860D-2(e)(1) includes “medical supplies associated with the injection of insulin (as defined in regulations of the Secretary)” in the definition of a “covered part D drug.” Our regulations at 42 CFR 423.100 specify that this includes syringes, needles, alcohol swabs, gauze, and supplies that are directly associated with delivering insulin into the body. CMS also specified in the preamble to the January 28, 2005 final rule that “insulin delivery devices not otherwise covered by Part B, such as insulin pens, pen supplies, and needle-free syringes” were included in the definition.

The examples that were previously provided were never intended to be an exhaustive list of products that could be covered under Part D. Instead, they represented our understanding of the types of medical supplies associated with the injection of insulin that were available at the time. Since that time, newer insulin delivery devices in the form of both mechanical and electronic insulin pumps have become available that are not coverable under the Medicare Part B durable medical equipment (DME) benefit. Consistent with the Part D policy to allow coverage of insulin delivery devices that are 1) directly associated with delivering insulin into the body and 2) not otherwise considered DME under Part B, Part D sponsors may provide coverage of such products under Part D as “medical supplies associated with the injection of insulin.”

We expect that technology will continue to advance and that “medical supplies associated with the injection of insulin” will become significantly more sophisticated. Part D sponsors may include such supplies in their benefit consistent with the policy discussed above. However, while CMS recognizes such products as medical supplies that are alternatives to insulin syringes, CMS does not require Part D sponsors to include them on their formularies, and sponsors may apply utilization management criteria if they include such products on their formularies. As new products become available, Part D sponsors may evaluate these products for formulary placement and medical necessity and, subject to Part D coverage determination and appeals requirements, allow access and restrict use accordingly.

If you have any questions concerning this memorandum, please send an e-mail to [PartDPolicy@cms.hhs.gov](mailto:PartDPolicy@cms.hhs.gov).