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TO: Part D Sponsors

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SUBJECT: IDPN/IPN Coverage under Medicare Part D

DATE: October 05, 2012

The purpose of this memorandum is to clarify Part D coverage of Intradialytic Parenteral Nutrition (IDPN) and Intraperitoneal Nutrition (IPN) provided to Medicare beneficiaries receiving renal dialysis services under the Medicare End Stage Renal Disease (ESRD) benefit. It is important that Part D sponsors understand which costs associated with these therapies are covered under Medicare Part B and which may be covered under Medicare Part D.

Chapter 6, Appendix C of the Medicare Prescription Drug Benefit Manual states that Part B coverage for parenteral nutrition is limited to individuals with a non-functioning digestive tract. Therefore, for ESRD patients, IDPN or IPN coverage may be available under Medicare Part D. Medicare Part D coverage of these products is limited to the drug ingredients that meet the definition of a Part D drug, along with dispensing fee, and subject to the requirements in 42 CFR 423.120(d) pertaining to compounded drug products.

While Medicare Part D may cover the Part D drugs in IDPN and IPN, Medicare Part B covers outpatient maintenance dialysis treatments when they are provided to ESRD patients by an approved ESRD facility. Medicare Part B pays for outpatient maintenance dialysis via a prospective payment system (PPS) that combines Medicare payment for dialysis services with payment for ESRD-related drugs and laboratory tests. CMS published a final rule on August 12, 2010 (75 FR 49056) to establish the ESRD PPS. The bundle of services that are reflected in the ESRD PPS payment includes all services that prior to January 1, 2011 were considered to be composite rate services. Those services include: all personal services, equipment and supplies, administrative services, overhead costs, and ESRD-related laboratory tests and biological. Directed nursing services include registered nurses, licensed practical nurses, technicians, social workers and dietitians. When an ESRD facility furnishes a non-ESRD drug, including IDPN or IPN, the staff time is already included in the ESRD PPS payment and, therefore, such costs should not be included in Part D payments.

IDPN is considered to be a Part D compound because dialysate is not included. There is Part D coverage for amino acids, dextrose, and lipids that meet the definition of Part D drugs. There is no Medicare coverage (under Part B or Part D) for ingredients such as sterile water, since non-covered drugs and other ingredients must be treated as general pharmacy overhead.

Reimbursement under Part D may include a dispensing fee to cover certain labor costs and pharmacy overhead as permitted under 42 CFR 423.100.

In the case that a pharmacy extemporaneously compounds IPN by adding amino acids to a dialysate, there has been confusion as to whether this falls under Part B or Part D. Dialysate is considered to be a supply relative to the ESRD facility which falls under the ESRD PPS payment and is not separately billable under Part B. Although the dialysate is not separately billable, it is still considered a Part B drug. Therefore, IPN is a Part B compound in accordance with 42 CFR 423.120(d)(1)(i) and coverage for the entire compound, including ingredients that would independently meet the definition of a Part D drug, would not be available under Medicare Part D.

Sponsors are reminded that their network pharmacies must be able to deliver home infused drugs in a form that can be easily administered in a clinically appropriate fashion in addition to ensuring that professional services and ancillary supplies necessary for the provision of such therapy are in place before dispensing, consistent with the quality assurance requirements for Part D sponsors described in 42 CFR 423.153(c). Thus, we would not expect to see separately billed amino acids for subsequent addition to a dialysate via a Y-site.

If you have any questions regarding this memorandum, please contact Stephanie Hammonds at 410-786-1646.