DEPARTMENT OF HEALTH & HUMAN SERVICES Centers for Medicare & Medicaid Services 7500 Security Boulevard Baltimore, Maryland 21244-1850



CENTER FOR BENEFICIARY CHOICES

March 10, 2006

Memorandum To: All Part D Sponsors

Subject: Home Infusion Therapy

From: Gary Bailey, Deputy Director, Center for Beneficiary Choices

As we move into the third month of implementing the Medicare Drug Benefit, we want to clarify for prescription drug plan sponsors the Part D benefit for home infusion therapy as we are hearing numerous complaints in this area. We believe that your review of this letter and attachments will assist us in making this benefit more effective for your members.

As you are aware, we require coverage of home infusion drugs under Part D that are not currently covered under Parts A and B of Medicare. Although the Medicare Part D benefit does not cover equipment, supplies, and professional services associated with home infusion therapy, it does cover the ingredient costs and dispensing fees associated with infused covered Part D drugs. Please refer to Attachment I to this letter which describes the payment obligations under Medicare for home infusion therapy.

Clear Directions to Access Home Infusion Pharmacy

We have been hearing complaints about the inability of beneficiaries and their providers to identify and access in-network systems capable of delivering home infusion drugs covered under Medicare Part D. We remind plan sponsors that they need to have in place through their customer and provider service lines clear directions on how to contact an in-network pharmacy for appropriate coverage of Part D home infused drugs.

Home Infusion Drugs Must be Provided In a Usable Form

We have been hearing complaints about beneficiaries receiving drugs to be used for their home infusion therapy in an unmixed, unusable form. It is important to emphasize that, while we do not expect the Part D plans to provide or pay for supplies, equipment, or the professional services needed for home infusion therapy, we do expect the plan sponsor's contracted pharmacy to deliver home infused drugs in a form that can be administered in a clinically appropriate fashion.

In addition, home infusion networks must have contracted pharmacies capable of providing infusible Part D drugs for both short term acute care (e.g. IV antibiotics) and long term chronic care (e.g. alpha¹ protease inhibitor) therapies. While the same network pharmacy does not

necessarily need to be capable of providing the full range of home infusion Part D drugs, the home infusion network, in aggregate, must have a sufficient number of pharmacies capable of providing the full range of home infusion Part D drugs to ensure enrollees have adequate access to medically necessary home infusion therapies when needed.

Assurances that Ancillary Services Will be Provided

Generally, facility discharge planners, in collaboration with a patient's physician, are responsible for ensuring that the components needed to safely administer a drug at home are present upon a patient's discharge. However, we also expect the Part D plan's in-network contracted pharmacy vendors -- particularly those that do not supply the necessary ancillary services (which are not a Medicare Part D benefit) -- to receive assurances that another entity can arrange for the provision of these services, such as a home health agency. In other words, Part D plans must require their contracted network pharmacies that deliver home infusion drugs to ensure that the professional services and ancillary supplies are in place before dispensing home infusion drugs. We would consider this action of obtaining assurances a minimum quality assurance requirement on Part D plans under 423.153(c). Please refer to Attachment II to this letter which describes the overall decision tree with respect to the coordination of home infusion therapy.

Time Sensitive Nature of Home Infusion Therapy

Home infusion therapy may serve as a vehicle to promote early hospital discharge. We understand that there have been unexpected delays in the approval of off-formulary requests for infusion drugs. This has resulted in some beneficiaries remaining in an inpatient setting before the home infusion therapy can be initiated while an exceptions request is submitted and resolved. Because the need for home infusion therapy is often of an urgent nature, physicians dealing with home infusion therapy situations may determine that an expedited coverage determination or redetermination is necessary for their patients and communicate this information to the Part D plans. Plan sponsors should resolve these requests as quickly as possible.

Thank you for your help in ensuring that Part D enrollees have timely access to medically necessary home infusion therapy.

Attachment I

Payment of Home Infusion Therapy for Medicare Beneficiaries

	Part A Home Health	Part B DME Benefit	Part C Medicare Advantage	Part D Prescription Drug Plan	State Medicaid Program	Other Payer Coverage
Requirement	Homebound and in need of part-time or intermittent skilled nursing or therapy services, if such services are reasonable and necessary to the treatment of the illness or injury.	If medically necessary for the drug to be administered through an infusion pump.	Coverage of at least Part A/B services. Coordinated care plans may include additional coverage and mechanisms to control utilization.	Drugs that are not currently covered under Parts A and B of Medicare, or otherwise excluded under Part D.	Provided that coverage is not available through Parts A, B, C, or D of Medicare, Medicaid home health benefit may cover services, equipment and supplies necessary to administer home infusion drugs.	Varies, but generally like Part C
Professional Fees	Yes	No	Yes	No	Yes – May be billed separately or as part of bundled rate.	Varies, but generally like Part C
Equipment and Supplies	Sometimes - Home Health Therapy responsible for providing hydration fluid and IV supplies if infusion is provided via gravity feed method	Yes – Supplies are billed separately by a DME vendor to appropriate DME Regional Carrier	Yes – Included in per diem payment (generally bundled)	No – Cost of supplies, equipment, and professional fees must be covered via Medicare Parts A or B, Medicare Advantage Plan, Medicaid, other insurance, or out-of- pocket	Yes – May be billed separately or as part of bundled rate	Varies, but generally like Part C
Drug Ingredient and Dispensing Fee	No – Drugs and biologicals are specifically excluded from the Part A home health benefit	Part B pays the drug costs as a part of the DME benefit but there is no separate dispensing fee paid	If covered under Part B, yes. If not covered under Part B, must be covered under Part D in a MA-PD plan.	Yes	No – Unless drugs are included in bundled rate, which does not trigger Medicaid FFP exclusion	Varies, but generally like Part C

Home Infusion Coordination Decision Tree

