Testimony of Varner Richards, PharmD

Chief Executive Officer

Intramed Plus, Inc.

Chairman, Board of Directors

National Home Infusion Association

Examining Bipartisan Legislation to Improve the Medicare Program

Before the

U.S. House of Representatives Committee on Energy and Commerce

July 20, 2017

Key Points

- The National Home Infusion Association supports passage of the *Medicare Part B Home Infusion Services Temporary Transitional Payment Act (HR 3163).*

- The home infusion therapy services temporary transition payment is of vital importance to Medicare beneficiaries that require infusion therapy at home.

- The legislation will allow providers of infusion therapy at home to continue servicing Medicare beneficiaries that suffer from life threatening illnesses that include:
    - Viral and/or fungal infections;
    - Cancer and cancer-related pain therapy;
    - Immune deficiency; and
    - Heart failure.

National Home Infusion Association Testimony

Introduction

Subcommittee Chairman Burgess, Subcommittee Ranking Member Green, and members of the Subcommittee, thank you for inviting me to share the National Home Infusion Association's (NHIA) insights on HR 3163, *Medicare Part B Home Infusion Services Temporary Transitional Payment Act*.

My name is Varner Richards and I serve as the chair of the NHIA board of directors. NHIA is a trade association that represents providers of home infusion therapy and other companies that supply and otherwise support the delivery of infusion therapy in the home.

I am also the Owner & CEO of Intramed Plus, Inc, a home infusion provider in South Carolina. We service to patients in South Carolina and border counties of North Carolina from three home infusion pharmacies located in Columbia; Greenville; and Charleston, SC. I am also a clinician who has been directly involved with providing infusion services to patients in their homes for over 30 years.

Infusion Therapy at Home

Infusion therapy involves the administration of medication through a needle or catheter. It is prescribed for patients whose condition is so severe that they cannot be treated effectively by oral medications. Typically, "infusion therapy" means that a drug is administered intravenously, but the term may also refer to situations where drugs are provided through other non-oral routes, such as the subcutaneous (under the skin) route when the infusion lasts longer than 15 minutes.

Diseases which require infusion therapy include infections that are unresponsive to oral antibiotics, cancer and cancer-related pain, dehydration, and gastrointestinal diseases or disorders which prevent normal functioning of the gastrointestinal system. Other conditions treated with infusion therapies include cancers, congestive heart failure, Crohn's Disease, hemophilia, hepatitis, immune deficiencies, multiple sclerosis and rheumatoid arthritis.

Several specialized services are necessary for the delivery of home infusion. Home infusion services that are performed by pharmacists and nurses include:

- Preparation and dispensing of sterile intravenous drugs;
- Intravenous drug administration;
- Comprehensive assessment that considers the patient's complete medication history, current physical and mental status, lab reports, cognitive and psychosocial status, family/caregiver support, prescribed treatment, concurrent oral prescriptions, and over-the-counter medications;
- Disease state management for highly complex chronic illnesses focused on reducing hospital admission, avoiding unnecessary emergency room visits, and improving patient quality of life;
- Care coordination with key stakeholders involved in patient care such as primary care physicians, specialists, home health, and ancillary services;
- Drug interaction monitoring and identification of potential drug, dose or drug-catheter incompatibilities;

- Admission procedures that include patient education of medical equipment, supply use, medication administration, medication storage and handling, emergency procedures, vascular access device management, proper storage and disposal of hazardous waste, as well as the recognition and reporting of adverse drug reactions;
- Care planning that considers actual or potential drug or equipment-related problems, therapy monitoring with specific patient centered goals, and coordination of activities with other providers such as home health agencies and physicians;
- Comprehensive patient monitoring and reassessment to ensure a positive response to treatment, proactively address potential complications, and improve patient compliance;
- Laboratory analysis and subsequent therapy change recommendations to other members of the patient's care team to adjust medication orders if necessary;
- Maintenance of appropriate physical facilities for storage, preparation, dispensing, and quality control of all infusion medications, supplies and equipment; and
- Quality assurance programs that include collection of clinical outcomes data, patient perception data, trending and analysis of these and other key performance indicators focused on maintaining a highly reliable healthcare organization.

Notably, patients treated at home with infusion therapy instead of in a facility are at a reduced risk of acquiring health care acquired infections (HAI). HAIs are a crucial safety consideration since many of these patients are at high risk of infection due to their disease process, age, and/or compromised immune system.

Commercial insurers, Medicaid programs, and many Medicare Advantage health plans (Medicare Part C) currently recognize that infusion therapy delivered at home is a cost-effective, low risk, and clinically-effective treatment option. Those programs provide comprehensive coverage of this therapy. Private sector coverage of home infusion has existed since the 1980s.

Home Infusion Medicare Coverage

The Medicare fee-for-service program provides piecemeal coverage for home infusion. Medicare Part B provides coverage under the durable medical equipment (DME) benefit for a limited number of infusion drugs that are administered using a mechanical or electronic external infusion pump. Because of the reliance on DME, the number of drugs that are covered under this benefit is limited to a small number of therapies for specific populations, such as: patients with fungal and viral infections, cancer and cancer related pain, immune deficiency and heart failure.

While we are focusing on Medicare Part B infusion coverage, I must note that most infusion drugs are covered as part of the Medicare Part D benefit. Medicare Part D reimburses providers for the drugs and a retail-based dispensing fee, which falls short of covering the costs associated with the safe provision of home infusion drugs. Importantly, Medicare Part D does not cover the specialized infusion-related services, equipment and supplies, and it is for this reason that most Medicare beneficiaries do not have access to infusion drugs in the home, despite the fact the drugs are covered in that setting. NHIA is seeking to fix this issue as part of the *Medicare Home Infusion Site of Care Act,* which was introduced by Representative Engel of this subcommittee and House Ways and Means Subcommittee on Health Chairman Tiberi in the 114th Congress.

Prior to passage of the *21st Century Cures Act* in December 2016 there were three components of home infusion that were reimbursable under the Part B DME program – the drug, the pump and other supplies associated with the infusion. Clinical services associated with these infusions were not explicitly covered by Medicare. However, the infusion drugs were being reimbursed at 95% of 2003 Average Wholesale Pricing (AWP) levels. The reimbursement of the drugs at this level essentially subsidized the costs associated with clinical services necessary for the infusions.

NHIA and the home infusion community have long advocated that Part B DME infusion drugs should be reimbursed by a more market driven calculation. The community supports an explicit payment for home infusion clinical services that are required to ensure effective patient care. The *21st Century Cures Act* contained two provisions that significantly affect the home infusion community. First, a provision contained in Section 5012 and scheduled to take effect in 2021, established a reimbursement for the professional services associated with Part B DME infusion drugs. NHIA thanks the committee for including this provision in the bill.

A second provision contained in Section 5004(a) changed the payment structure for infusion drugs under the Medicare Part B DME benefit from the AWP metric to an Average Sales Price (ASP) payment methodology to better align the drug payment with the way physician offices are currently reimbursed. Home infusion providers were not expressly opposed to this change as long as a payment for the services could be addressed.

The gap in the *Cures Act* between the implementation date for establishment of ASP reimbursement (2017) and the date established for a home infusion services payment (2021) needed to be addressed. Members of this committee last year committed to work on the issue in 2017. We thank the committee for your commitment to work on this issue and that is why we are here today.

The Medicare Part B Home Infusion Services Temporary Transitional Payment Act

The Medicare Part B Home Infusion Services Temporary Transitional Payment Act (HR 3163) will allow the most vulnerable of patients to have access to life-saving home infusion therapy. This legislation would create a temporary transitional payment beginning January 1, 2019, for services related to Part B DME infusion drugs.

Specifically, HR 3163 will create a temporary payment for home infusion services associated with Part B infusion drugs, which will allow Medicare beneficiaries to continue to access therapy in the home until the permanent services payment that was created in the *Cures Act* is implemented in 2021. NHIA supports HR 3163 and urges passage of the bill. Providing this temporary and transitional payment will allow the home infusion community to continue to service the most fragile patients until the Centers for Medicare & Medicaid Services (CMS) finalizes the services payment included in the *Cures Act*.

Conclusion

NHIA thanks the committee and its staff for their hard work in getting this legislation prepared for consideration today. NHIA knows that this legislation is very technical in nature and we commend all who were involved in this effort.

Thank you for your time today and please accept NHIA's support of HR 3163.