Memorandum

To: National Home Infusion Association Board, Future of Infusion Advisory Counsel, and National Home Infusion Association Membership

From: Kendall Van Pool, Vice President of Government Affairs
National Home Infusion Association

Date: July 9, 2018

Re: NHIA Executive Summary of CMS Proposed Rule Implementing Home Infusion Therapy Services Temporary Transitional Payment and Permanent Payment

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Executive Summary

On July 2nd the Centers for Medicare and Medicaid Services (CMS) released a proposed rule entitled:

> *"CY 2019 Home Health Prospective Payment System Rate Update and CY 2020 Case-Mix Adjustment Methodology Refinements; Home Health Value-Based Purchasing Model; Home Health Quality Reporting Requirements; Home Infusion Therapy Requirements; and Training Requirements for Surveyors of National Accrediting Organizations"*

This proposed rule includes a description of how CMS intends to implement the home infusion Part B services reimbursement included in section 5012 of the *21st Century Cures Act* and the transitional home infusion services reimbursement included in section 50401 of the *Bipartisan Budget Act of 2018*. This is a proposed rule and is open for comment until August 31st.

The proposed rule's home infusion provisions are broken into two sections "Requirements for Home Infusion Suppliers" and "Accreditation for Home Infusion Therapy Suppliers". Much of the explanatory text and revisions to the Code of Federal Regulations (CFR) focus on accreditation. However, the section regarding requirements for home infusion suppliers outlines many paramount issues for home infusion companies. This section includes definitions for an infusion drug administration calendar day and the required services of a home infusion supplier, among other provisions. Lastly, in the explanatory text, CMS solicits public comment on several issues pertaining to the permanent home infusion benefit starting in calendar year (CY) 2021, including the benefit's relationship to Durable Medical Equipment (DME); the definition of an infusion drug administration day; payment basis, limitations on payment, and payment adjustments; prior authorization; and the benefit's relationship to home health.

The proposed definition of an infusion drug administration calendar day is of great concern. The proposed definition has two policy components. First, a home infusion drug administration calendar day requires a skilled professional to be physically present in the patient's home on the day of administration. Second, the proposed definition requires that the services the skilled professional provides are "so inherently complex that they can only be safely and effectively performed by, or under the supervision of, professional or technical personnel". The proposed definition of an administration calendar day will greatly restrict Medicare beneficiary's access to home infusion.

NHIA will be working with our members and stakeholders to coordinate comments on the proposed rule; weigh in with members of Congress to urge CMS to modify the proposed rule; and communicate to press outlets concerns over the policies included in this proposed rule. We encourage you to become familiar with the rule and be prepared to weigh in with CMS and your members of Congress.

Attached to this document is a memorandum provided by NHIA's regulatory and lobbying consultants Crowell & Moring, LLP. This document provides a top line review of the rule for your review.

Background and Explanation of Rulemaking

The *21st Century Cures Act* was passed in late 2016 with an effective date for section 5012 of January 1, 2021. Section 5012 of this legislation created a permanent home infusion services reimbursement structure for CMS to implement by the January 1, 2021 deadline. Similarly, Congress passed the *Bipartisan Budget Act of 2018* earlier this year and section 50208 of the legislation has an effective date of January 1, 2019. Section 50208 waived the rulemaking process to expedite implementation of the legislation.

CMS has, however, chosen to initiate the implementation process for both section 5012 of the *21st Century Cures Act* and section 50208 of the *Bipartisan Budget Act of 2018* using the rulemaking process. When issuing regulations, CMS follows an open public process that is statutorily laid out in the *Administrative Procedure Act*. The process includes publishing proposed and final rules in the *Federal Register* and opening proposed rules for comment. The process also allows CMS to solicit comment on issues they are considering for rulemaking, but have not formalized into a proposed rule. For more on the rulemaking process you can visit this website: https://www.federalregister.gov/uploads/2011/01/the_rulemaking_process.pdf.

The proposed rule that will initiate the implementation process of section 5012 of the *21st Century Cures Act* and section 50208 of the *Bipartisan Budget Act of 2018* was published on July 2nd and has an open comment period ending on August 31st. The full text of the rule can be accessed here: https://s3.amazonaws.com/public-inspection.federalregister.gov/2018-14443.pdf. Rules are broken down into two distinct sections the preamble and the regulatory text. The preamble is the majority of the text in the document and it provides discussion regarding CMS' justification of their planned implementation of the legislation and rules. The second section includes the actual alterations to the Code of Federal Regulations (CFR).

NHIA encourages association members and stakeholders to read the rule and plan to comment. NHIA will be providing our members and stakeholders with additional information to help develop a draft set of comments that they can use to produce their own comments.