Summary of Home Infusion Therapy Provisions in CMS Proposed 2020 Home Health PPS Rule

On July 11, the Centers for Medicare & Medicaid Services (CMS) issued a proposed rule: “Medicare and Medicaid Programs; CY 2020 Home Health Prospective Payment System Rate Update; Home Health Value-Based Purchasing Model; Home Health Quality Reporting Requirements; and Home Infusion Therapy Requirements” (Proposed Rule). The Proposed Rule will be published in the July 18 Federal Register and comments are due by 5:00 PM on September 9. The rule is intended to become effective, January 1, 2020.

The Proposed Rule would update the transitional payment for home infusion therapy services for calendar year (CY) 2020 and propose payment provisions for home infusion therapy services for CY 2021 and beyond.

No Change to the Definition of “Infusion Drug Administration Calendar Day”

In the background and overview section, CMS notes that in the CY 2019 Home Health Prospective Payment System (HH PPS) final rule with comment, it finalized the definition of “infusion drug administration calendar day” for both the temporary transitional payment and permanent home infusion therapy benefit as “the day on which home infusion therapy services are furnished by skilled professional(s) in the individual’s home on the day of infusion drug administration.” In the CY 2019 final rule with comment, CMS stated that it would carefully monitor the effects of this definition on access to care and would engage in additional rulemaking or guidance regarding the definition “if warranted.” In the Proposed Rule, CMS states that it has been monitoring the utilization of home infusion therapy services since January 1, 2019 but it does not yet have sufficient data on utilization to determine the effects of its definition on access to care. The agency states that it will address the comments received in response to the CY 2019 HH PPS final rule with comment as well as those received in response to the Proposed Rule in the CY 2020 HH PPS final rule.

A summary of the Proposed Rule’s other major home infusion therapy services provisions are as follows:

CY 2020 Temporary Transitional Payment Rates for Home Infusion Therapy Services

CMS proposes to update the temporary transitional payments based on the CPT code payment amounts in the CY 2020 physician fee schedule. CMS notes that it does not yet have the CY 2020 physician fee schedule rates and it will publish the updated rates in the CY 2020 physician fee schedule final rule.

Proposed Home Infusion Therapy Services for CY 2021 and Subsequent Years

CMS states that it is proposing changes for CY 2021 and beyond in the Proposed Rule to allow enough time for home infusion therapy suppliers to make any necessary software and business process changes in time for implementation on January 1, 2021.

Scope of Benefit and Conditions for Payment

- Home Infusion Drugs

CMS proposes to continue the definition of “home infusion drugs” (with the exception of
Hizentra®) as defined under the current temporary transitional payment. For home infusion therapy services furnished under the permanent benefit, beginning on January 1, 2021, CMS proposes that “home infusion drugs” are “parenteral drugs and biologicals administered intravenously, or subcutaneously for an administration period of 15 minutes or more, in the home of an individual through a pump that is an item of DME covered under the Medicare Part B DME benefit.” CMS notes that the teaching and therapy provided under the home infusion therapy benefit is intended to provide teaching and therapy on the provision of home infusion drugs and is not intended to duplicate the teaching and training already covered under the durable medical equipment (DME) benefit. **CMS is soliciting comments on continuing the definition of “home infusion drugs” under the permanent home infusion therapy services benefit.**

- **Patient Eligibility and Plan of Care Requirements**

CMS is proposing a number of changes to the permanent home infusion therapy payment system. CMS proposes to add a new regulatory subpart to implement the conditions for payment. CMS proposes conforming regulations to require that home infusion therapy services be furnished to an eligible beneficiary by, or under arrangement with, a qualified home infusion therapy supplier that meets health and safety standards. CMS also proposes that qualified home infusion therapy suppliers ensure that a beneficiary meets certain eligibility criteria and ensure that plan of care requirements are met. CMS also proposes that a beneficiary must be under the care of a physician, nurse practitioner or physician assistant and that a beneficiary be under a plan of care established by a physician. The physician’s orders for services must include the type of home infusion therapy services, the type of professional, as well as specify the frequency with which the services will be furnished. **CMS solicits comments on the proposed conditions for payment, including patient eligibility and plan of care requirements.**

- **Qualified Home Infusion Therapy Suppliers and Professional Services**

CMS states that payment to a qualified home infusion therapy supplier is for an infusion drug administration calendar day, which “refers to payment only for the date on which professional services were furnished to administer such drugs to such individual.” CMS adds that it is necessary for the home infusion therapy supplier to be in the patient’s home on days the drug is being administered “in order to provide an accurate assessment to the physician responsible for ordering the home infusion drug and services.” CMS notes that some amount of care coordination or monitoring outside of an infusion drug administration calendar day may be necessary but that these services are included in the bundled payment. Care coordination furnished by the DME supplier is paid for under the DME benefit and care coordination furnished by the physician who establishes the plan of care is separately paid for under the physician fee schedule.

- **Home Infusion Therapy and the Interaction with Home Health**

CMS states that for home infusion therapy services furnished in CY 2019 and CY 2020, for a patient who is considered homebound and under a Medicare home health plan of care, the home health agency should continue to furnish the professional services for administering transitional home infusion drugs as home health services and bill for those services under the Medicare home health benefit. If a home infusion supplier is under contract with a home health agency to provide
the home infusion therapy services under a home health plan of care, those services would be
considered home health services and billed by the home health agency under the Medicare home
health benefit, not the home infusion therapy benefit. CMS states that the home infusion therapy
supplier would seek payment from the home health agency and would not bill Medicare for the
temporary transitional payment. CMS states that this clarification is not intended to limit access
to home infusion therapy services to those beneficiaries receiving home health services under the
Medicare home health benefit.

Solicitation of Public Comments Regarding Notification of Infusion Therapy Options Available
Prior to Furnishing Home Infusion Therapy Services

CMS notes that it is seeking comments in the CY 2020 physician fee schedule proposed rule
regarding the appropriate form, manner and frequency that a physician must use to provide
notification to his/her patient of the treatment options available for infusion therapy under
Medicare Part B. In this Proposed Rule, CMS also invites comments on any additional
interpretations of the notification requirement and whether it is already being met under the
temporary transitional payment.

Proposed Payment Categories and Amounts for Home Infusion Therapy Services for CY 2021

CMS states that under the temporary transitional payment, there are three payment categories with an
associated J-code for each transitional home infusion drug. CMS proposes to continue the three
temporary transitional payment categories for the home infusion therapy services payment in CY 2021.
CMS states that there are several drugs that are paid for under the transitional benefit that would not be
defined as a home infusion drug under the permanent benefit that begins January 1, 2021. CMS states
that services related to the administration of Hizentra would not be covered under the benefit in 2021
because it is listed on a self-administered drug exclusion list by the Medicare Administrative Contracts
(MACs). In addition, home infusion therapy services related to the administration of Ziconotide and
Floxuridine also will be excluded as the drugs are given via intrathecal and intra-arterial routes
respectively and do not meet the definition of a home infusion drug. CMS is soliciting comments on
retaining the three payment categories as identified in Table 28 on page 288 of the PDF.

Proposed Payment Amounts

CMS proposes to continue the payment methodology for the temporary transitional payments and
to pay a single amount for each infusion drug administration calendar day in the individual’s
home for drugs assigned under each proposed payment category. CMS proposes that the single
payment amount be set at an amount equal to five hours of infusion therapy administration
services in a physician’s office for each infusion drug administration calendar day. CMS notes
that while the physician payments would account for varying time spent furnishing care to
individual patients, payment for an infusion drug administration calendar day is a unit of single
payment and would not vary within each category. CMS states that it believes that setting the
payment amount at the statutory maximum of five hours – an increase over the temporary
transitional payment rate of four hours – is necessary “to ensure that payment for home infusion
therapy adequately covers the different patient care needs and level of complexity of services
provided.” To take into account that the first visit furnished by a home infusion therapy supplier
may be longer or more resource intensive than subsequent visits, CMS proposes to increase the
payment amounts for each of the three payment categories for the first visit by the relative
payment for a new patient rate over an existing patient rate using the physician evaluation and
management payment amounts for a given year. This will result in a small decrease to the payment amounts for the second and subsequent visits. If a patient receiving home infusion therapy services is discharged, there must be a gap of more than 60 days in order to bill a “first visit” again. CMS states that it will monitor home infusion therapy service lengths of visits in order to evaluate whether the data supports a payment increase for the first visit and whether it should re-evaluate whether, or how much, to increase the initial payment amount. **CMS is soliciting comments on the proposed CY 2021 payment amounts per category.**

**Required Payment Adjustments for CY 2021 Home Infusion Therapy Services**

**Proposed Home Infusion Therapy Geographic Wage Index Adjustment**

In the 2019 HH PPS proposed rule, CMS stated that it was considering using the Geographic Practice Cost Indices (GPCIs) to account for regional variations in wages and to adjust the payment for home infusion therapy professional services. In the Proposed Rule, however, CMS states that further analysis and consideration has caused it to believe the geographic adjustment factor (GAF) may be a more appropriate alternative to adjust home infusion therapy payments based on variations in geographic wages. CMS notes that the GAF is not specific to any of the home infusion drug categories and that it would apply the appropriate GAF value to the home infusion therapy single payment amount based on the beneficiary’s site of service. While CMS considered other options to account for variations in geographic wages, it proposes to use the GAF, in part, because it is the most operationally feasible. CMS proposes using a budget neutrality factor, which would result in some adjusted payments being higher than the average and others being lower. **CMS solicits comments on its proposal to use the GAF to wage adjust the home infusion therapy services payment and solicits suggestions on whether a factor other than the GAF should be used.**

**Consumer Price Index**

CMS proposes to increase the single payment amount by the percent increase in the Consumer Price Index for all urban consumers (CPI-U) for the 12-month period ending with June of the prior year, reduced by the ten-year moving average of changes in annual economy-wide private nonfarm business multifactor productivity (MFP). CMS notes that this may result in payment being less than in the prior year.

**Other Optional Payment Adjustments/Prior Authorization for CY 2021 Home Infusion Therapy Services**

**Prior Authorization**

In the 2019 HH PPS, CMS solicited comments regarding whether and how prior authorization could potentially be used in home infusion. Based on the comments received, CMS has decided that prior authorization is not appropriate for the home infusion therapy benefit at this time. CMS believes that it is not necessary because services are contingent on the requirements under the DME benefit. CMS plans to monitor the provision of home infusion therapy infusion services and to revisit the need for prior authorization if warranted.

**Payments for High-Cost Outliers for Home Infusion Therapy Services**
CMS has determined that high cost outlier payments currently are not necessary. CMS plans to monitor the future need for such payments and will address outlier situations in a future rulemaking if needed.

Billing Procedures for CY 2021 Home Infusion Therapy Services

CMS plans to require that home infusion therapy suppliers submit all home infusion therapy service claims to the Medicare A/B MACs. CMS would require DME suppliers that are also enrolled as qualified home infusion therapy suppliers to submit claims for DME to the DME MAC and claims for professional services to the Medicare A/B MAC. CMS stated that it plans to issue a Change Request with more detailed instructions regarding billing and policy information for home infusion therapy services when it releases the CY 2020 final rule.

Regulatory Impact Analysis

CMS estimates that the cost related to updates to the temporary transitional payments for home infusion therapy in CY 2020 will be less than $1 million in either an increase or decrease in payments to home infusion therapy suppliers, depending on the final payment rates under the CY 2020 physician fee schedule. For CY 2021, CMS estimates the cost related to implementation of the permanent home infusion therapy benefit to be a $3 million reduction in payments to home infusion therapy suppliers (based on the CY 2019 physician fee schedule payment amounts).